# Rezumatul deciziilor Uniunii Europene privind autorizațiile de introducere pe piață pentru medicamentele de la 1 iunie 2012 până la 30 iunie 2012

*(Deciziile luate în temeiul articolului 34 din Directiva 2001/83/CE [1] sau al articolului 38 din Directiva 2001/82/CE [2])*

(2012/C 224/02)

## — Emiterea, prelungirea sau modificarea unei autorizații naționale de introducere pe piață

| Data deciziei | Denumirea medicamentului (medicamentelor) | Titularul (titularii) autorizației de introducere pe piață | Statul membru în cauză | Data notificării |
|---|---|---|---|---|
| 14/6/2012 | Tilmicosin | A se vedea anexa I | A se vedea anexa I | 18/6/2012 |
| 18/6/2012 | Milaxyn plus and associated names | A se vedea anexa II | A se vedea anexa II | 20/6/2012 |
| 28/6/2012 | Flutiform and associated names | A se vedea anexa III | A se vedea anexa III | 3/7/2012 |
| 28/6/2012 | Iffeza and associated names | A se vedea anexa IV | A se vedea anexa IV | 3/7/2012 |

[1] JO L 311, 28.11.01, p. 67.
[2] JO L 311, 28.11.01, p. 1.

*ANEXA I*

**LISTA CU DENUMIRILE COMERCIALE, FORMELE FARMACEUTICE, SUBSTANȚA ACTIVĂ, CONCENTRAȚIA PRODUSELOR MEDICAMENTOASE DE UZ VETERINAR, SPECIILE DE ANIMALE, DEȚINĂTORII AUTORIZAȚIILOR DE PUNERE PE PIAȚĂ DIN STATELE MEMBRE**

| Stat membru UE/SEE | Deținătorul autorizației de punere pe piață | Denumire | DCI | Concentrație | Formă farmaceutică | Specii de animale |
|---|---|---|---|---|---|---|
| Austria | Richter Pharma AG<br>Feldgasse 19<br>A-4600 Wels<br>AUSTRIA | Pulmotil G 100 g/kg Arzneimittel-Vormischung zur Herstellung von Fütterungsarzneimitteln für Schweine und Kaninchen | Tilmicosin (as phosphate) | 100 g tilmicosin per kg premix | Premix pentru furaje cu conținut medicamentos | Porci, iepuri |
| Austria | Richter Pharma AG<br>Feldgasse 19<br>A-4600 Wels<br>AUSTRIA | Pulmotil G 200 g/kg Arzneimittel-Vormischung zur Herstellung von Fütterungsarzneimitteln für Schweine und Kaninchen | Tilmicosin (as phosphate) | 200 g tilmicosin per kg premix | Premix pentru furaje cu conținut medicamentos | Porci, iepuri |
| Belgia | Eli Lilly Benelux N.V.<br>Elanco Animal Health<br>Rue de l'Etuve 52<br>Stoofstraat 52<br>1000 Brussel<br>BELGIA | Pulmotil 40 VET Pre-mix | Tilmicosin (as phosphate) | 40 g tilmicosin per kg premix | Premix pentru furaje cu conținut medicamentos | Porci, iepuri |
| Belgia | Eli Lilly Benelux N.V.<br>Elanco Animal Health<br>Rue de l'Etuve 52<br>Stoofstraat 52<br>1000 Brussel<br>BELGIA | Pulmotil 100 VET Pre-mix | Tilmicosin (as phosphate) | 100 g tilmicosin per kg premix | Premix pentru furaje cu conținut medicamentos | Porci, iepuri |
| Belgia | Eli Lilly Benelux N.V.<br>Elanco Animal Health<br>Rue de l'Etuve 52<br>Stoofstraat 52<br>1000 Brussel<br>BELGIA | Pulmotil 100 Granules | Tilmicosin (as phosphate) | 100 g tilmicosin per kg premix | Premix pentru furaje cu conținut medicamentos | Porci, iepuri |
| Belgia | Eli Lilly Benelux N.V.<br>Elanco Animal Health<br>Rue de l'Etuve 52<br>Stoofstraat 52<br>1000 Brussel<br>BELGIA | Pulmotil 200 VET Pre-mix | Tilmicosin (as phosphate) | 200 g tilmicosin per kg premix | Premix pentru furaje cu conținut medicamentos | Porci, iepuri |

