ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EKYFLOGYL 1.8mg/ml + 8.7mg/ml gel for horses

2. STATEMENT OF ACTIVE SUBSTANCES

Prednisolone (as acetate)	1.8 mg
Lidocaine (as hydrochloride monohydrate)	8.7 mg

3. PHARMACEUTICAL FORM

Gel

4. PACKAGE SIZE

125ml

5. TARGET SPECIES

Horses (non-food producing)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Cutaneous use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period :
Not authorised for use in horses intended for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

Prevent children from coming into contact with the product or the treated animal.
Wear impermeable gloves when administering this product or touching the treated area.
Pregnant women should not handle this product.

10. EXPIRY DATE

EXP
After opening, use within 30 days.

Date to be discarded

11. SPECIAL STORAGE CONDITIONS

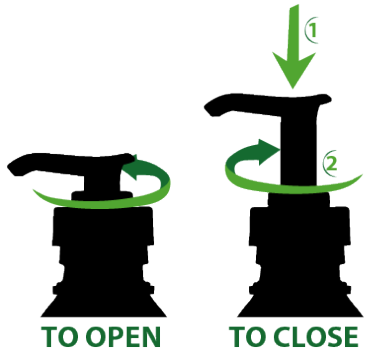
Do not store above 30°C
Store in the outer carton in order to protect from light

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.
'To be supplied only on veterinary prescription'



14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

AUDEVARD
37-39 rue Médéric
92110 Clichy
France

16. MARKETING AUTHORISATION NUMBER

Vm 44684/4004

17. MANUFACTURER'S BATCH NUMBER

LOT

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EKYFLOGYL 1.8mg/ml + 8.7mg/ml gel for horses

2. STATEMENT OF ACTIVE SUBSTANCES

Prednisolone (as acetate)	1.8 mg
Lidocaine (as hydrochloride monohydrate)	8.7 mg

3. PHARMACEUTICAL FORM

Gel

4. PACKAGE SIZE

125ml

5. TARGET SPECIES

Horses

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Cutaneous use
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period:
Not authorised for use in horses intended for human consumption.

9. SPECIAL WARNING, IF NECESSARY

Prevent children from coming into contact with the product or the treated animal.
Wear impermeable gloves when administering this product or touching the treated area.
Pregnant women should not handle this product.

10. EXPIRY DATE

EXP
After opening, use within 30 days. Date to be discarded

11. SPECIAL STORAGE CONDITIONS

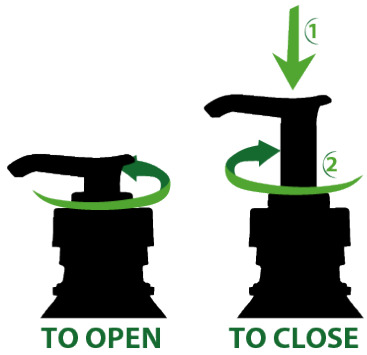
Do not store above 30°C
Store in the outer carton in order to protect from light

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.



14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

AUDEVARD
37-39 rue Médéric
92110 Clichy
France

16. MARKETING AUTHORISATION NUMBER(S)

Vm 44684/4004

17. MANUFACTURER'S BATCH NUMBER

LOT

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
EKYFLOGYL gel for Horses

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
AUDEVARD
37-39 rue Médéric
92110 Clichy
France

Manufacturer responsible for batch release:
DOPHARMA FRANCE, 23 rue du Prieuré, Saint Herblon, 44150 VAIR SUR LOIRE (France)

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

EKYFLOGYL 1.8mg/ml + 8.7mg/ml gel for horses

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Gel
Clear viscous liquid.

One ml contains

Active substances:

Prednisolone (as acetate)	1.8 mg
Lidocaine (as hydrochloride monohydrate)	8.7 mg

Excipient:

Dimethyl sulfoxide	968 mg

4. INDICATION(S)

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

5. CONTRAINDICATIONS

Do not use in known cases of hypersensitivity to the active substances or to any of the excipients. 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.

6. ADVERSE REACTIONS

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)

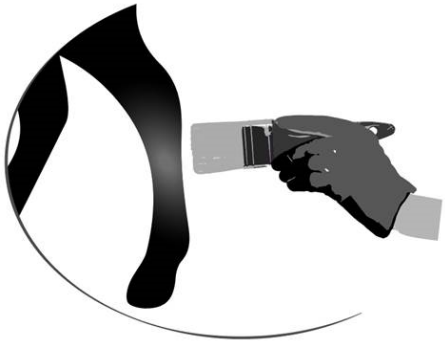
If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

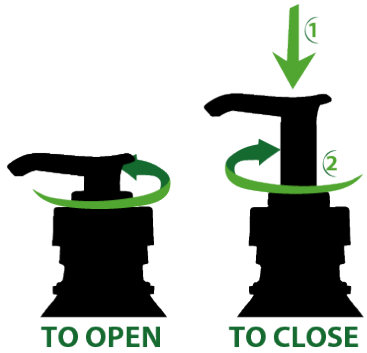
Horses (non-food producing)

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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.



9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

Not authorised for use in horses intended for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not store above 30°C
Store in the outer carton in order to protect from light
Shelf life after first opening the container: 30 days
After first opening, the date on which any remaining product should be discarded should be calculated using the in-use shelf-life mentioned in this leaflet. The calculated discard date should be recorded in the space available on the carton and label.
Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

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.

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.

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

Interaction with other medicinal products and other forms of interaction:
Do not use with other products, in particular topical products on the treated area.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

March 2022

15. OTHER INFORMATION

Box of one bottle of 125ml

Vm 44684/4004

POM-V

Approved 04 March 2022