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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:

- **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

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Combined File of all Documents

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