| Stat membru UE/SEE | Deținătorul autorizației de punere pe piață | Denumire | DCI | Concentrație | Formă farmaceutică | Specii de animale |
|---|---|---|---|---|---|---|
| Cipru | Eli Lilly Regional Operations GmbH<br>Elanco Animal Health<br>Kolblgasse 8-10<br>1030 Wien<br>AUSTRIA | Pulmotil pre-mix 200 g/kg, πρόμιγμα για φαρμακούχο ζωοτροφή, για χοίρους και κονίκλους. | Tilmicosin (as phosphate) | 200 g tilmicosin per kg premix | Premix pentru furaje cu conținut medicamentos | Porci, iepuri |
| Republica Cehă | Eli Lilly Regional Operations GmbH<br>Elanco Animal Health<br>Kolblgasse 8-10<br>1030 Wien<br>AUSTRIA | Pulmotil 200 mg/g pre-mix pro medikaci krmiva | Tilmicosin (as phosphate) | 200 g tilmicosin per kg premix | Premix pentru furaje cu conținut medicamentos | Porci, iepuri |
| Germania | Lilly Deutschland GmbH<br>Abt. Elanco Animal Health<br>Werner-Reimers-Str. 2-4<br>D-61352 Bad Homburg<br>GERMANIA | Pulmotil G 40 | Tilmicosin (as phosphate) | 40 g tilmicosin per kg premix | Premix pentru furaje cu conținut medicamentos | Porci, iepuri |
| Germania | Lilly Deutschland GmbH<br>Abt. Elanco Animal Health<br>Werner-Reimers-Str. 2-4<br>D-61352 Bad Homburg<br>GERMANIA | Pulmotil G 100 | Tilmicosin (as phosphate) | 100 g tilmicosin per kg premix | Premix pentru furaje cu conținut medicamentos | Porci, iepuri |
| Germania | Lilly Deutschland GmbH<br>Abt. Elanco Animal Health<br>Werner-Reimers-Str. 2-4<br>D-61352 Bad Homburg<br>GERMANIA | Pulmotil G 20 % AMV | Tilmicosin (as phosphate) | 200 g tilmicosin per kg premix | Premix pentru furaje cu conținut medicamentos | Porci, iepuri |
| Danemarca | Elanco Animal Health<br>Eli Lilly Danmark A/S<br>Nybrovej 110<br>DK-2800 Kongens Lyngby<br>DANEMARCA | Pulmotil Vet. | Tilmicosin (as phosphate) | 40 g tilmicosin per kg premix | Premix pentru furaje cu conținut medicamentos | Porci, iepuri |
| Danemarca | Elanco Animal Health<br>Eli Lilly Danmark A/S<br>Nybrovej 110<br>DK-2800 Kongens Lyngby<br>DANEMARCA | Pulmotil Vet. | Tilmicosin (as phosphate) | 100 g tilmicosin per kg premix | Premix pentru furaje cu conținut medicamentos | Porci, iepuri |

| Stat membru UE/SEE | Deținătorul autorizației de punere pe piață | Denumire | DCI | Concentrație | Formă farmaceutică | Specii de animale |
|---|---|---|---|---|---|---|
| Danemarca | Elanco Animal Health<br>Eli Lilly Danmark A/S<br>Nybrovej 110<br>DK-2800 Kongens Lyngby<br>DANEMARCA | Pulmotil Vet. | Tilmicosin (as phosphate) | 200 g tilmicosin per kg premix | Premix pentru furaje cu conținut medicamentos | Porci, iepuri |
| Grecia | Eli Lilly Regional Operations GmbH<br>Elanco Animal Health<br>Kolblgasse 8-10<br>1030 Wien<br>AUSTRIA | PULMOTIL 200 | Tilmicosin (as phosphate) | 200 g tilmicosin per kg premix | Premix pentru furaje cu conținut medicamentos | Porci, iepuri |
| Spania | ELANCO VALQUÍMICA, S.A.<br>Avda. de la Industria 30<br>28108 Alcobendas<br>Madrid<br>SPANIA | PULMOTIL G 40 | Tilmicosin (as phosphate) | 40 g tilmicosin per kg premix | Premix pentru furaje cu conținut medicamentos | Porci, iepuri |
| Spania | ELANCO VALQUÍMICA, S.A.<br>Avda. de la Industria 30<br>28108 Alcobendas<br>Madrid<br>SPANIA | PULMOTIL G 100 | Tilmicosin (as phosphate) | 100 g tilmicosin per kg premix | Premix pentru furaje cu conținut medicamentos | Porci, iepuri |
| Spania | ELANCO VALQUÍMICA, S.A.<br>Avda. de la Industria 30<br>28108 Alcobendas<br>Madrid<br>SPANIA | PULMOTIL G 200 | Tilmicosin (as phosphate) | 200 g tilmicosin per kg premix | Premix pentru furaje cu conținut medicamentos | Porci, iepuri |
| Franța | LILLY France<br>13 Rue Pages<br>92158 Suresnes<br>Cedex<br>FRANȚA | PULMOTIL TILMICOSINE 40 PORC-LAPIN | Tilmicosin (as phosphate) | 40 g tilmicosin per kg premix | Premix pentru furaje cu conținut medicamentos | Porci, iepuri |
| Franța | QALIAN<br>34 Rue Jean Monnet<br>Zi D'Etriche<br>49500 Serge<br>FRANȚA | SANTAMIX TILMICOSINE 40 PORCINS - LAPINS | Tilmicosin (as phosphate) | 40 g tilmicosin per kg premix | Premix pentru furaje cu conținut medicamentos | Porci, iepuri |

