

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norobrittin 15% w/v Suspension for Injection.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

15% w/v Ampicillin (as Ampicillin Trihydrate 17.32% w/v)

Excipients:

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Suspension for injection
An off-white oily suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle
Sheep
Pigs

4.2 Indications for use, specifying the target species

For the treatment of systemic infections caused by or associated with organisms sensitive to ampicillin including:

Bordetella bronchiseptica
Arcanobacterium (Actinomyces) pyogenes
Erysipelothrix rhusiopathiae
Mannheimia haemolytica
Pasteurella multocida
Staphylococcus spp (non-penicillinase producing)
Streptococcus spp

The product will therefore be effective in the treatment of infections caused by susceptible organisms including:

Erysipelas, navel/joint ill, respiratory tract infections including pneumonia and atrophic rhinitis, meningitis, septicaemia, urogenital tract infections and the control of secondary bacterial invaders in diseases of primary viral origin

It will also have some effect in the treatment of enteritis caused by *Salmonella* spp. As *Salmonella* species show variable susceptibility to Ampicillin, sensitivity testing is recommended prior to treatment.

4.3 Contra-indications

Do not administer to penicillin sensitive animals.
Do not administer to small herbivores such as gerbils, guinea pigs, hamsters, and rabbits.

4.4 Special Warnings for each target species

No special warnings.

4.5 Special precautions for use

Special precautions for use in animals

Due to likely variability (time, geographical) in the occurrence of resistant bacteria for ampicillin, bacteriological sampling and susceptibility testing are recommended.

To ensure that the product is administered by deep intramuscular injection, a needle of the appropriate length should be used.

Although normally non-irritant, it may occasionally cause local reaction at the site of injection.

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

Care should be taken to avoid accidental self-injection.

Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross-reactions to cephalosporins and vice versa. Allergic reactions to these substances may occasionally be serious.

1. Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations.
2. Handle this product with great care to avoid exposure, taking all recommended precautions.
3. If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

No known undesirable effects.

4.7 Use during pregnancy, lactation or lay

Can be safely administered to pregnant or lactating animals.

4.8 Interaction with other medicinal products and other forms of interaction

Not recommended that bacteriostatic antimicrobials be administered concomitantly.

4.9 Amounts to be administered and administration route

Shake vial before use.

Administration is by deep intramuscular injection only, after shaking the vial to ensure suspension of active material.

The recommended dosage rate is 7.5 mg/kg bodyweight (1 ml per 20 kg) given once daily for up to 5 days.

To ensure the correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing.

Swab the septum before removing each dose.
Use a dry sterile needle and syringe.

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

Penicillins possess a wide safety margin.

4.11 Withdrawal period

Cattle: Meat - 18 days

Milk - 24 hours

Pigs: Meat - 18 days

Sheep: Meat - 18 days

Milk - Do not use in sheep producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use.

ATC Vet Code: QJ01CA01

5.1 Pharmacodynamic properties

Ampicillin (a beta-lactam antibiotic) prevents formation of the bacterial cell wall by interfering with the final stage of peptidoglycan synthesis. It inhibits the activity of transpeptidase enzymes which catalyse cross-linkage of glycopeptide polymer units that form the cell wall.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium Stearate
Triton x 200
Ethyl Oleate

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 Years
Shelf life after first opening the immediate packaging: 28 Days

6.4 Special precautions for storage

Do not store above 25 C.
Protect from light.
The product does not contain an antimicrobial preservative.
Following withdrawal of the first dose, use the product within 28 days. Discard unused material.

6.5 Nature and composition of immediate packaging

Clear Type II 50 ml or 100 ml multidose glass vials closed with rubber nitril bungs with aluminium overseals.

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

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

Norbrook Laboratories Limited
Station Works
Newry
Co. Down, BT35 6JP
Northern Ireland

8. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4104

9. DATE OF FIRST AUTHORISATION

24th August 1994

10. DATE OF REVISION OF THE TEXT

November 2008.