Vulketan 2.5 mg/g gel for horses

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vulketan 2.5 mg/g gel for horses
ketanserin (as ketanserin tartrate)

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Contains ketanserin tartrate 3.45 mg/g (equivalent to ketanserin 2.5 mg/g)

3. PHARMACEUTICAL FORM

Gel

4. PACKAGE SIZE

75 g

5. TARGET SPECIES

Horses

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Cuteanous use
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Meat and offal and milk: zero days

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP:
Shelf life after first opening the immediate packaging: 28 days.

11. SPECIAL STORAGE CONDITIONS

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 completed locally

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
42-46 Rue Médéric
92110 Clichy
France

16. MARKETING AUTHORISATION NUMBER(S)

Vm 44684/4005

17. MANUFACTURER'S BATCH NUMBER

Batch:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

ALU TUBE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vulketan 2.5 mg/g gel for horses
ketanserin (as ketanserin tartrate)

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Contains ketanserin tartrate 3.45 mg/g (equivalent to ketanserin 2.5 mg/g)

3. PHARMACEUTICAL FORM

Gel

4. PACKAGE SIZE

75 g

5. TARGET SPECIES

Horses

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For cutaneous use only..
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Meat and offal and milk: zero days

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP:
Shelf life after first opening the immediate packaging: 28 days.
Once opened used by: …….

11. SPECIAL STORAGE CONDITIONS

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

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

For animal treatment only.
To be completed locally

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

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Audevard
42-46 Rue Médéric
92110 Clichy
France

16. MARKETING AUTHORISATION NUMBER(S)

Vm 44684/4005

17. MANUFACTURER'S BATCH NUMBER

Batch:

PACKAGE LEAFLET
Vulketan 2.5 mg/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:
Audevard
42-46 Rue Médéric
92110 Clichy
France

Manufacturer for the batch release:
Sanochemia Pharmazeutika AG
Landegger Strasse 7
A-2491 Neufeld/Leitha
Austria

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vulketan vet 2.5 mg/g gel for horses
Ketanserin (as ketanserin tartrate)

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

Each gram of clear, transparent gel contains:

Active substance:	Ketanserin tartrate (equivalent to 2.5 mg ketanserin)	3.45 mg
Excipient(s):	Methyl parahydroxybenzoate (E218)	1.35 mg
	Propyl parahydroxybenzoate	0.15 mg

4. INDICATION(S)

- To encourage wound healing
- Prevention of the formation of hyper-granulation tissue (proud flesh)

5. CONTRAINDICATIONS

Do not use for deep (e.g. penetrating or puncture wounds) or infected wounds, or immediately following surgery.
Do not use in known cases of hypersensitivity to the active substance or to any of the excipients.
Do not apply in eyes and on mucous membranes.

6. ADVERSE REACTIONS

None.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Horses

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

For cutaneous use only
Dosage
Clean the wound thoroughly with clean potable water and then apply the product, after bleeding has ceased, to the entire surface of the wound and the edges twice daily.
Washing with clean warm water is recommended before every treatment. Bandaging of
the wound and restraint of the limb are not necessary.

The product is sterile until first opened. It is important to keep the tube as clean as possible during use. Product should be applied to the wound using sterile disposable gloves and neither the tube nor remaining product within it should be allowed to touch the wound area.

9. ADVICE ON CORRECT ADMINISTRATION

Read section 'Special warnings' below.

10. WITHDRAWAL PERIOD

Meat and offal: zero days
Milk: zero hours

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.
Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf-life after first opening the immediate packaging: 28 days.
When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the carton should be discarded should be worked out. This discard date should be written in the space provided.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and tube after “EXP”. The expiry date refers to the last day of that month

12. SPECIAL WARNING(S)

For cutaneous use only
In the absence of compatibility studies, this product should not be mixed with other veterinary medicinal products.

Special precautions for use in animals

- In view of its stimulating effect on microcirculation the product should not be applied on fresh wounds until bleeding has stopped.
- If exuberant granulation tissue (proud flesh) has already developed in older wounds, it should be surgically removed before treatment is started.
- Stabled horses with leg wounds may develop oedema and should be allowed some outside exercise during treatment.
- In order to facilitate twice daily treatment it is not recommended to bandage the wounds when being treated with the product.
- Wash the wound with clear warm water prior to each treatment to remove the film of gel which forms over the wound.
- Remove any sequestors or necrotic tissue from the wound prior to treatment with the product.

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

Wear disposable gloves when handling the product. Wash hands thoroughly after use.
In case of accidental eye contact with the veterinary medicinal product, rinse with water.
In case of accidental spillage onto skin, wash off immediately with soap and water.
In case of ingestion of the product by a child, seek medical attention immediately and show the package leaflet to the doctor.

Use during pregnancy, lactation or lay

Can be used during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction

None known.

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

None known.

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

[AT, DE, FR, IE, IT, LU, NL, PT, DK, FI, IS, SE]
Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

[UK only]
Medicines should not be disposed of via wastewater.

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

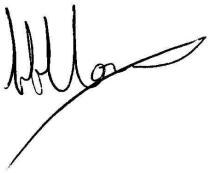
14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

December 2020

15. OTHER INFORMATION

75 g aluminum tubes with HDPE screw cap.
For animal treatment only.

To be completed locally



Approved 21 December 2020