| Stat membru UE/SEE | Deținătorul autorizației de punere pe piață | Denumire | DCI | Concentrație | Formă farmaceutică | Specii de animale |
|---|---|---|---|---|---|---|
| Franța | SOGEVAL<br>200 Route de Mayenne<br>Zi des Touches<br>53000 Laval<br>FRANCE | CONCENTRAT VO 08 TILMICOSINE PORCIN-LAPIN | Tilmicosin (as phosphate) | 40 g tilmicosin per kg premix | Premix pentru furaje cu conținut medicamentos | Porci, iepuri |
| Ungaria | Eli Lilly Regional Operations GmbH<br>Elanco Animal Health<br>Kolblgasse 8-10<br>1030 Wien<br>AUSTRIA | Pulmotil G 200 gyógypre-mix | Tilmicosin (as phosphate) | 200 g tilmicosin per kg premix | Premix pentru furaje cu conținut medicamentos | Porci, iepuri |
| Irlanda | Eli Lilly and Company Ltd<br>Elanco Animal Health<br>Lilly House<br>Priestly Road<br>Basingstoke<br>Hampshire RG24 9NL<br>REGATUL UNIT | Pulmotil G40 Pre-mix for medicated feedingstuff | Tilmicosin (as phosphate) | 40 g tilmicosin per kg premix | Premix pentru furaje cu conținut medicamentos | Porci, iepuri |
| Irlanda | Eli Lilly and Company Ltd<br>Elanco Animal Health<br>Lilly House<br>Priestly Road<br>Basingstoke<br>Hampshire RG24 9NL<br>REGATUL UNIT | Pulmotil G100 Pre-mix for medicated feedingstuff | Tilmicosin (as phosphate) | 100 g tilmicosin per kg premix | Premix pentru furaje cu conținut medicamentos | Porci, iepuri |
| Irlanda | Eli Lilly and Company Ltd<br>Elanco Animal Health<br>Lilly House<br>Priestly Road<br>Basingstoke<br>Hampshire RG24 9NL<br>REGATUL UNIT | Pulmotil G200 Pre-mix for medicated feedingstuff | Tilmicosin (as phosphate) | 200 g tilmicosin per kg premix | Premix pentru furaje cu conținut medicamentos | Porci, iepuri |
| Italia | ELI LILLY ITALIA SPA<br>VIA GRAMSCI<br>731/733 - SESTO FIORENTINO – FI<br>ITALIA | PULMOTIL G 200 PRE-MIX | Tilmicosin (as phosphate) | 200 g tilmicosin per kg premix | Premix pentru furaje cu conținut medicamentos | Porci, iepuri |

| Stat membru UE/SEE | Deținătorul autorizației de punere pe piață | Denumire | DCI | Concentrație | Formă farmaceutică | Specii de animale |
|---|---|---|---|---|---|---|
| Italia | CEVA VETEM SpA<br>via Colleoni<br>15 20041 Agrate Brianza (MB)<br>ITALIA | MICLOZAN 200 PRE-MIX | Tilmicosin (as phosphate) | 200 g tilmicosin per kg premix | Premix pentru furaje cu conținut medicamentos | Porci, iepuri |
| Țările de Jos | Eli Lilly Nederland B.V.<br>Elanco Animal Health<br>Grootslag 1-5<br>3991 RA Houten<br>ȚĂRILE DE JOS | PULMOTIL® G40 pre-mix voor gemedicineerd voer voor varkens | Tilmicosin (as phosphate) | 40 g tilmicosin per kg premix | Premix pentru furaje cu conținut medicamentos | Porci, iepuri |
| Țările de Jos | Eli Lilly Nederland B.V.<br>Elanco Animal Health<br>Grootslag 1-5<br>3991 RA Houten<br>ȚĂRILE DE JOS | PULMOTIL® G100 pre-mix voor gemedicineerd voer voor varkens | Tilmicosin (as phosphate) | 100 g tilmicosin per kg premix | Premix pentru furaje cu conținut medicamentos | Porci, iepuri |
| Țările de Jos | Eli Lilly Nederland B.V.<br>Elanco Animal Health<br>Grootslag 1-5<br>3991 RA Houten<br>ȚĂRILE DE JOS | PULMOTIL® G200 pre-mix voor gemedicineerd voer voor varkens | Tilmicosin (as phosphate) | 200 g tilmicosin per kg premix | Premix pentru furaje cu conținut medicamentos | Porci, iepuri |
| Portugalia | Lilly Portugal – Produtos Farmacêuticos, Lda.<br>Rua Cesário Verde, nº5- piso 4<br>Linda-a-Pastora<br>2790 – 326 QUEIJAS<br>PORTUGALIA | Pulmotil G40 Pré-mistura medicamentosa para alimento medicamentoso para suínos e coelhos | Tilmicosin (as phosphate) | 40 g tilmicosin per kg premix | Premix pentru furaje cu conținut medicamentos | Porci, iepuri |
| Portugalia | Lilly Portugal – Produtos Farmacêuticos, Lda.<br>Rua Cesário Verde, nº5- piso 4<br>Linda-a-Pastora<br>2790 – 326 QUEIJAS<br>PORTUGALIA | Pulmotil G100 Pré-mistura medicamentosa para alimento medicamentoso para suínos e coelhos | Tilmicosin (as phosphate) | 100 g tilmicosin per kg premix | Premix pentru furaje cu conținut medicamentos | Porci, iepuri |

