

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Genebile Solution for Injection 100 mg/ml

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance

Menbutone 100 mg

Excipients

Chlorocresol 2 mg

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Solution for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Horses, cattle, sheep and pigs.

4.2 Indications for use, specifying the target species

As a choleric compound for stimulating gastrointestinal function.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredient.
Not recommended for use in animals with cardiac disease.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precaution(s) for use in animals

Administer by slow intravenous injection.

Intravenous injection given too rapidly may give rise to a transient reaction.

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

None.

4.6 Adverse reactions (frequency and seriousness)

After injection there will often be discharge of dark stained faeces (bile), increased motility of the rumen, salivation and tear secretion.

4.7 Use during pregnancy, lactation or lay

This product may be given to 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 intravenous administration. Genebile should be administered at a dose of 1 ml per 10 kg bodyweight.

A further dose may be given after 24 hours

Genebile should be administered by SLOW intravenous (jugular vein) injection.

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

None known.

4.11 Withdrawal Period(s)

Animals must not be slaughtered until 2 days after intravenous injection.

Milk for human consumption must not be taken within 2 days of treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Bile therapy

ATCvet code: QA05AX90

5.1 Pharmacodynamic properties

Genebile has a choloretic effect, demonstrated clearly in animals who have decreased bile secretion, whereas it only has a minor effect in normal animals.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Monoethanolamine

Chlorocresol

Sodium metabisulphite

Edetic acid

Water for injections

6.2 Incompatibilities

Not to be used with:

- 1) Solutions containing calcium salts.
- 2) Solutions containing procaine penicillin.
- 3) Solutions containing vitamin B complex.

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

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

Multidose clear glass Type I (Ph. Eur.) injection vials with steel blue chlorobutyl rubber stoppers and aluminium crimp caps containing 100 ml Genebile solution.

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

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

7 MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Limited
Ellesfield Avenue
Bracknell
Berkshire RG12 8YS
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10007/020/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2009

10 DATE OF REVISION OF THE TEXT

18th May 2011