

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Selenate Long Acting 50 mg/ml Suspension for Injection for Cattle.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substance

Selenium 50 mg
(equivalent to 177.48 mg Barium Selenate.)

Excipients

Chlorocresol 2 mg

For a full list of excipients, see 6.1

3 PHARMACEUTICAL FORM

Suspension for Injection.

A white aqueous suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle.

4.2 Indications for use, specifying the target species

For the treatment and prevention of selenium deficiency in cattle.

4.3 Contraindications

Do not overdose.

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

Do not administer intramuscularly.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Use aseptic technique.

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

Self-inoculation could cause serious localised reactions.

This product contains mineral oil. Accidental injection/self injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given.

If you are accidentally injected with this product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you.

If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:

This product contains mineral oil. Even if small amounts which have been injected, accidental injection with this product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

4.6 Adverse reactions (frequency and seriousness)

Allergic reactions occur occasionally to selenium.

Local tissue reaction may occur at the site of injection, but this will be transient and disappear in less than one month.

In very rare cases, anaphylactic type reactions, including death, have been reported.

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 interaction

Do not use simultaneously with any other preparation

4.9 Amounts to be administered and administration route

Shake the vial vigorously to re-suspend the solid prior to use.

Inject into a clean site in the neck area by subcutaneous injection only, using aseptic technique. Actual dose will depend on the selenium status and clinical condition of the animal. The recommended treatment dose is 1 mg Se/kg bodyweight corresponding to 1 ml per 50 kg bodyweight.

To ensure a correct dosage, bodyweight should be determined as accurately as possible to avoid overdosing

Due to the long acting nature of the product, do not administer more frequently than once a year.

Do not administer more than 10 ml.

The vial can only be broached a maximum of 20 times.

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

Overdosage with this product is unlikely as its characteristics are for slow release of selenium, in selenium deficient animals under the instructions of a veterinary practitioner.

In case of overdose, the following symptoms have been described: dyspnoea, colic, polyuria, cyanosis, prostration, depression and ataxia.

4.11 Withdrawal Period(s)

Meat and Offal: 31 days
Milk: Zero hours

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic Group: Mineral Supplements, selenium combinations.
ATC Vet Code: QA12CE99

5.1 Pharmacodynamic properties

This product is recommended for the treatment of selenium deficiency in cattle. The principal mechanism of action for physiological and pharmacological effects of selenium is its antioxidative effect at the cell membrane against hydrogen peroxide and lipoperoxidases. The effects are related to the enzymatic activity of glutathione peroxidases which contain selenocysteine.

The treatment of animals in early to mid-pregnancy will provide a good selenium status in the newly born offspring.

5.2 Pharmacokinetic properties

The product will provide a prolonged rise in the selenium status in animals, lasting up to 12 months.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Chlorocresol
Light Liquid Paraffin
Stearoyl macroglycerides
Water for Injection
Sodium Hydroxide – pH adjustment
Hydrochloric acid – pH adjustment

6.2 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

Keep the vial in the outer carton to protect from light.

6.5 Nature and composition of immediate packaging

Cardboard box with 1 amber glass (Type II) vial of 50 ml vial with a nitril rubber stopper and gold coloured aluminium seal.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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

Cross Vetpharm Group Limited
Broomhill Road,
Tallaght,
Dublin 24.

8 MARKETING AUTHORISATION NUMBER(S)

VPA10960/073/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

27th January 2012

10 DATE OF REVISION OF THE TEXT