| Stat membru UE/SEE | Deținătorul autorizației de punere pe piață | Denumire | DCI | Concentrație | Formă farmaceutică | Specii de animale |
|---|---|---|---|---|---|---|
| Portugalia | Lilly Portugal – Produtos Farmacêuticos, Lda.<br>Rua Cesário Verde, nº5- piso 4<br>Linda-a-Pastora<br>2790 – 326 QUEIJAS<br>PORTUGALIA | Pulmotil G200 Pré-mistura medicamentosa para alimento medicamentoso para suínos e coelhos | Tilmicosin (as phosphate) | 200 g tilmicosin per kg premix | Premix pentru furaje cu conținut medicamentos | Porci, iepuri |
| România | Eli Lilly Regional Operations GmbH<br>Elanco Animal Health<br>Kolblgasse 8-10<br>1030 Wien<br>AUSTRIA | PULMOTIL 200 g/kg pre-mix | Tilmicosin (as phosphate) | 200 g tilmicosin per kg premix | Premix pentru furaje cu conținut medicamentos | Porci, iepuri |
| Republica Slovacă | Elli Lilly and Company Limited<br>Speke Operations Fleming RoadSpeke<br>Liverpool<br>L24 9LN<br>REGATUL UNIT | Pulmotil G 200 pre-mix ad us.vet. | Tilmicosin (as phosphate) | 200 g tilmicosin per kg premix | Premix pentru furaje cu conținut medicamentos | Porci, iepuri |
| Regatul Unit | Eli Lilly and Company Ltd<br>Elanco Animal Health<br>Lilly House<br>Priestly Road<br>Basingstoke<br>Hampshire RG24 9NL<br>REGATUL UNIT | Pulmotil G100 Pre-mix for Medicated Feedingstuff | Tilmicosin (as phosphate) | 100 g tilmicosin per kg premix | Premix pentru furaje cu conținut medicamentos | Porci, iepuri |
| Regatul Unit | Eli Lilly and Company Ltd<br>Elanco Animal Health<br>Lilly House<br>Priestly Road<br>Basingstoke<br>Hampshire RG24 9NL<br>REGATUL UNIT | Pulmotil G200 Pre-mix for Medicated Feedingstuff | Tilmicosin (as phosphate) | 200 g tilmicosin per kg premix | Premix pentru furaje cu conținut medicamentos | Porci, iepuri |

*ANEXA II*

**LISTA DENUMIRILOR, FORMA FARMACEUTICA, CONCENTRAȚIILOR PRODUSELOR MEDICINALE VETERINARE, SPECIILE DE ANIMALE, CALEA DE ADMINISTRARE, DEȚINĂTORILOR AUTORIZAȚIILOR DE COMERCIALIZARE ÎN STATELE MEMBRE**

| Stat Membru EU/EEA | Deținător al autorizației de comercializare | Nume | INN/Concentrații | Forme farmaceutice | Specii de animale |
|---|---|---|---|---|---|
| Austria | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Exitel Plus Tabletten für Hunde | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Austria | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Prazitel Plus Tabletten für Hunde | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Belgia | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Cazitel Plus Tabletten für Hunde | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Belgia | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Exitel Plus Tabletten für Hunde | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Belgia | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Prazitel Plus Tabletten für Hunde | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Bulgaria | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Cazitel Plus таблетки за кучета | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Bulgaria | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Exitel Plus таблетки за кучета | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Bulgaria | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Prazitel Plus таблетки за кучета | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |

| Stat Membru EU/EEA | Deținător al autorizației de comercializare | Nume | INN/Concentrații | Forme farmaceutice | Specii de animale |
|---|---|---|---|---|---|
| Cipru | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Exitel Plus Δισκία Για Σκύλους | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Republica Cehă | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Cazitel Plus tablety pro psy | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Republica Cehă | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Exitel Plus tablety pro psy | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Republica Cehă | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Prazitel Plus tablety pro psy | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Danemarca | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Exitel Plus | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Danemarca | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Prazitel Plus | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Estonia | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Cazitel Plus tabletid koertele | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Estonia | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Exitel Plus tabletid koertele | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Finlanda | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Cazitel Plus 50 mg/144 mg/ 150 mg tablet | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |

