

This leaflet has been reviewed and approved 1/2018

SUMMARY OF PRODUCT CHARACTERISTICS
Veterinarian Prescription only medicine
For animal use only

1. NAME FORM AND STRENGTH OF THE VETERINARY MEDICIN

Amoxy LA Veterinary, Suspension for injection, I.M, 15% W/V

2. ACTIVE INGREDIENTS

Each ml contains:

Amoxicillin (As Trihydrate) 150 mg

For a full list of excipients, see section 13 "further information"

3. Indications for use

For the treatment of infections due to susceptible organisms in cattle, sheep, pigs, dogs and cats

where a single injection giving prolonged activity is required.

Not effective against beta-lactamase producing organisms.

Therapeutic Group: antibiotic

4. Contraindications

This product is not suitable for intravenous or intrathecal use

This product should not be administered to rabbits, hamsters, gerbils or guinea pigs.

Not for use in known cases of hypersensitivity to penicillins or cephalosporins.

5. Adverse reactions (frequency and seriousness)

Occasional local tissue reaction may result from injection.

Side effects can be reported to the Ministry of Health by clicking on the link "Reporting adverse events due to drug treatment" found on the home page of the Ministry of Health website (www.health.gov.il) which refers to the online form for reporting adverse events, or by entering the link:

[https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffe
ctMedic@moh.gov.il](https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffe
ctMedic@moh.gov.il)

6. Target Species:

Cattle, Sheep, Pigs, Dogs, Cats

7. Amounts to be administered and administration route

To ensure administration of a correct dose, bodyweight should be determined as accurately as possible to avoid underdosing.

The recommended dosage rate is 15 mg per kg bodyweight, repeatable if

necessary after 48 hours.

Animal	Weight (kg)	Dosage volume (ml)
Cattle	450 kg	45.0 ml
Sheep	65 kg	6.5 ml
Pigs	150 kg	15.0 ml
Dogs	20 kg	2.0 ml
Cats	5 kg	0.5 ml

Dose volume is equivalent to 1 ml per 10 kg bodyweight. If dose volume exceeds 20 ml, it should be divided and injected into two sites.

An appropriately graduated syringe must be used to allow accurate administration of the required dose volume. This is particularly important when injecting small volumes.

8. How to use the preparation:

Shake well before use. Massage the injection site.

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

A separate injection site should be used for each administration.

As with other injectable preparations normal aseptic precautions should be observed.

9. Withdrawal period

Cattle: Meat: 23 days.

Milk: 79 hours.

Sheep and Pigs:

Meat: 16 days.

Not for use in sheep producing milk for human consumption.

10. Special warnings and precautions for use:

- Special precautions for use in animals:

Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local epidemiological information.

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

- Care should be taken to avoid accidental self-injection. In the case of accidental self-injection, seek medical advice immediately.
- 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 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.

- Use during pregnancy, lactation or lay

Can be safely administered during pregnancy and lactation.

- Interaction with other medicinal products and other forms of interaction:

It is not generally recommended to use bactericidal and bacteriostatic antibiotics at the same time.

- Overdose:

Penicillins have a wide safety margin.

11. **Storage instructions**

- Prevent poisoning! This medicine and any other medicine should be kept in a safe place out of the reach of children and / or infants and thereby prevent poisoning.
- Do not use this medicine after the exp date on the package. The expiration date refers to the last day of that month.
- Storage conditions: Store below 25°C. protect from light.
- Shelf-life after first opening the immediate packaging: 28 days. Remedies should be destroyed after 28 days.
- This product does not contain an antimicrobial preservative.

12. **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 as toxic waste. Do not dispose of sewage.

13. **FURTHER INFORMATION:**

In addition to the active ingredient the product also contains:

Aluminium Distearate, Butylated Hydroxyanisole, Butylated Hydroxytoluene, Propylene Glycol Dicaprylate

Pharmaceutical form:

- An off-white oily non-aqueous suspension. Packed in a 100 ml volume glass vial

Registration holder: :Comex Ltd, Nablus Rd. No.1, POB 19943, Jerusalem 97200

Manufacturer: Norbrook Laboratories Limited , Station Works, Newry, Northern Ireland, BT35 6JP, UK

Product registration number: 080-83-92195-00