

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Forketos Oral Solution for Cattle and Sheep

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances

<u>Qualitative composition</u>	<u>Quantitative composition</u>
Propylene glycol	80 % v/v
Cobalt sulphate heptahydrate (Equivalent to 0.21 mg/ml elemental cobalt)	0.1 % w/v

Excipients

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral solution.
A clean, bright, pale pink, odourless solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle and sheep.

4.2 Indications for use, specifying the target species

As an aid in the treatment of acetonemia (ketosis) in cattle and pregnancy toxaemia in sheep.

4.3 Contraindications

None known.

4.4 Special warnings for each target species

No special warnings.

4.5 Special precautions for use

i. Special precautions for use in animals

None known.

- ii. Special precautions for the person administering the veterinary medicinal product to animals

In case of accidental eye contact, wash eyes with plenty of clean water. If irritation occurs, seek medical attention.

In case of contact with skin, remove any contaminated clothing and wash affected area thoroughly with soap and water. If irritation occurs seek medical advice.

Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

No special precautions.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amount(s) to be administered and administration route

To be administered orally as a drench.

Cattle: 150 - 200 ml twice daily for 3 - 4 days.

Sheep: 2 ml/kg bodyweight up to a maximum of 120 ml.

This dose may be repeated 7 - 8 hours later if necessary.

Do not exceed stated dose.

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

Propylene glycol toxicity can result in incoordination and narcosis. Signs of cobalt overdose are loss of weight, anorexia and muscular incoordination.

4.11 Withdrawal period(s)

Meat: zero days

Milk: zero hours

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group:

Drugs for treatment of acetonaemia.

ATC Vet Code:

QA16QA01

5.1 Pharmacodynamic properties

Propylene glycol is a glucose precursor. Cobalt is an essential trace element.

5.2 Pharmacokinetic properties

Propylene glycol is metabolised and excreted rapidly. Cobalt is converted in the rumen to Vitamin B12 by bacterial flora.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water, purified

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
Protect from light.
Protect from frost.

6.5 Nature and composition of immediate packaging

1 litre and 25 litre high density polyethylene bottles with a high density polyethylene cap (screw fit).
Not all pack sizes may be marketed.

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

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

Alfasan Nederland B.V.
Kuipersweg 9
3449 JA Woerden
The Netherlands

8. MARKETING AUTHORISATION NUMBER

36408/4015

9. DATE OF FIRST AUTHORISATION

9 June 1993

10. DATE OF REVISION OF THE TEXT

August 2021

Approved 18 August 2021

A handwritten signature in black ink, appearing to read "Hunter.", is positioned below the approval date. The signature is stylized and includes a period at the end.