SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EKYFLOGYL 1.8mg/ml + 8.7mg/ml Gel for Horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains

Active substances:
Prednisolone (as acetate) 1.8 mg

Lidocaine (as hydrochloride monohydrate) 8.7 mg

Excipient:
Dimethyl sulfoxide 968 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Gel
Clear viscous liquid.

4. CLINICAL PARTICULARS

4.1 Target species

Horses (non-food producing)

4.2 Indications for use, specifying the target species

For the alleviation of pain and inflammation associated with localised musculoskeletal disorders.

4.3 Contraindications

Do not use in known cases of hypersensitivity to the active substances or to any of the excipients. See section 4.7. Do not use in horses with hepatic or renal disease. The product should not be used in horses with ongoing viral, or fungal infections or in immunocompromised horses.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

This product should not be used on irritated or broken skin.
Oral ingestion of the product by treated animals or animals having contact with treated animals should be avoided.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

- This product may cause allergic reactions. People with known hypersensitivity to prednisolone, lidocaine, other local anaesthetics or dimethyl sulfoxide (DMSO) should not handle the product.
- Prednisolone may cause harm to the unborn foetus. Pregnant women should therefore not handle this product.
- This product may be harmful after dermal and oral exposure. Lidocaine may form genotoxic metabolites in humans. A long-term toxicology study in rats has shown evidence that these metabolites can also induce carcinogenic effects at high doses. The product is also irritating to the skin (reactions including erythema and pruritus) and to the eye.
- Avoid contact with skin, eye and mouth, including hand-to-mouth and hand-to-eye contact. Wash hands after use. In the event of accidental contact with the skin or eyes, rinse thoroughly with water.
- Personal protective equipment consisting of impermeable single-use protective gloves should be worn when handling the veterinary medicinal product or touching the treated area.
- Prevent children from touching the treated horse during the period of treatment and 12 days after the end of the treatment.
- Do not touch the treated area. If this is necessary for horse care, wear impermeable single-use protective gloves.
- In the event of accidental ingestion or persistent skin or eye irritation, seek medical advice immediately and show the package leaflet or the label to the physician.
- Additional material or devices used to apply the product such as a brush should be cleaned up thoroughly or disposed of according to local requirements.
- Keep the bottle with the dosing pump in the outer carton and in safe place out of the sight and reach of children until ready to use. The device should be locked after each use (see details in section 4.9).

4.6 Adverse reactions (frequency and seriousness)

Local reactions (pain, heat, loss of hair, squamosis/scaly skin, burn marks, swelling) have been very rarely reported.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports)

4.7 Use during pregnancy, lactation

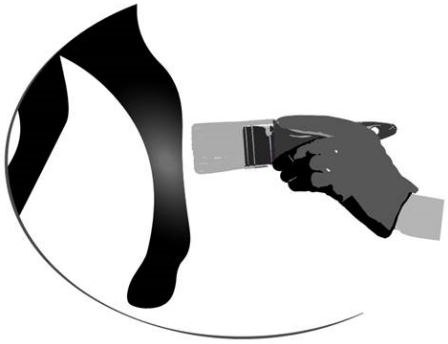
Studies in laboratory animals have produced evidence of embryotoxic effects of prednisolone.
Lidocaine crosses the placental barrier and can cause nerve and cardiorespiratory effects in the foetus and newborn animals. The safety of the product in the target animals has not been assessed during pregnancy and lactation.
Do not use the product in pregnant or lactating mares.

4.8 Interaction with other medicinal products and other forms of interaction

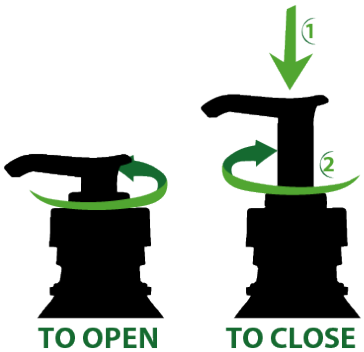
Do not use with other products, in particular topical products on the treated area.

4.9 Amounts to be administered and administration route

Cutaneous use. Apply the product to a localised area over the underlying lesion with a small brush (paintbrush or similar). If needed, a non-compressive dressing may be applied to cover the treated area. Apply 11 to 32 ml twice daily, corresponding to 6 to 18 actuations of the pump dispenser, depending on the nature of the lesion.



Pump must be primed twice before use.
Continue the treatment until the clinical signs are resolved, but do not use the product for more than 12 days.
To open the device, turn the snap cap as indicated on the top. After each use, close the device by turning the snap cap in the opposite direction.



4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No information available.

4.11 Withdrawal period(s)

Not authorised for use in horses intended for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: 'other topical product for joint and muscular pain, combinations'
ATC vet code: QM02AX99

5.1 Pharmacodynamic properties

Prednisolone is a synthetic glucocorticoid with anti-inflammatory action. It has anti-exudative properties and an anti-granulomatous action. It decreases the fibroblastic reaction by stabilising the cell membranes and prevents cellular destruction and therefore inflammation of the treated area. In addition, it increases local vascular tonus and decreases oedema. Finally, it prevents the depolymerisation of mucopolysaccharides.
Lidocaine is a local anaesthetic.
Dimethyl sulfoxide (DMSO) improves the transcutaneous penetration of the active ingredients by increasing cellular permeability.

5.2 Pharmacokinetic particulars

No specific information is available following cutaneous application of the combination product to horses.

When applied topically to intact skin, lidocaine is subject to limited and delayed absorption. Greater absorption of lidocaine should be expected in cases of compromised skin barrier function. Lidocaine is cleared by hepatic metabolism to active and inactive metabolites, then excreted via the kidneys. Terminal half-life is less than 2 hours in most animal species.

When applied topically to intact skin, prednisolone is subject to limited and delayed absorption. Greater absorption of prednisolone should be expected in cases of compromised skin barrier function. Metabolism occurs at both hepatic and extrahepatic (including the kidney) sites. Terminal half-life in horses is about 3 hours. The parent drug and its metabolites are excreted in the urine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Dimethyl sulfoxide
Hydroxyethylcellulose
Purified water

6.2 Major incompatibilities

In absence of compatibility studies, this medicinal product should not be mixed with other medicinal products.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years
Shelf life after first opening the immediate packaging: 30 days

6.4 Special precautions for storage

Do not store above 30°C
Store in the outer carton in order to protect from light

6.5 Nature and composition of immediate packaging

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.
Box of one 125 ml bottle

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

AUDEVARD
37-39 rue Médéric
92110 Clichy
France

8. MARKETING AUTHORISATION NUMBER

Vm 44684/4004

9. DATE OF FIRST AUTHORISATION

07 September 2021

10. DATE OF REVISION OF THE TEXT

March 2022

Approved 04 March 2022