1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EKYFLOGYL 1.8mg/ml + 8.7mg/ml GEL FOR HORSES

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One ml contains

Active substances:
Prednisolone (as acetate) 1.8 mg
(equivalent to 2 mg of prednisolone acetate)

Lidocaine (as hydrochloride monohydrate) 8.7 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Dimethyl sulfoxide	968 mg
Hydroxyethylcellulose	
Purified water	

Clear viscous gel.

3. CLINICAL INFORMATION

3.1 Target species

Horses.

3.2 Indications for use for each target species

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

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.
See section 3.7. Do not use in horses with hepatic or renal disease.Do not usein horses with ongoing viral, or fungal infections or in immunocompromised horses.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

This veterinary medicinal product should not be used on irritated or broken skin.
Oral ingestion of the veterinary medicinal 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 veterinary medicinal product may cause allergic reactions. People with known hypersensitivity to prednisolone, lidocaine, other local anesthetics or any of the excipients should not handle the veterinary medicinal product.
- Prednisolone may cause harm to the unborn foetus. Pregnant women should therefore not handle this veterinary medicinal product.
- This veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal 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 3.9).

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Application site reactions (pain, warmth, hair loss, skin squamosis, burn, swelling)

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and 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 veterinary medicinal product in the target animals has not been assessed during pregnancy and lactation.
Do not use the veterinary medicinal product in pregnant or lactating mares.

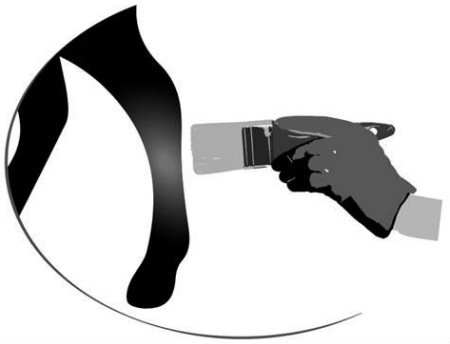
3.8 Interaction with other medicinal products and other forms of interaction

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

3.9 Administration routes and dosage

Cutaneous use. Apply the product veterinary medicinal 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 10 to 30 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 veterinary medicinal 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No information available.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Meat and offal: 10 days
Not authorised for use in animals producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:QM02AX99.

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

No specific information is available following cutaneous application of the combination veterinary medicinal 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 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.

5.3 Special precautions for storage

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

5.4 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.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

AUDEVARD

7. MARKETING AUTHORISATION NUMBER(S)

VPA10481/002/001

8. DATE OF FIRST AUTHORISATION

11/10/2019

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

09/02/2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).