C/2024/2198

27.3.2024

Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 February 2024 to 29 February 2024

(Decisions taken pursuant to Article 34 of Directive 2001/83/EC [1], Article 38 of Directive 2001/82/EC [2] or Article 5 of Regulation (EU) 2019/6 of the European Parliament and of the Council [3])

(C/2024/2198)

— Issuing, maintenance or modification of a national marketing authorisation

Date of the decision	Name(s) of the medicinal product	INN (International Non-Proprietary Name)	Holder(s) of the marketing authorisation	Member State concerned	Date of notification
23.2.2024	Procactive 300 mg/ml suspension for injection for cattle, sheep and pigs and associated names	procaine benzylpenicillin	See Annex	See Annex	26.2.2024

[1] OJ L 311, 28.11.2001, p. 67.
[2] OJ L 311, 28.11.2001, p. 1.
[3] OJ L 4, 7.1.2019, p. 43.

ANNEX

List of the names, pharmaceutical form, strength of the veterinary medicinal products, animal species, route of administration, marketing authorisation holder in the Member States

Member State EU/EEA	Marketing authorisation holder	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Belgium	Laboratorios Syva S.A.U. Avenida Párroco Pablo Díez, 49-57 (24010) León Spain	Peniyet vet 300 mg/ml suspension injectable pour bovins, ovins et porcins	Procaine benzylpenicillin	300 mg/ml	Suspension for injection	Cattle, sheep, pigs	Intramuscular use
Bulgaria	Laboratorios Syva S.A.U. Avenida Párroco Pablo Díez, 49-57 (24010) León Spain	Procactive 300 mg/ml инжекционна суспензия за говеда, овце и прасета	Procaine benzylpenicillin	300 mg/ml	Suspension for injection	Cattle, sheep, pigs	Intramuscular use
Denmark	Laboratorios Syva S.A.U. Avenida Párroco Pablo Díez, 49-57 (24010) León Spain	Syvacillin vet	Procaine benzylpenicillin	300 mg/ml	Suspension for injection	Cattle, sheep, pigs	Intramuscular use
Estonia	Laboratorios Syva S.A.U. Avenida Párroco Pablo Díez, 49-57 (24010) León Spain	Procactive 300 mg/ml süstesuspensioon veistele, lammastele ja sigadele	Procaine benzylpenicillin	300 mg/ml	Suspension for injection	Cattle, sheep, pigs	Intramuscular use
Finland	Laboratorios Syva S.A.U. Avenida Párroco Pablo Díez, 49-57 (24010) León Spain	Syvacillin vet 300 mg/ml injektioneste, suspensio naudoille, lampaille ja sioille	Procaine benzylpenicillin	300 mg/ml	Suspension for injection	Cattle, sheep, pigs	Intramuscular use

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Member State EU/EEA	Marketing authorisation holder	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
France	Laboratorios Syva S.A.U. Avenida Párroco Pablo Díez, 49-57 (24010) León Spain	Procactive suspension injectable pour bovins, ovins et porcins	Procaine benzylpenicillin	300 mg/ml	Suspension for injection	Cattle, sheep, pigs	Intramuscular use
Germany	Laboratorios Syva S.A.U. Avenida Párroco Pablo Díez, 49-57 (24010) León Spain	Procactive 300 mg/ml Injektionssuspension für Rinder, Schafe und Schweine	Procaine benzylpenicillin	300 mg/ml	Suspension for injection	Cattle, sheep, pigs	Intramuscular use
Greece	Laboratorios Syva S.A.U. Avenida Párroco Pablo Díez, 49-57 (24010) León Spain	Syvacillin vet 300 mg/ml ενέσιμο εναιώρημα για βοοειδή, πρόβατα και χοίρους	Procaine benzylpenicillin	300 mg/ml	Suspension for injection	Cattle, sheep, pigs	Intramuscular use
Hungary	Laboratorios Syva S.A.U. Avenida Párroco Pablo Díez, 49-57 (24010) León Spain	Procactive 300 mg/ml szuszpenziós injekció szarvasmarhák, juhok és sertések számára A.U.V.	Procaine benzylpenicillin	300 mg/ml	Suspension for injection	Cattle, sheep, pigs	Intramuscular use
Ireland	Laboratorios Syva S.A.U. Avenida Párroco Pablo Díez, 49-57 (24010) León Spain	Procactive 300 mg/ml suspension for injection for cattle, sheep and pigs	Procaine benzylpenicillin	300 mg/ml	Suspension for injection	Cattle, sheep, pigs	Intramuscular use
Italy	Laboratorios Syva S.A.U. Avenida Párroco Pablo Díez, 49-57 (24010) León Spain	Procactive 300 mg/ml sospensione iniettabile per bovini, ovini e suini	Procaine benzylpenicillin	300 mg/ml	Suspension for injection	Cattle, sheep, pigs	Intramuscular use
Norway	Laboratorios Syva S.A.U. Avenida Párroco Pablo Díez, 49-57 (24010) León Spain	Peniyet vet 300 mg/ml injeksjonsvæske, suspensjon til storfe, sau og gris	Procaine benzylpenicillin	300 mg/ml	Suspension for injection	Cattle, sheep, pigs	Intramuscular use

Member State EU/EEA	Marketing authorisation holder	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Portugal	Laboratorios Syva S.A.U. Avenida Párroco Pablo Díez, 49-57 (24010) León Spain	Procactive 300 mg/ml suspensão injetável para bovinos, ovinos e suínos	Procaine benzylpenicillin	300 mg/ml	Suspension for injection	Cattle, sheep, pigs	Intramuscular use
Spain	Laboratorios Syva S.A.U. Avenida Párroco Pablo Díez, 49-57 (24010) León Spain	Procactive 300 mg/ml Suspensión inyectable para bovino, ovino y porcino	Procaine benzylpenicillin	300 mg/ml	Suspension for injection	Cattle, sheep, pigs	Intramuscular use
Sweden	Laboratorios Syva S.A.U. Avenida Párroco Pablo Díez, 49-57 (24010) León Spain	Peniyet vet 300 mg/ml injektionsvätska, suspension för nötkreatur, får och grisar	Procaine benzylpenicillin	300 mg/ml	Suspension for injection	Cattle, sheep, pigs	Intramuscular use
The Netherlands	Laboratorios Syva S.A.U. Avenida Párroco Pablo Díez, 49-57 (24010) León Spain	Peniyet vet 300 mg/ml suspensie voor injectie bij runderen, schapen en varkens	Procaine benzylpenicillin	300 mg/ml	Suspension for injection	Cattle, sheep, pigs	Intramuscular use
United Kingdom (Northern Ireland)	Laboratorios Syva S.A.U. Avenida Párroco Pablo Díez, 49-57 (24010) León Spain	Procactive 300 mg/ml suspension for injection for cattle, sheep and pigs	Procaine benzylpenicillin	300 mg/ml	Suspension for injection	Cattle, sheep, pigs	Intramuscular use

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