PACKAGE LEAFLET
(inside of tear-open label)

PACKAGE LEAFLET FOR:

Tendease 50,000 IU/100 g 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:
Eurovet Animal Health BV
Handelsweg 25
5531 AE Bladel
The Netherlands

BE:
Dechra Regulatory BV
Handelsweg 25
5531 AE Bladel
The Netherlands

Manufacturer responsible for batch release:

GENERA Inc.
Svetonedeljska cesta 2
Kalinovica
10436 Rakov Potok
Croatia

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tendease 50,000 IU/100 g gel for horses

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

100 g gel contains:
Active substances:

Heparin sodium	50,000 IU
Hydroxyethyl salicylate	5.0 g
Levomenthol	0.5 g

A clear green gel.

4. INDICATION(S)

For the treatment of local inflammatory swellings and bruising, including tendonitis, tenosynovitis, bursitis and other acute inflammatory conditions of the musculo-skeletal system in the horse. Tendease also promotes the early reabsorption of haematoma and oedematous swelling resulting from such conditions.

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

Animals may, in rare cases, experience a mild skin reaction (which includes hair loss and blisters) following use of this product. If this occurs any remaining product should be thoroughly washed off, product use discontinued and veterinary attention sought.
The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s)
- common (more than 1 but less than 10 animals in 100 animals treated)

- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, 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.

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

For cutaneous administration. Using slight fingertip pressure, up to a total daily quantity of 50 g gel is massaged onto the skin of the affected area according to the veterinarian's instructions, until clinical signs have subsided.

9. ADVICE ON CORRECT ADMINISTRATION

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10. WITHDRAWAL PERIOD(S)

Meat and offal: 0 days.
Not authorised for use in animals producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not store above 30 ˚C.
Do not use after the expiry date stated on the label after EXP. The expiry date refers to the last day of that month.
Shelf life after first opening the bottle: 6 months.

12. SPECIAL WARNING(S)

Special precautions for use in animals:
Avoid contact with the eyes. Do not apply to mucous membranes, open wounds or skin lesions.
Discontinue treatment if local reactions occur.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Avoid contact with the eyes, mucous membranes or skin lesions.
In case of accidental contact with the eyes, mucous membranes or skin lesions, cleanse the affected areas with clean water and seek medical advice if irritation or other clinical signs occur.
Do not handle the product in case of known hypersensitivity to any of the ingredients. To avoid sensitisation, impervious gloves should be worn when applying the product.

Use in pregnancy, lactation or lay:
The safety of the veterinary medicinal product has not been established during pregnancy. Use of the product during pregnancy or lactation is not recommended.

Interaction with other medicinal products and other forms of interaction:
None known.

Overdose (symptoms, emergency procedures, antidotes):
A threefold overdose resulted in mild skin reactions (wrinkling of the skin and hair loss). If this occurs, any remaining product should be thoroughly washed off and product use discontinued until full recovery of the patient.

Incompatibilities:
None known.

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

Any unused veterinary medicinal product or waste material 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

15. OTHER INFORMATION

Pack sizes: 300 g, 6 x 300 g.
Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.