

EKYFLOGYL 1.8 MG/ML + 8.7 MG/ML GEL FOR HORSES

Authorised

- Prednisolone acetate
- Lidocaine hydrochloride monohydrate

Product identification

Medicine name:

EKYFLOGYL 1.8 MG/ML + 8.7 MG/ML GEL FOR HORSES

Active substance:

Prednisolone acetate

Lidocaine hydrochloride monohydrate

Target species:

Horse

Route of administration:

Cutaneous use

Product details

Active substance and strength:

Prednisolone acetate

2.00 milligram(s) / 1.00 millilitre(s)

Lidocaine hydrochloride monohydrate

10.70 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:

Gel

Withdrawal period by route of administration:

Cutaneous use:

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Horse

- Meat and offal. 10 day
- Milk. no withdrawal period

Not authorised for use in animals producing milk for human consumption.

Anatomical therapeutic chemical veterinary (ATCvet) codes:

QM02AX99

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

Authorisation status:

Valid

Authorised in:

Denmark

Package description:

Box of one 125 ml Brown Type III glass bottle with a dosing pump made of high-density polyethylene / polypropylene and a dip tube made of low-density polyethylene and polypropylene. Polypropylene screw-fit cap.

Additional information

Entitlement type:

Marketing Authorisation

Legal basis of product authorisation:

Hybrid application (Article 13(3) of Directive No 2001/82/EC)

Marketing authorisation holder:

Audevard

Marketing authorisation date:

9/09/2019

Manufacturing sites for batch release:

Dopharma France

Responsible authority:

Danish Medicines Agency

Authorisation number:

61449

Date of authorisation status change:

9/09/2019

Reference member state:

France

Procedure number:

FR/V/0344/001

Concerned member states:

Austria Denmark Finland Germany Ireland Luxembourg Netherlands Norway
Poland Portugal Sweden

To consult adverse reactions on veterinary medicinal products please go to
www.adrreports.eu/vet

Documents

Summary of Product Characteristics

This document does not exist in this language (English). You can find it in another language below.

Combined File of all Documents

eu-puar-frv0344001-mr-rpe532-en.pdf