ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tessie 0.3 mg/ml oral solution for dogs
tasipimidine

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains: 0.3 mg tasipimidine.

3. PHARMACEUTICAL FORM

Oral solution

4. PACKAGE SIZE

15 ml bottle
Oral syringe

5. TARGET SPECIES

Dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

This product may be harmful after ingestion or skin contact or cause hypersensitivity reactions. Avoid oral ingestion and skin contact including hand-to-mouth contact.

10. EXPIRY DATE

EXP:
Once opened use within 12 months.

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator. Keep the bottle in the outer carton in order to protect from light.
Read the package leaflet for more information.

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

Disposal: read package leaflet.

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

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

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Orion Corporation
Orionintie 1
FI-02200 Espoo
Finland

16. MARKETING AUTHORISATION NUMBER(S)

06043/5004

17. MANUFACTURER'S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tessie 0.3 mg/ml oral solution
tasipimidine

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

0.3 mg/ml

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

15 ml

4. ROUTE(S) OF ADMINISTRATION

Oral use

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot:

7. EXPIRY DATE

EXP:
Once opened use within 12 months.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET
Tessie 0.3 mg/ml oral solution for dogs

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

Marketing authorisation holder:
Orion Corporation
Orionintie 1
FI-02200 Espoo
Finland

Manufacturers responsible for batch release:
Orion Corporation Orion Pharma
Tengströminkatu 8
FI-20360 Turku
Finland

Orion Corporation Orion Pharma
Joensuunkatu 7
FI-24100 Salo
Finland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tessie 0.3 mg/ml oral solution for dogs
tasipimidine

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

Each ml contains:

Active substance:
Tasipimidine 0.3 mg
(equivalent to 0.427 mg tasipimidine sulfate)

Excipients:
Sodium benzoate (E211) 0.5 mg
Tartrazine (E102)
Brilliant blue (E133)

Clear green solution.

4. INDICATION(S)

Short term alleviation of situational anxiety and fear in dogs triggered by noise or owner departure.

5. CONTRAINDICATIONS

The dog should not be given Tessie if it:
- is allergic to tasipimidine or any of the other ingredients of this medicine
- has a severe disease such as liver, kidney or heart disease
- is obviously sedated (shows signs of e.g. drowsiness, uncoordinated movements, decreased responsiveness) due to previous medication.

See section 12 Pregnancy and lactation

6. ADVERSE REACTIONS

Tessie may cause the following adverse reactions:

Very common:
- tiredness
- vomiting

Common:
- drowsiness
- behavioural disorders (barking, avoidance, disorientation, increased reactivity)
- paleness of the mucous membranes
- ataxia
- diarrhoea
- uncontrolled urination
- nausea
- gastroenteritis
- excessive thirst
- low white blood cell count
- allergic reactions
- loss of appetite.

In addition, decrease in heart rate, blood pressure and body temperature may occur.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reactions)
- 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.

7. TARGET SPECIES

Dogs

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

The recommended dose is 0.1 ml/kg. The veterinarian has prescribed the correct dose for the dog. Administer the product orally.

9. ADVICE ON CORRECT ADMINISTRATION

The product is intended for short term use. If needed, it can be safely administered for up to 9 consecutive days.

Do not feed the dog for one hour before to one hour after treatment as absorption may be delayed. A small treat can be given to ensure that the dog swallows the solution. Water can be freely available.

Test dose:
When giving the very first dose, observe the dog for 2 hours to make sure that the dose is not too high for the dog. If the dog appears drowsy, its movements are uncoordinated or it responds to your call abnormally slowly after receiving treatment, the dose could be too high. In such case do not leave the dog alone and contact your veterinarian for possible dose reduction for the next use.

Anxiety and fear triggered by noise:
Give the first dose one hour before expected start of the noise or as soon as the dog shows the first signs of anxiety. Observe the dog. If the noise continues and the dog starts to show signs of anxiety and fear again, a new dose can be given when at least 3 hours has passed from the previous dose. The product can be given up to 3 times within every 24 hours.

Anxiety and fear triggered by owner departure:
Give the dose one hour before leaving the dog alone. A new dose can be given when at least 3 hours has passed from the previous dose. The product can be given up to 3 times within every 24 hours.

See the detailed instructions for administration at the end of this leaflet.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store in a refrigerator (2°C to 8°C). Keep the bottle in the outer carton in order to protect from light.

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

Shelf life after first opening the bottle is 12 months in a refrigerator (2°C to 8°C) or 1 month below 25°C.

12. SPECIAL WARNINGS

Special precautions for use in animals:

Typical signs of anxiety and fear are panting, trembling, pacing (frequent change of place, running around, restlessness), seeking people (clinging, hiding behind, pawing, following), hiding (under furniture, in dark rooms), trying to escape, freezing (absence of movements), refusing to eat food or treats, inappropriate urination, inappropriate defecation, salivation, etc. These signs may be alleviated but may not be completely eliminated.

In extremely nervous, excited or agitated animals, the response to the medicine may be reduced.

Consideration should be given to use of a behavioural modification programme, especially when dealing with a chronic condition such as separation anxiety.

The safety of administering tasipimidine to puppies younger than 6 months and dogs over 14 years of age or weighing less than 3 kg has not been studied.

If the dog is drowsy, do not leave it alone, do not give food or water and keep it warm.