| Stat Membru EU/EEA | Deținător al autorizației de comercializare | Nume | INN/Concentrații | Forme farmaceutice | Specii de animale |
|---|---|---|---|---|---|
| Finlanda | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Exitel Plus 50 mg/144 mg/ 150 mg tablet | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Finlanda | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Prazitel Plus 50 mg/144 mg/ 150 mg tablet | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Franța | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Milaxyn comprimé pour chiens | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Franța | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Strantel comprimé pour chiens | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Franța | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Prazical comprimé pour chiens | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Franța | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Voxical comprimé pour chiens | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Germania | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Cazitel Tabletten für Hunde | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Germania | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Exitel Tabletten für Hunde | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Germania | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Strantel Tabletten für Hunde | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |

| Stat Membru EU/EEA | Deținător al autorizației de comercializare | Nume | INN/Concentrații | Forme farmaceutice | Specii de animale |
|---|---|---|---|---|---|
| Grecia | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Cazitel plus Δισκία Για Σκύλους | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Grecia | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Exitel plus Δισκία Για Σκύλους | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Grecia | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Prazitel plus Δισκία Για Σκύλους | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Ungaria | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Cazitel Plus tabletta kutyák részére A.U.V | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Ungaria | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Exitel Plus tabletta kutyák részére A.U.V | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Ungaria | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Prazitel Plus tabletta kutyák részére A.U.V | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Islanda | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Exitel Plus töflur fyrir hunda | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Islanda | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Prazitel Plus töflur fyrir hunda | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Irlanda | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Cazitel Plus tablets for dogs | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |

| Stat Membru EU/EEA | Deținător al autorizației de comercializare | Nume | INN/Concentrații | Forme farmaceutice | Specii de animale |
|---|---|---|---|---|---|
| Irlanda | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Exitel Plus tablets for dogs | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Irlanda | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Milaxyn Plus tablets for dogs | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Irlanda | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Prazical Plus tablets for dogs | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Irlanda | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Prazitel Plus tablets for dogs | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Irlanda | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Strantel Plus tablets for dogs | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Irlanda | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Voxical Plus tablets for dogs | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Italia | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Canitel Plus compresse per cani | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Italia | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Exitel Plus compresse per cani | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Italia | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Prazitel compresse per cani | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |

| Stat Membru EU/EEA | Deținător al autorizației de comercializare | Nume | INN/Concentrații | Forme farmaceutice | Specii de animale |
|---|---|---|---|---|---|
| Letonia | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Cazitel tablets Tabletes suņiem | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Letonia | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Exitel tablets Tabletes suņiem | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Letonia | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Prazitel tablets Tabletes suņiem | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Lituania | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Cazitel Plus tabletės šunims | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Lituania | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Exitel Plus tabletės šunims | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Lituania | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Prazitel Plus tabletės šunims | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Luxemburg | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Exitel Plus tabletten voor honden | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Luxemburg | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Prazitel Plus tabletten voor honden | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Țările de Jos | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Cazitel Plus tabletten voor honden | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |

| Stat Membru EU/EEA | Deținător al autorizației de comercializare | Nume | INN/Concentrații | Forme farmaceutice | Specii de animale |
|---|---|---|---|---|---|
| Țările de Jos | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Exitel Plus tabletten voor honden | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Țările de Jos | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Prazitel Plus tabletten voor honden | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Norvegia | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Exitel Vet | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Norvegia | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Prazitel Vet | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Polonia | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Cazitel Plus tabletki dla psów | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Polonia | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Exitel Plus tabletki dla psów | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Polonia | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Prazitel Plus tabletki dla psów | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Portugalia | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Cazitel Plus Comprimidos para cães | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Portugalia | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Exitel Plus Comprimidos para cães | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |

| Stat Membru EU/EEA | Deținător al autorizației de comercializare | Nume | INN/Concentrații | Forme farmaceutice | Specii de animale |
|---|---|---|---|---|---|
| Portugalia | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Prazitel Plus Comprimidos para cães | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| România | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Cazitel Plus Comprimate pentru câini | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| România | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Exitel Plus Comprimate pentru câini | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| România | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Prazitel Plus Comprimate pentru câini | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Slovacia | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Cazitel Plus tablety pre psov | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Slovacia | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Exitel Plus tablety pre psov | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Slovacia | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Prazitel Plus tablety pre psov | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Slovenia | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Cazitel Plus tablete za pse | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Slovenia | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Exitel Plus tablete za pse | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |

