

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Theranekron D6 – solution for injection for animals

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains:

Active substance:

Tarantula cubensis D6 1 ml

Excipients:

Ethanol 286 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Clear, colourless solution for injection.

Homeopathic medicinal product.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle, horse, sheep, goat, swine, dog, cat.

4.2 Indications for use, specifying the target species

The indications for use are derived from the homeopathic drug pictures. They include:

Septic conditions, skin suppuration, inflammatory claw diseases (panaritium), phlegmons, ulcers, carbuncle, boil and purulent necrotising processes, and for demarcation of pathologically altered tissue in all target species.

The use of this homeopathic medicinal product in the listed indications for use is based solely on homeopathic experience.

In severe cases of the listed diseases a clinically proven treatment is indicated.

4.3 Contraindications

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

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Prolonged non indicated use of homeopathic medicinal products may produce drug proving symptoms.

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

In case of accidental self-injection or ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

Occasionally local reactions at the injection site may occur.

Note: Treatment with homeopathic medicinal products may cause temporary worsening of existing symptoms (initial aggravation). Such reactions are usually harmless. If symptoms do not improve, treatment should be discontinued. When initial aggravation has resolved, the veterinary medicinal product can be administered again. If symptoms aggravate again, discontinue treatment and consult a veterinarian.

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).

4.7 Use during pregnancy, lactation or lay

The safety of the homeopathic veterinary medicinal product has not been established during pregnancy and lactation. During pregnancy and lactation this homeopathic veterinary medicinal product should be used only after risk/benefit assessment of the treating veterinarian.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

For subcutaneous use.

Dosage:

Cattle, horse	5 – 10 ml
Sheep, goat	3 – 5 ml
Swine	3 – 6 ml
Dogs	0.5 – 3 ml
Cats	0.2 – 0.5 ml

In horses do not administer more than 5 ml per injection site.

The dose can be repeated at weekly intervals.

Duration of treatment depends on the present disease picture.

If there is no improvement within 24 hours or the condition deteriorates, a veterinarian should be consulted.

The rubber stopper can be punctured safely a maximum of 25 times.

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

There are no data available.

4.11 Withdrawal period(s)

Horse, cattle, sheep, goat, swine:
Meat and offal: 0 days

Horse, cattle, sheep, goat:
Milk: 0 days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotheapeutic group: other therapeutic products
ATCvet code: QV03AX

5.1 Pharmacodynamic properties

Homeopathy is a regulation therapy. Knowledge about the healing effects of homeopathic single remedies derived from plants, animals and minerals is obtained from drug provings in healthy people (drug proving symptoms), use in sick people and animals, and toxicological data. Summary of, this empirical knowledge constitutes the drug picture that forms the basis for homeopathic therapy. Where the disease picture matches the drug picture, treatment efficacy primarily depends on the frequency of dose repetition rather than on dosage.

5.2 Pharmacokinetic particulars

No pharmacokinetic studies have been conducted.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol
Water for injections

6.2 Incompatibilities

None known.

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

Keep the vial in the outer carton in order to protect from light.
This veterinary medicinal product does not require any special temperature storage conditions.

6.5 Nature and composition of immediate packaging

Clear glass vial with bromobutyl rubber stopper and aluminium cap.
Package size: 50 ml

6.6 Special precautions for the disposal of unused veterinary medicinal product 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

VetViva Richter GmbH, Durisolstrasse 14, 4600 Wels, Austria

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10. DATE OF REVISION OF THE TEXT

April 2023

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

CONDITIONS OR RESTRICTIONS REGARDING SUPPLY

To be supplied on veterinary prescription.