[Version 8.1,01/2017]

ANNEX III

LABELLING AND PACKAGE LEAFLET

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Maysulprim solution for use in drinking water/milk

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release:
Laboratorios Maymó, S.A
Vía Augusta, 302
08017 Barcelona
Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Maysulprim solution for use in drinking water/milk
Sulfadiazine
Trimethoprim

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each ml contains:
Active substances:
Sulfadiazine ... . 83,35 mg
Trimethoprim ... 16,65 mg

Excipients, q.s.

Yellow solution

4. INDICATION(S)

In calves, lambs, swine, rabbits and poultry:
For the treatment and metaphylaxis of respiratory and digestive diseases caused by microorganisms susceptible to sulfadiazine and trimethoprim association.

5. CONTRAINDICATIONS

Do not use in case of hypersensitivity to the active substances or any of the excipients
Do not use in animals with severe renal or hepatic impairment.

6. ADVERSE REACTIONS

None known.
The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Calves, lambs, pigs, rabbits and poultry.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

In drinking water/milk use.
In calves and lambs:
12.5 mg of sulfadiazine and 2.5 mg of trimethoprim per kg bodyweight every 12 hours for 4 to 7 consecutive days, orally, corresponding to 1, 5 ml of solution per 10 kg of live weight every 12 hours for 4 to 7 consecutive days, to be mixed with the breastfeeding food (when adding the water).

In pigs, rabbits and poultry:
25 mg of sulfadiazine and 5 mg of bimethoprim per kg body weight per day for 4 to 7 days consecutive doses, corresponding to 3 ml solution per 10 kg live weight per day in continuous for 4 to 7 consecutive days, to be diluted in drinking water or liquid food.

The amount of drinking water or liquid food consumed by animals depends on their condition physiological and clinical.

In order to obtain the recommended dosage, the concentration of sulfadiazine and in trimethoprim should be adjusted accordingly.

To ensure a correct dosage and avoid underdosing, mean body weights in the group of animals and daily water consumption should be determined as accurately as possible.

The medicated drinking water should be the sole source of drinking water for the treatment duration. Any medicated water which is not consumed within 24 hours should be discarded.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

Meat and offal: 12 days

Eggs: Not for use in birds producing or intended to produce eggs for human consumption. Do not use within 4 weeks of onset the start of the laying period".

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions

Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 3 months
Shelf life after dilution according to directions: 24 hours
Shelf life after incorporation into milk according to directions: use immediately

12. SPECIAL WARNING(S)

Special warnings for each target species:
None.
Special precautions for use in animals:
Official, national and regional antimicrobial policies should be taken into account when this veterinary medicinal product is used.
Wherever possible, the use of this veterinary medicinal product should be only based on susceptibility testing.

Use of the veterinary medicinal product deviating from the instructions in the SPC may increase the risk of development and selection of resistant bacteria to the sulfadiazine and trimethoprim and may decrease the effectiveness of treatment with sulphonamides and diaminopyrimidines due to the potential for cross-resistance.
Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This product contains sulfadiazine, trimethoprim and macrogol, which can cause allergic reactions in some people. Hypersensitivity to sulphonamides may lead to cross reactions with other antibiotics. Allergic reactions to these substances may occasionally be serious.
People with known hypersensitivity (allergy) to sulphonamides, trimethoprim or macrogol should avoid contact with the veterinary medicinal product.
This veterinary medicinal product may cause skin or eye irritation. During the preparation and administration of medicated drinking water, skin and eyes contact has to be avoided. Wear personal protective equipment consisting in waterproof gloves and safety glasses when handling the veterinary medicinal product. In case of contact with the eyes or skin, wash the affected area with plenty of water, and if skin rash occurs, seek medical advice and show the package leaflet or the label to the physician.
This veterinary medicinal product may be harmful if ingested. Do not smoke, eat or drink while handling the veterinary medicinal product. In case of accidental ingestion, seek medical advice and show the package leaflet or the label to the physician.
Wash hands after use.Pregnancy, lactation and lay:
Teratogenic and foetotoxic effects have been observed in laboratory animals at the above recommended therapeutic doses.
The use is not recommended during pregnancy and lactation.
Do not use in birds in lay and within 4 weeks before the onset star of the laying period.
Interaction with other medicinal products and other forms of interaction:
None known
Overdose (symptoms, emergency procedures, antidotes):
None known
Incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.
Sulfadiazine is known to be hazardous to terrestrial plants and cyanobacteria. Do not contaminate surface waters or ditches with product or used container.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

<15. OTHER INFORMATION>

For animal treatment only. To be supplied only on veterinary prescription.

Environmental properties
Sulfadiazine and Trimethoprim are persistent in soil.
Sulfadiazine is known to be toxic to terrestrial plants and for groundwater biota.

Pack sizes:
Bottle of 1 L
Bottle of 5 L
Not all pack sizes may be marketed.

Expired date
EXP {month/year}

Once opened use by ….
Once diluted into water use within 24 hours.
Once diluted into milk use immediately.

Marketing Authorisation Number
XXXXX

Manufacturer's batch number
Lot {number}
PROHIBITION OF SALE, SUPPLY AND/OR USE