| Stat Membru EU/EEA | Deținător al autorizației de comercializare | Nume | INN/Concentrații | Forme farmaceutice | Specii de animale |
|---|---|---|---|---|---|
| Slovenia | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Prazitel Plus tablete za pse | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Spania | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Cazitel comprimidos para perros | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Spania | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Exitel comprimidos para perros | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Spania | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Prazitel comprimidos para perros | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Suedia | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Exitel vet. 150 mg/<br>144 mg/50 mg tablett för hund | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Suedia | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Strantel vet. 150 mg/<br>144 mg/50 mg tablett för hund | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Regatul Unit | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Cazitel plus tablets for dogs | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Regatul Unit | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Easimax plus tablets for dogs | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |
| Regatul Unit | Chanelle Pharmaceuticals Manufacturing Ltd.<br>IE-Loughrea<br>Co. Galway<br>Irlanda | Prazitel plus tablets for dogs | Praziquantel 50 mg<br>Pyrantel 50 mg (echivalentul a 144 mg pyrantel embonate)<br>Febantel 150 mg | Comprimate | Câini |

*ANEXA III*

**LISTA CU DENUMIRILE COMERCIALE, FORMAFARMACEUTICĂ, CONCENTRAȚIA, CALEADE ADMINISTRARE A MEDICAMENTELOR, SOLICITANTUL ÎN STATELE MEMBRE**

| Statul Membru UE/SEE | Solicitantul | Numele inventat | Concentrația | Forma farmaceutică | Calea de administrare |
|---|---|---|---|---|---|
| AT - Austria | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Flutiform®<br>Flutiform 50 Mikrogramm/<br>5 Mikrogramm pro Sprühstoß<br>Druckgasinhalation | 50 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| AT - Austria | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Flutiform®<br>Flutiform 125 Mikrogramm/<br>5 Mikrogramm pro Sprühstoß<br>Druckgasinhalation | 125 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| AT - Austria | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Flutiform®<br>Flutiform 250 Mikrogramm/<br>10 Mikrogramm pro Sprühstoß<br>Druckgasinhalation | 250 mcg/10 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| BE - Belgia | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Flutiform®<br>Flutiform 50 mcg/5 mcg, aërosol, suspensie | 50 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| BE - Belgia | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Flutiform®<br>Flutiform 125 mcg/5 mcg, aërosol, suspensie | 125 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| BE - Belgia | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Flutiform®<br>Flutiform 250 mcg/10 mcg, aërosol, suspensie | 250 mcg/10 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| BG - Bulgaria | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Flutiform® | 50 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |

| Statul Membru UE/SEE | Solicitantul | Numele inventat | Concentrația | Forma farmaceutică | Calea de administrare |
|---|---|---|---|---|---|
| BG - Bulgaria | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Flutiform® | 125 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| BG - Bulgaria | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Flutiform® | 250 mcg/10 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| CY - Cipru | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Flutiform® | 50 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| CY - Cipru | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Flutiform® | 125 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| CY - Cipru | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Flutiform® | 250 mcg/10 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| CZ - Republica Cehă | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Flutiform® | 50 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| CZ - Republica Cehă | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Flutiform® | 125 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| CZ - Republica Cehă | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Flutiform® | 250 mcg/10 mcg | Suspensie de inhalat presurizată | Inhalatorie |

| Statul Membru UE/SEE | Solicitantul | Numele inventat | Concentrația | Forma farmaceutică | Calea de administrare |
|---|---|---|---|---|---|
| DK - Danemarca | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Flutiform® | 50 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| DK - Danemarca | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Flutiform® | 125 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| DK - Danemarca | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Flutiform® | 250 mcg/10 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| FI - Finlanda | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Flutiform® | 50 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| FI - Finlanda | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Flutiform® | 125 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| FI - Finlanda | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Flutiform® | 250 mcg/10 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| FR - Franța | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Flutiform® | 50 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| FR - Franța | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Flutiform® | 125 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |

| Statul Membru UE/SEE | Solicitantul | Numele inventat | Concentrația | Forma farmaceutică | Calea de administrare |
|---|---|---|---|---|---|
| FR - Franța | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Flutiform® | 250 mcg/10 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| DE - Germania | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Flutiform® | 50 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| DE - Germania | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Flutiform® | 125 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| DE - Germania | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Flutiform® | 250 mcg/10 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| IS - Islanda | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Flutiform® | 50 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| IS - Islanda | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Flutiform® | 125 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| IS - Islanda | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Flutiform® | 250 mcg/10 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| IE - Irlanda | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Flutiform® | 50 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |

