ANNEX III

LABELLING AND PACKAGE LEAFLET

LABEL-LEAFLET

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AQUACEN OXITETRACICLINA HIDROCLORURO 1000 mg/g PREMEZCLA MEDICAMENTOSA (ES)
AQUACEN OXYTETRACYCLINE HYDROCHLORIDE 1000 mg/g MEDICATED PREMIX (EL, PT)
OSSITETRACICLINA CENAVISA 1000 mg/g premix for medicated feeding stuff (IT)

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:
CENAVISA, S.L.
Camí Pedra Estela s/n
43205 Reus (SPAIN)
Tel. +34 977 75 72 73

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

AQUACEN OXITETRACICLINA HIDROCLORURO 1000 mg/g PREMEZCLA MEDICAMENTOSA (ES)
AQUACEN OXYTETRACYCLINE HYDROCHLORIDE 1000 mg/g MEDICATED PREMIX (EL, PT)
OSSITETRACICLINA CENAVISA 1000 mg/g premix for medicated feeding stuff (IT)

Oxytetracycline hydrochloride

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Oxytetracycline hydrochloride 1000 mg/g
Yellow crystalline powder

4. INDICATIONS

For the treatment of infections due to *Lactococcus garvieae* (lactococcosis), *Aeromonas hydrophila* (aeromoniosis) *and Vibrio anguillarum* (vibriosis) sensitive to oxytetracycline.

5. CONTRAINDICATIONS

Do not use in case of known allergy to oxytetracycline or other substance belonging to the tetracycline group.
Do not use in cases of hypersensitivity to oxytetracycline or other substance belonging to the tetracycline groups.
Do not use in case of known resistance to tetracyclines.

6. ADVERSE REACTIONS

None.

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
https://www.aemps.gob.es/vigilancia/medicamentosVeterinarios/docs/formulario_tarjeta_verde.doc

7. TARGET SPECIES

Salmonids (*Salmo* sp, *Oncorhynchus* sp), seabass (*Dicentrarchus labrax*), sea bream (*Sparus aurata*), turbot (*Psetta maxima*), european eel (*Anguilla anguilla*), european carp (*Cyprinus carpio*)

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

Administration in the food.

The recommended daily dose rate is 55 mg of oxytetracycline per kg of fish bodyweight, for 7-10 days, orally.

The premix should be incorporated in pelleted feed. Incorporation rates vary depending on the water temperature and the size of the fish. Corresponding to a daily intake of 1.5% body weight, the dosage of oxytetracycline hydrochloride in the feed would be about 4 kg of premix per ton of feed.

Due to the mode of administration, since feed intake depends on the clinical condition of the animal and its physiological state (age) to ensure proper dosing, the concentration of the antimicrobial will be adjusted taking into account the daily feed intake.

9. ADVICE ON CORRECT ADMINISTRATION

Medicated premix is added to pelleted feed and then fish or vegetable oil is added for adhere well the premix on the surface of the pellets.

10. WITHDRAWAL PERIOD

Meat: 300 degree days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not store above 30°C.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP.
Shelf life after first opening the container: 3 months.
Shelf life after incorporation into pelleted feed: 3 months.

12. SPECIAL WARNINGS

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 (regional, farm level) epidemiological information about susceptibility of the target bacteria.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
- People with known hypersensitivity to oxytetracycline or other substance belonging to the tetracycline group should avoid any contact with the veterinary medicinal product.
- Avoid contact with skin and eyes. In case of contact, wash immediately with plenty of water.
- Avoid inhalation of veterinary medicine.
- Use personal protective equipment consisting of safety glasses, gloves and mask filtering (standard CEN FFP1).
- Wash hands after use of the veterinary medicinal product.
- If symptoms appear following exposure such as a skin rash, consult a doctor showing these warnings. The swelling of the face, lips or eyes or difficulty on breathing are more serious signs that need urgent medical attention.

Interaction with other medicinal products and other forms of interaction:
Absorption of oxytetracycline can be reduced in the presence of high amounts of Ca^{2+}, Fe^{2+}, Mg^{2+} or Al^{3+} in the diet.
It is not recommended to mix this product with feeding stuff containing other antibiotics.

Incompatibilities
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

Overdose (symptoms, emergency procedures, antidotes):
Do not exceed the stated dose.

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 or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

PACKAGE SIZE
Bags containing 20 kg.
Bags containing 1 kg.
Not all pack sizes may be marketed.

For animal treatment only. To be supplied only on veterinary prescription.
To be administered by a veterinary surgeon or under their direct responsibility.

Consideration should be given to official guidance on the incorporation of medicated premixes in final feeds.

Premix for medicated feeding stuff

EXPIRY DATE

EXP {month/year}
Once opened, use by...

MARKETING AUTHORISATION NUMBER

MANUFACTURER'S BATCH NUMBER

Batch: