MINIMUM PARTICULARS TO APPEAR ON THE LABEL WHERE THERE IS NO PACKAGE LEAFLET

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

Marketing authorisation holder:
MSD Animal Health UK Ltd.
Walton Manor, Walton
Milton Keynes
Buckinghamshire, MK7 7AJ

Manufacturer responsible for batch release[1]:
MSD Animal Health UK Limited
Walton Manor, Walton
Milton Keynes
Buckinghamshire, MK7 7AJ
United Kingdom

Intervet GesmbH
Siemensstrasse 107
1210 Vienna
Austria

[1] The printed label will only state the name and address of the manufacturer responsible for the release of the concerned batch.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Florocol Premix for Medicated Feeding Stuff 500 mg/g for Atlantic Salmon
Florfenicol

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

Each gram contains 500 mg florfenicol.

White free flowing powder.

4. PHARMACEUTICAL FORM

Premix for medicated feeding stuff.

5. PACKAGE SIZE

2 kg

6. INDICATION(S)

For the treatment of furunculosis (*Aeromonas salmonicida*) infection of Atlantic salmon.

7. CONTRAINDICATIONS

Do not use in brood stock.

8. ADVERSE REACTIONS

None known.

If you notice any side effects, or you think that the medicine has not worked, please inform your veterinary surgeon.

9. TARGET SPECIES

Atlantic salmon.

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

In-feed use.

Dose: 10 mg/kg bodyweight.
The incorporation rate in feed must be calculated to achieve this dosage.
Affected fish should receive the medicated feed daily for 10 consecutive days.

The intake of medicated feed depends on the clinical condition of the fish. In order to ensure the correct dosage is administered the concentration of Florocol in feed must be adjusted accordingly.

Table: Examples of incorporation rates:

Feeding rate (as % of fish bodyweight)	Quantity (kg) of Florocol per tonne of medicated feed	Fish (kg) medicated daily per tonne of medicated feed
0.5	4	200,000 kg
1.0	2	100,000 kg
2.0	1	50,000 kg

11. ADVICE ON CORRECT ADMINISTRATION

For incorporation into dry feed at a registered mill.
A manufacturer who is approved to incorporate veterinary medicinal products, or premixtures containing such products, directly at any concentration must be responsible for mixing when incorporation is less than 2 kg per tonne for final feed.

The premix should be mixed with oil before incorporation into dry feed. To ensure thorough dispersion, the product should first be mixed with, or surface-coated onto, a suitable quantity of feed before incorporation in the final mix.

12. WITHDRAWAL PERIOD

Withdrawal period: 150 degree days. (15 days from the last treatment at 10 °C).

13. SPECIAL STORAGE PRECAUTIONS

Do not store above 30°C. Protect from light.
Store in a dry place.
Store away from food, drink, and animal feeding stuffs.

Shelf life after incorporation into pelleted feed: 3 months.

14. SPECIAL WARNING(S)

Special precautions for use in animals:
Use of the product should be based on susceptibility testing of the strain of bacteria isolated from the fish. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria

Chloramphenicol type antibacterials may prolong the effects of anaesthetics.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Wear either a disposable half-mask respirator conforming to European standard EN 149 or a non-disposable respirator to European Standard EN 140 with a filter to EN 143, chemically resistant gloves, protective coveralls and goggles while incorporating the premix into the feed.
Wear gloves and do not smoke or eat while handling the product or medicated feed.
Wash hands thoroughly with soap and water after use of the product or medicated feed.
Thoroughly clean all equipment used in medicating feed.

Overdose:
No adverse effects were noticed at up to ten times the recommended dose

15. EXPIRY DATE

Expiry: {DD/MM/YY}
No pre-printed text on label. The complete batching legend and expiry information is printed on line during production.

16. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

17. DATE ON WHICH THE TEXT WAS LAST APPROVED

June 2021

18. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

POM-V
To be supplied only on veterinary prescription.

19. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of sight and reach of children.

20. MARKETING AUTHORISATION NUMBER

Vm 01708/4591

21. MANUFACTURER'S BATCH NUMBER

Batch: {number}
No pre-printed text on label. The complete batching legend and expiry information is printed on line during production.

22. OTHER INFORMATION

Further information: In the UK it is essential to obtain a discharge consent from the local regional office of the Environment Agency or SEPA.
Package size: 2 kg sachet.

Distributor in Northern Ireland:
Intervet Ireland Ltd.
Magna Drive, Magna Business Park
Citywest Road, Dublin 24, Ireland

Approved 08 July 2021