ΠΑΡΑΡΤΗΜΑ 1: ΠΕΡΙΛΗΨΗ ΤΩΝ ΧΑΡΑΚΤΗΡΙΣΤΙΚΩΝ ΤΟΥ ΠΡΟΪΟΝΤΟΣ

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BACOLAM,amoxicillin and colistin, suspension for injection for cattle, sheep, goats, swine, horses.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains:
Active substances:
amoxicillin (as amoxicillin trihydrate).....100 mg
colistin sulphate.....250000 I.U.
Excipients: q.s. to.....1 ml

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.

4. CLINICAL PARTICULARS

4.1. Target species

Cattle, sheep, goats, swine, horses.

4.2. Indications for use, specifying the target species

BACOLAM suspension for injection is indicated in the treatment of infections to the gastrointestinal, bronchopulmonary, urinary and cutaneous systems due to Gram-positive and Gram-negative microorganisms sensitive to the amoxicillin-colistin association.

4.3. Contraindications

Do not administer in cases of hypersensitivity to amoxicillin or to colistin.
BACOLAM suspension for injection is contraindicated in animals affected by renal diseases of a degenerative nature.

4.4. Special warnings for each target species

Use only after ascertaining the sensitivity of the microorganisms to the active substances. It is recommended that a sensitivity test be performed prior to the start of treatment.
In performing injections, adopt the normal aseptic procedures.
In the case of larger animals, for which the volume to be injected is high, it is advisable to subdivide the injection between two or more points.
Not permitted for use in horses producing milk for human consumption.

4.5. Special precautions for use

Special precautions for use in animals

Improper use of BACOLAM can lead to an increase in the incidence of bacteria resistant to amoxicillin and to colistin.
Do not exceed the recommended dosage.

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

None.

4.6. Adverse reactions (frequency and severity)

In rare cases allergic reactions are possible.
Painfulness and hardening of the injection site are possible.

4.7. Use during pregnancy, lactation or lay

Use in accordance with an evaluation of the risk/benefit ratio by the Veterinary surgeon.
Do not administer to lactating animals whose milk or derivatives are intended for human consumption.

4.8. Interaction with other medicinal products and other forms of interaction

Not known.

4.9. Amounts to be administered and administration route

Shake the bottle vigorously prior to use.
Cattle, sheep, goats, swine, horses: 10 ml/100 kg b.w. per day (equivalent to 10 mg/kg b.w. of amoxicillin and 25000 I.U./kg b.w. of colistin sulphate per day).
Administer once or twice a day by the deep intramuscular route.

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

In the target species, at therapeutic doses, the medicinal product was well tolerated. Large doses of colistin may produce renal block with tubular necrosis: in these cases, suspend the treatment immediately.

4.11. Withdrawal periods

Cattle, sheep, goats, swine, horses
Meats: 28 days.

Not permitted for use in horses producing milk for human consumption.
Do not administer to lactating animals whose milk or derivatives are intended for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: association of antibacterial agents
ATCvet Code: QJ01RA01

5.1. Pharmacodynamic properties

BACOLAM is a preparation based on two antibiotics, amoxicillin and colistin.
Amoxicillin, a semisynthetic penicillin active against Gram-positive and Gram-negative bacteria, acts by inhibition of synthesis of the bacterial cell wall.

Colistin, a cyclic polypeptide antibiotic, similar to polymixins, is selectively active against Gram-negative microorganisms such as *E. coli*, *Salmonella spp.*, *Enterobacter aerogenes*, *Haemophilus spp.*, *Pseudomonas spp.*, *Shigella spp.*, *Bordetella spp.*, while its efficacy is poor against Gram-positive bacteria.
Colistin acts by disorganising the cell membrane with loss of intracellular material. The phenomenon of resistance, not completely understood, seems rare, however.

5.2. Pharmacokinetic particulars

Amoxicillin is stable in an acidic environment and shows gastroenteric absorption higher than 80% of the dose administered; by the parenteral route, absorption is rapid and complete. Approximately 15% of the quantity present in the blood binds to plasma proteins. It distributes widely and rapidly, permitting blood and tissue concentrations to be obtained which are higher than the mean MICs. It shows a high pulmonary tropism, reaching a concentration in bronchial mucous which is twice the blood concentration; bacterial lysis is much more rapid than that obtained with ampicillin. It shows no toxicity. It is eliminated in active form particularly by the urinary route.
Colistin, stable in an acidic environment (pH between 3 and 6), following oral administration in the form of the sulphate, is not absorbed from the gastroenteric tract, exerting only a local antibacterial action and thus permitting therapy directed at the gastrointestinal tract, where infections are normally due to Gram-negative microorganisms.
When administered by the parenteral route, colistin is rapidly absorbed and distributes easily, reaching tissue levels which are higher and more persistent than those in the blood.
The colistin-amoxicillin association for oral use shows an additional effect and permits, owing to the different pharmacokinetics of the active substances, to produce a specific therapy in the gastrointestinal tract by colistin (which is not absorbed enterically) and, at the same time, a systemic therapy, in particular of the respiratory, urinary and integumentary systems, due to amoxicillin (which is absorbed enterically). The same association, used by the parenteral route, permits systemic therapy by both active substances, guaranteeing a greater possibility of success by overcoming any resistance, principally by Gram-positive bacteria.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Polyoxyethylene glycol ricinoleate
Medium chain saturated triglycerides

6.2. Incompatibilities

Certain cephalosporins, erythromycin and kanamycin.

6.3. Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.

6.4. Special precautions for storage

Store in a cool, dry place, protected from light and at a temperature not exceeding 25°C.

6.5. Nature and composition of immediate packaging

Cardboard box containing a Type I glass bottle of 100, 250 or 500 ml capacity, closed with an elastomer closure and aluminium collar.
1000ml polyethelene (PE)bottles with a closure system composed of chlorobutyl based elastomer rubber cap with a flip-off type aluminium collar and a tamper-proof polypropelene seal.
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

FATRO S.p.A. - Via Emilia, 285 - Ozzano Emilia (Bologna), Italy.

Concessionaire for Italy:
AZIENDA TERAPEUTICA ITALIANA A.T.I. S.r.l. - Via della Libertà, 1 - Ozzano Emilia (Bologna), Italy

8. MARKETING AUTHORISATION NUMBER

19058

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1/11/2000
Date of renewal: 22/3/2012

10. DATE OF REVISION OF THE TEXT

22/3/2012