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Termőföldtől az asztalig

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National Food Chain Safety Office
Directorate of Veterinary Medicinal Products

Reg. no.: 02,2/02672/0035/2014

Officer: Dr. Hajós Anna

Attachment: Package Leaflet and labelling

Re.: Amendment of registration of
Ovopel Hungary A.U.V. product

Mailing address: Dr. Horváth László, Interfish Kft.
1122 Budapest, Kánai út 5. fsz. 6.

Interfish Kft.
Budapest

Dear Dr. Hováth László,

Please be informed that the Ovopel Hungary A.U.V. product registered under no. 001/2005/ÁOGYTI is now registered with the attached amended package leaflet and labelling.

The administrative service fee for this regulatory procedure is HUF 30,000, which amount was paid on September 8, 2014.

Dated in Budapest, on September 18, 2014

(illegible signature and stamp)

Dr. Kulcsár Gábor
Director

In two copies.

The following shall be notified:

1. Client
2. Archive

PACKAGE LEAFLET
OVOPEL Hungary A.U.V.

Veterinary medicinal product for the induction of synchronized ovulation and/or spermiation of ornamental fish and non-food producing species.

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

INTERFISH Halszaporító és Tanácsadó Kft.
1112 Budapest, Kánai út 5. fsz. 6.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

OVOPEL Hungary A.U.V.

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

Each pellet (50-55 mg) contains:

Active substance:

GnRH oligopeptide analogue: 25µg

Metoclopramide: 20mg

Excipients and carriers:

Lactose, dextrose, potato starch, calcium and magnesium compounds

4. INDICATION(S)

Veterinary medicinal product for the induction of synchronized ovulation and/or spermiation of ornamental fish and non-food producing species.

5. CONTRAINDICATIONS

Do not use in cases of known hypersensitivity to the active substance or any of the excipients.

6. ADVERSE REACTIONS

Each component of the product is synthetic, and, therefore, the possibility of virus transfer from one high value ornamental fish to another or within the broodstock is excluded.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Ornamental fish and non-food producing species*

* Small number of broodstock fish, destined for breeding purposes and non-food producing, carrying the typical characteristics of the species / variety in their appearance and production, that has been previously selected through phenotypic mass selection, has been kept and handled separately and makes up a genetically valuable small stand.

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

One pellet contains the sufficient amount of active substance to induce one-time ovulation in 1 kg of healthy, mature spawner fish. To induce spermiation in male fish it is enough to use the half amount of the above.

9. ADVICE ON CORRECT ADMINISTRATION

Preparing the solution and administration

1. Weigh precisely in grams the fish to be treated (for propagation).
2. Count exact number of pellets required.
3. Crush pellets in porcelain crucible.
4. Add active substances to 0.6% saline solution (1 mL 0.6% NaCl solution / 1 pellet).
5. Aspire supernatant into a plastic syringe.
6. Inject appropriate amount of solution into the fish based on the measured weight. The calculated amount of solution should be administered as an intra-peritoneal injection at the base of the abdominal fin.
7. Confirm the occurrence of ovulation based on the changed behaviour of fish (mating dance starts in the incubating pool). This may occur 11-12 hours after treatment depending on the temperature.
8. Collect (strip) and in vitro fertilise sex products.
9. As an alternative: fish lay eggs on the water plants placed in the pool.

10. WITHDRAWAL PERIOD

The product is not authorized for food-producing fish.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach of children.

Store in a dry place

Store below 25°

Do not store in refrigerator.

Shelf life of the veterinary medicinal product as packaged for sale: 2 years. This veterinary medicinal product can only be used before the expiry date stated on the label. Expiry date refers to the last day of the specified month.

12. SPECIAL WARNING(S)

Special warning for operators treating the animals:

People with known hypersensitivity to the active substance should avoid contact with the veterinary medicinal product.

Operators should wash their hands after use of the product. Do not eat, drink or smoke when using this product. Avoid skin contact.

Interaction with other medicinal products and other forms of interaction:

No information is available.

Overdose (symptoms, emergency procedures, antidotes):

No information is available.

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

Do not contaminate natural water with OVOPEL Hungary product.

Ask your veterinarian about the proper disposal of unused veterinary medicinal products. These measures protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

18 September 2014

15. OTHER INFORMATION

For veterinary use only.

No marketing restrictions.

Registration number: 001/2005/ÁOGYTI

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{Box of 20 vials of 20 ml (each vial contains 100 pellets)}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

OVOPEL Hungary A.U.V.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 pellet (50-55 mg) contains:

Active substances:

GnRH oligopeptide analogue: 25µg

Metoclopramide: 20mg

Adjuvants and excipients:

Lactose, dextrose, potato starch, calcium and magnesium compounds

3. PHARMACEUTICAL FORM

Pellet

4. PACKAGE SIZE

20x100 pellets

5. TARGET SPECIES

Ornamental fish and non-food producing species*

* Small number of broodstock fish, destined for breeding purposes and non-food producing, carrying the typical characteristics of the species / variety in their appearance and production, that has been previously selected through phenotypic mass selection, has been kept and handled separately and makes up a genetically valuable small stand.

6. INDICATION(S)

Veterinary medicinal product for the induction of synchronized ovulation and/or spermiation of ornamental fish and non-food producing species.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use

8. WITHDRAWAL PERIOD

The product is not authorized for food-producing fish.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use!

10. EXPIRY DATE

EXP {month/year}

After dilution, the product should be used immediately.

11. SPECIAL STORAGE CONDITIONS

Store in a dry place.

Store below 25°.

Do not store in refrigerator.

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

Do not contaminate natural water with OVOPEL Hungary product.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

No marketing restrictions.

14. THE WORDS “KEEP OUT OF THE REACH AND SIGHT OF CHILDREN”

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

INTERFISH Halszaporító és Tanácsadó Kft.

1112 Budapest, Kánai út 5. fsz. 6.

16. MARKETING AUTHORISATION NUMBER(S)

Registration number: 001/2005/ÁOGYTI

17. MANUFACTURER'S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

20 ml vial containing 100 pellets

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

OVOPEL Hungary A.U.V.

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

GnRH oligopeptide analogue: 25µg
Metoclopramide: 20mg

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

100 pieces of 50-55 mg pellets

4. ROUTE(S) OF ADMINISTRATION

5. WITHDRAWAL PERIOD

The product is not authorized for food-producing fish.

6. BATCH NUMBER

Lot

7. EXPIRY DATE

Expiry date:
After dilution, the product should be used immediately.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.