| Statul Membru UE/SEE | Solicitantul | Numele inventat | Concentrația | Forma farmaceutică | Calea de administrare |
|---|---|---|---|---|---|
| IE - Irlanda | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Flutiform® | 125 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| IE - Irlanda | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Flutiform® | 250 mcg/10 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| IT - Italia | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Flutiformo® | 50 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| IT - Italia | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Flutiformo® | 125 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| IT - Italia | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Flutiformo® | 250 mcg/10 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| LU - Luxemburg | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Flutiform® | 50 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| LU - Luxemburg | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Flutiform® | 125 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| LU - Luxemburg | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Flutiform® | 250 mcg/10 mcg | Suspensie de inhalat presurizată | Inhalatorie |

| Statul Membru UE/SEE | Solicitantul | Numele inventat | Concentrația | Forma farmaceutică | Calea de administrare |
|---|---|---|---|---|---|
| NL - Olanda | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Flutiform®<br>Flutiform 50 microgram/<br>5 microgram/dosis aërosol, suspensie | 50 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| NL - Olanda | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Flutiform®<br>Flutiform 125 microgram/<br>5 microgram/dosis aërosol, suspensie | 125 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| NL - Olanda | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Flutiform®<br>Flutiform 250 microgram/<br>10 microgram/dosis aërosol, suspensie | 250 mcg/10 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| NO - Norvegia | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Flutiform® | 50 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| NO - Norvegia | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Flutiform® | 125 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| NO - Norvegia | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Flutiform® | 250 mcg/10 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| PL - Polonia | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Flutiform® | 50 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| PL - Polonia | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Flutiform® | 125 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |

| Statul Membru UE/SEE | Solicitantul | Numele inventat | Concentrația | Forma farmaceutică | Calea de administrare |
|---|---|---|---|---|---|
| PL - Polonia | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Flutiform® | 250 mcg/10 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| PT - Portugalia | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Flutiform | 50 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| PT - Portugalia | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Flutiform | 125 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| PT - Portugalia | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Flutiform | 250 mcg/10 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| RO - România | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Flutiform®<br>Flutiform 50 micrograme/<br>5 micrograme suspensie de inhalat presurizată | 50 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| RO - România | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Flutiform®<br>Flutiform 125 micrograme/<br>5 micrograme suspensie de inhalat presurizată | 125 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| RO - România | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Flutiform®<br>Flutiform 250 micrograme/<br>10 micrograme suspensie de inhalat presurizată | 250 mcg/10 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| SK - Republica Slovacia | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Flutiform®50/5 µg | 50 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |

| Statul Membru UE/SEE | Solicitantul | Numele inventat | Concentrația | Forma farmaceutică | Calea de administrare |
|---|---|---|---|---|---|
| SK - Republica Slovacia | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Flutiform® 125/5 µg | 125 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| SK - Republica Slovacia | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Flutiform® 250/10 µg | 250 mcg/10 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| SE - Suedia | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Flutiform® | 50 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| SE - Suedia | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Flutiform® | 125 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| SE - Suedia | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Flutiform® | 250 mcg/10 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| UK - Marea Britanie | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Flofera® | 50 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| UK - Marea Britanie | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Flofera® | 125 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| UK - Marea Britanie | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Flofera® | 250 mcg/10 mcg | Suspensie de inhalat presurizată | Inhalatorie |

*ANEXA IV*

**LISTA CU DENUMIRILE COMERCIALE, FORMAFARMACEUTICĂ, CONCENTRAȚIA, CALEADE ADMINISTRARE A MEDICAMENTELOR, SOLICITANTUL ÎN STATELE MEMBRE**

| Statul Membru UE/SEE | Solicitantul | Numele inventat | Concentrația | Forma farmaceutică | Calea de administrare |
|---|---|---|---|---|---|
| AT - Austria | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Iffeza 50 Mikrogramm/5 Mikrogramm pro Sprühstoß Druckgasinhalation | 50 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| AT - Austria | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Iffeza 125 Mikrogramm/5 Mikrogramm pro Sprühstoß Druckgasinhalation | 125 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| AT - Austria | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Iffeza 250 Mikrogramm/10 Mikrogramm pro Sprühstoß Druckgasinhalation | 250 mcg/10 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| BE - Belgia | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Iffeza 50 mcg/5 mcg, aërosol, suspensie | 50 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| BE - Belgia | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Iffeza 125 mcg/5 mcg, aërosol, suspensie | 125 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| BE - Belgia | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Iffeza 250 mcg/10 mcg, aërosol, suspensie | 250 mcg/10 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| BG - Bulgaria | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Iffeza | 50 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |

| Statul Membru UE/SEE | Solicitantul | Numele inventat | Concentrația | Forma farmaceutică | Calea de administrare |
|---|---|---|---|---|---|
| BG - Bulgaria | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Iffeza | 125 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| BG - Bulgaria | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Iffeza | 250 mcg/10 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| CY - Cipru | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Iffeza | 50 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| CY - Cipru | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Iffeza | 125 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| CY - Cipru | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Iffeza | 250 mcg/10 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| CZ - Republica Cehă | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Iffeza | 50 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| CZ - Republica Cehă | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Iffeza | 125 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| CZ - Republica Cehă | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Iffeza | 250 mcg/10 mcg | Suspensie de inhalat presurizată | Inhalatorie |

