CLAMOXON SP INJECTION

Description and Composition
CLAMOXON SP INJECTION is an off white to grayish yellow oily suspension. Each ml contains 150mg of Amoxicillin trihydrate and 40mg Gentamicin (as sulphate) as its active ingredients and 50mg Benzyl alcohol as preservative.

Pharmacodynamics
Amoxicillin is a bactericidal antibiotic belonging to the group of penicillins. It inhibits mucopeptide synthesis, one of the rigid components of bacterial cell wall that gives mechanical stability to the bacterium, destroying bacteria in the growth phase.

Gentamicin is an aminoglycoside antibiotic that acts directly on the ribosome, in which it inhibits protein biosynthesis. Gentamicin penetration in the cell increases as the permeability of the bacterial cell wall is altered by amoxicillin. This allows the use of aminoglycoside smaller quantities.

Amoxicillin and gentamicin together have a broad antibacterial spectrum, including Gram positive (corynebacteria) and Gram negative bacteria (*E. coli, Pasteurella* spp. and *Salmonella* spp.). Its association improving the therapeutic properties of each of these antibiotics administered alone.

Pharmacokinetics
Amoxicillin is well absorbed after parenteral administration. 17-20% of the active substance is bound to plasma proteins. It is excreted primarily in the urine unchanged and to a lesser extent for milk and bile.

Gentamicin is poorly absorbed from the gastrointestinal tract, however, it is well absorbed after parenteral administration. It is rapidly distributed reaching kidney, liver, lung, endometria and parenchyma. It has biphasic excretion, first rapid phase corresponding to the distribution of the active substance in the tissue and the second phase corresponding to the slow release of the active substance tissues to the plasma and subsequent elimination from the plasma.

Indication
Cattle:
For the treatment of pneumonia caused by strains of *Pasteurella multocida* and *Arcanobacterium pyogenes* sensitive to amoxicillin and gentamicin.
For the treatment of diarrhoea caused by strains of *Escherichia coli* and *Salmonella* spp sensitive to amoxicillin and gentamicin.

Pigs:
For the treatment of pneumonia caused by strains of *Pasteurella multocida*, *Haemophilus parasuis* and *Actinobacillus pleuropneumoniae* sensitive to amoxicillin and gentamicin.
For the treatment of colibacillosis caused by susceptible strains sensitive to amoxicillin and gentamicin.

Recommended Dose
By intramuscular injection.
Cattle and pigs: 15mg of amoxicillin trihydrate and 4mg gentamicin per kg body weight which is equivalent to 1ml Clamoxon SP per 10kg body weight for 3 days.

Route of Administration
By intramuscular route for cattle and pigs.

Contraindication
Do not use in case of hypersensitivity to the active substance or any of the excipients.
Do not use in animals hypersensitive to penicillins.
Do not use in animals with impaired renal function.
Do not use in pregnant animals.

Warning and Precautions
Special warning for each target species:
None known.

Special precautions for use in animals:
Shake the product thoroughly before use. When the vial has been sitting for some time, separation into two layers it is normal and is easily resuspended by shaking.

In the administration of high doses, it is advisable to divide the drug between two or more injection points in order to promote absorption.
It requires good clinical practice to base treatment on susceptibility testing of the bacteria isolated from sick animals. If this is not possible, therapy should be based on the (regional, farm level) epidemiological information about susceptibility of different strains of the bacterial species commonly involved in the infection.

Special precautions to be taken by the person administering the drug to the animals:
In case of accidental self-injection, seek medical advice and show the package insert or label.
People with known hypersensitivity to gentamicin and / or penicillin should avoid contact with the veterinary medicinal product.

Interaction with Other Medicinal Product
Not for use with bacteriostatic antibiotics.

Pregnancy and Lactation
The product crosses the placental barrier and can cause ototoxicity and nephrotoxicity in the fetus. Its use is not recommended during pregnancy.

Side Effects
On very rare occasions, in prolonged treatment with higher than recommended doses, renal dysfunction may occur.
Very rarely, in susceptible animals, hypersensitivity reactions occur.

The frequency of adverse reactions should be classified under the following groups:
- Very frequently (more than 1 animal per 10 treated animals has adverse reactions)
- Frequently (more than 1 but less than 10 animals per 100 treated animals)
- Infrequently (more than 1 but less than 10 animals per 1000 treated animals)
- Rarely (more than 1 but less than 10 animals per 10,000 treated animals)
- Very rarely (less than 1 animal for every 10,000 treated animals, including isolated cases).

Symptoms and Treatment of Overdose
In case of poisoning by overdose, discontinue the medication and administer symptomatic treatment. For drug administration in pigs and cattle, an injection of three times the recommended dose causes injuries evident in the area of administration; pigs may show symptoms related to hepatitis or nephritis.

Storage Condition
Store below 30ºC. Keep away from direct sunlight.

Shelf life
3 years. Following withdrawal of first dose, use the product within 24 hours. Any unused material should be discarded.

Withdrawal Period
Cattle: Meat: 140 days.
Pigs: Meat: 84 days.
Do not use in animals producing milk for human consumption.
Do not use in pregnant animals whose milk is used for human consumption within 2 months prior to the expected date of delivery.

Packing
100ml vial.

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	Product Registration Holder & Manufacturer:
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