Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Vulketan 2.5 mg/g gel for horses

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g of 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

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gel.
Clear transparent sterile gel.

4 CLINICAL PARTICULARS

4.1 Target Species

Horses

4.2 Indications for use, specifying the target species

- To encourage wound healing
- Prevention of the formation of hyper-granulation tissue

4.3 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.

4.4 Special warnings for each target species

None

4.5 Special precautions for use

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 so they 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.

4.6 Adverse reactions (frequency and seriousness)

None.

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interactions

None known.

4.9 Amounts to be administered and administration route

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.

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

None known.

4.11 Withdrawal period(s)

Meat and offal: zero days
Milk: zero hours

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: dermatologicals, cicatrizants, ketanserin
ATCvet code: QD03AX90

5.1 Pharmacodynamic properties

Ketanserin is a potent and selective serotonin S2-receptor antagonist. Ketanserin has also a slight antagonistic effect on the α_1-adrenergic, histamine H1-and dopamine-D2-receptors. Ketanserin has no *in vitro* antibacterial properties.

The wound-healing properties of ketanserin are based on its antiserotonin S2-effect: through the antagonism of serotonin-induced vasoconstriction, blood platelet aggregation and the subsequent release of mediators, and the serotonin-induced increase in vascular permeability resulting in a better microcirculation and oxygen supply in the lesion. In addition, ketanserin inhibits the formation of hypergranulation tissue by means of its effect on myofibroblasts.

5.2 Pharmacokinetic particulars

After cutaneous application, only a negligible quantity of ketanserin is absorbed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl Parahydroxybenzoate (E218)
Propyl Parahydroxybenzoate
Propylene Glycol (E1520)
Hypromellose 2208 (E464)
Water for injection

6.2 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary 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: 28 days.

6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

The product is packed in 75 g aluminum tubes with HDPE screw cap.

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

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

7 MARKETING AUTHORISATION HOLDER

AUDEVARD
42/46 Rue Mederic
92110 Clichy
France

8 MARKETING AUTHORISATION NUMBER(S)

VPA10481/003/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19 August 2011
Date of last renewal: 29 July 2016

10 DATE OF REVISION OF THE TEXT

August 2019