| Statul Membru UE/SEE | Solicitantul | Numele inventat | Concentrația | Forma farmaceutică | Calea de administrare |
|---|---|---|---|---|---|
| DK - Danemarca | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Iffeza | 50 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| DK - Danemarca | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Iffeza | 125 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| DK - Danemarca | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Iffeza | 250 mcg/10 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| FI - Finlanda | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Iffeza | 50 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| FI - Finlanda | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Iffeza | 125 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| FI - Finlanda | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Iffeza | 250 mcg/10 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| FR - Franța | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Iffeza | 50 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| FR - Franța | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Iffeza | 125 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |

| Statul Membru UE/SEE | Solicitantul | Numele inventat | Concentrația | Forma farmaceutică | Calea de administrare |
|---|---|---|---|---|---|
| FR - Franța | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Iffeza | 250 mcg/10 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| DE - Germania | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Iffeza | 50 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| DE - Germania | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Iffeza | 125 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| DE - Germania | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Iffeza | 250 mcg/10 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| IS - Islanda | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Iffeza® | 50 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| IS - Islanda | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Iffeza® | 125 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| IS - Islanda | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Iffeza® | 250 mcg/10 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| IE - Irlanda | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Iffeza | 50 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |

| Statul Membru UE/SEE | Solicitantul | Numele inventat | Concentrația | Forma farmaceutică | Calea de administrare |
|---|---|---|---|---|---|
| IE - Irlanda | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Iffeza | 125 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| IE - Irlanda | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Iffeza | 250 mcg/10 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| IT - Italia | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Iffeza | 50 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| IT - Italia | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Iffeza | 125 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| IT - Italia | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Iffeza | 250 mcg/10 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| LU - Luxemburg | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Iffeza | 50 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| LU - Luxemburg | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Iffeza | 125 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| LU - Luxemburg | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Iffeza | 250 mcg/10 mcg | Suspensie de inhalat presurizată | Inhalatorie |

| Statul Membru UE/SEE | Solicitantul | Numele inventat | Concentrația | Forma farmaceutică | Calea de administrare |
|---|---|---|---|---|---|
| NL - Olanda | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Iffeza 50 microgram/5 microgram/dosis aërosol, suspensie | 50 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| NL - Olanda | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Iffeza 125 microgram/5 microgram/dosis aërosol, suspensie | 125 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| NL - Olanda | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Iffeza 250 microgram/10 microgram/dosis aërosol, suspensie | 250 mcg/10 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| NO - Norvegia | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Iffera® | 50 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| NO - Norvegia | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Iffera® | 125 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| NO - Norvegia | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Iffera® | 250 mcg/10 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| PL - Polonia | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Iffeza | 50 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| PL - Polonia | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Iffeza | 125 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |

| Statul Membru UE/SEE | Solicitantul | Numele inventat | Concentrația | Forma farmaceutică | Calea de administrare |
|---|---|---|---|---|---|
| PL - Polonia | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Iffeza | 250 mcg/10 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| PT - Portugalia | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Iffeza | 50 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| PT - Portugalia | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Iffeza | 125 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| PT - Portugalia | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Iffeza | 250 mcg/10 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| RO - România | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Iffeza 50 micrograme/5 micrograme suspensie de inhalat presurizată | 50 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| RO - România | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Iffeza 125 micrograme/5 micrograme suspensie de inhalat presurizată | 125 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| RO - România | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Iffeza 250 micrograme/10 micrograme suspensie de inhalat presurizată | 250 mcg/10 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| SK - Republica Slovacia | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Iffeza 50/5 µg | 50 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |

| Statul Membru UE/SEE | Solicitantul | Numele inventat | Concentrația | Forma farmaceutică | Calea de administrare |
|---|---|---|---|---|---|
| SK - Republica Slovacia | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Iffeza 125/5 µg | 125 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| SK - Republica Slovacia | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Iffeza 250/10 µg | 250 mcg/10 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| SE - Suedia | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Iffeza | 50 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| SE - Suedia | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Iffeza | 125 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| SE - Suedia | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Iffeza | 250 mcg/10 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| UK - Marea Britanie | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Iffeza | 50 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| UK - Marea Britanie | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Iffeza | 125 mcg/5 mcg | Suspensie de inhalat presurizată | Inhalatorie |
| UK - Marea Britanie | Napp Pharmaceuticals Limited<br>Cambridge Science Park<br>Milton Road<br>Cambridge CB4 0GW<br>United Kingdom | Iffeza | 250 mcg/10 mcg | Suspensie de inhalat presurizată | Inhalatorie |