

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Chanatol Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances

Cobalt sulphate heptahydrate 0.099 % w/v

Propylene glycol to 100 % w/v

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Oral solution.

A clear, light pink coloured solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle, sheep and goats.

4.2 Indications for use, specifying the target species

For the treatment of acetonaemia in cattle and pregnancy toxemia in sheep and goats.

4.3 Contraindications

Do not use in animals known to be hypersensitive to the active substances.

4.4 Special warnings for each target species

None known.

4.5 Special precautions for use

Special precautions for use in animals

None known.

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

Wash splashes from the skin.

4.6 Adverse reactions (frequency and seriousness)

None known at the correct dosage.

4.7 Use during pregnancy, lactation or lay

The product may be used safely in pregnant and lactating animals.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

For oral administration only.

Shake well before use.

Cattle: 200 ml morning and evening for the first day followed by 100 ml twice a day for 3 days.

Sheep and goats: 100 ml daily for 6 days.

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

Cobalt and propylene glycol are relatively non-toxic.

4.11 Withdrawal Period(s)

Foodstuffs must not be taken for human consumption during the treatment period

Edible tissues:

Cattle, Sheep, Goats: 3 days

Milk:

Cattle, Sheep, Goats 3 days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group; Treatment of acetonemia

ATC code; QA16QA

Propylene glycol is a glucose precursor which provides a source of replacement carbohydrate as required for the treatment of ketosis (acetonemia, pregnancy toxemia).

Cobalt is a component of cyanocobalamin and hydroxocobalamin, which are forms of vitamin B12. A concurrent deficiency may add to the severity of ketosis.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Purified water

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

Clear pink solution contained in a high density polyethylene container with polyethylene closure.

Pack size: 500 ml, 1 L, 2.5 L and 5 L.

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

Any unused product or waste material should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Limited
Loughrea
Co. Galway

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10987/033/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2006

10 DATE OF REVISION OF THE TEXT

January 2014