Always maintain the minimum interval (3 hours) between two doses even if the dog vomits after receiving Tessie.

Pregnancy and lactation:
The safety of this veterinary medicinal product has not been established during pregnancy and lactation in the dog. Do not use the product during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:
The safety of tasipimidine in combination with tricyclic antidepressant clomipramine (1.2-2.0 mg/kg), serotonin reuptake inhibitor fluoxetine (1.1-1.6 mg/kg), anaesthesia premedications (dexmedetomidine, methadone), induction agents (propofol) and inhalation anaesthetics (isoflurane) has been demonstrated in small-scale studies (N = 4-7) in laboratory dogs. When used concomitantly with clomipramine or fluoxetine, the tasipimidine dose should be reduced to 20 µg/kg bodyweight.

The use of other central nervous system depressants is expected to potentiate the effects of tasipimidine and therefore an appropriate dose adjustment should be made.

Overdose (symptoms, emergency procedures, antidotes):
Overdose can cause drowsiness, lowering of heart rate, blood pressure and body temperature. If this occurs the animal should be kept warm.
If an overdose occurs, contact a veterinary surgeon as soon as possible.
The effects of tasipimidine can be eliminated using a specific antidote (reversal medicine).

Information for the veterinary surgeon:
The level and duration of sedation is dose dependent, and signs of sedation may therefore particularly occur in case the dose is exceeded. Dogs receiving a high overdose of the product have a higher risk of aspirating vomit due to the emetic and CNS depressant effects associated with the active substance. A very high overdose can potentially be life-threatening.

Reduced heart rate may be seen after administration of higher than recommended doses of Tessie. Blood pressure decreases slightly below normal levels. Respiration rate can occasionally decrease. Higher than recommended doses of Tessie may also induce a number of other alpha-2 adrenoceptor mediated effects, which include increase in blood pressure, decrease in body temperature, lethargy, vomiting and a QT prolongation.

As demonstrated in a preclinical study, the effects of tasipimidine can be reversed using a specific antidote, atipamezole (alpha-2 adrenoceptor antagonist). One hour after treatment with tasipimidine at 60 µg/kg body weight, an atipamezole dose of 300 µg/kg bodyweight, corresponding to 0.06 ml/kg bodyweight of solution containing 5 mg/ml, was administered i.v. Results of this study demonstrated that the effects of tasipimidine could be reversed. However, as the half-life of tasipimidine exceeds that of atipamezole, some signs of tasipimidine effects may reappear.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Exposure to tasipimidine may cause adverse effects such as drowsiness, decrease in respiratory rate and volume, lowering of heart rate and blood pressure.

Avoid oral ingestion and skin contact including hand-to-mouth contact.

In order to prevent children from getting access to the product, don't leave the filled dosing syringe unattended while preparing the dog for administration. The used syringe and the closed bottle should be returned to the original carton and stored (in the refrigerator) out of the sight and reach of children.

In case of skin contact, wash the exposed skin immediately with water and remove contaminated clothes. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician. Do not drive, as drowsiness and changes in blood pressure may occur.

This product may cause slight eye irritation. Avoid eye contact including hand-to-eye contact. In case of eye contact, rinse the eyes immediately with water.

This veterinary medicinal product may cause hypersensitivity (allergy). People with known hypersensitivity to tasipimidine or any of the excipients should avoid contact with the veterinary medicinal product.

Wash hands after use.

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

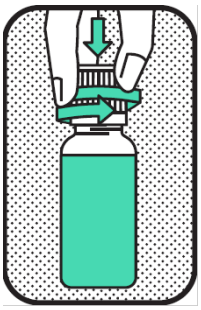
Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

August 2023

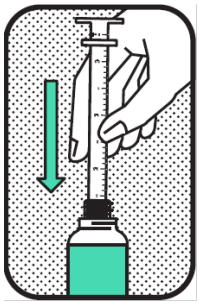
15. OTHER INFORMATION

INSTRUCTIONS FOR ADMINISTRATION:



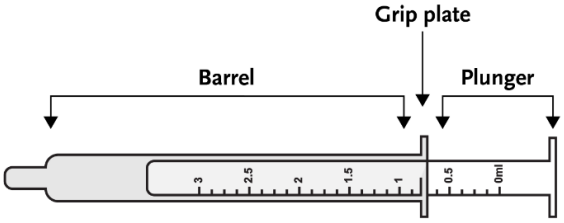
1. REMOVE CAP

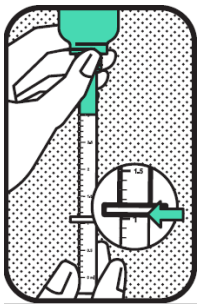
Remove the cap from the bottle (press down and twist). Save the cap for reclosure.



2. CONNECT SYRINGE

Push the syringe tightly into the adapter located at the top of the bottle. Use only the syringe provided with the product.





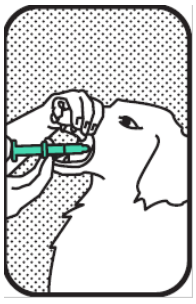
3. SELECT DOSE

Turn the bottle with the syringe in place upside down. Pull the plunger out until the black line of correct dose (ml) (prescribed by your veterinarian) can be seen under the grip plate of the syringe barrel.

If the dog weighs more than 30 kg, the total dose will be given in two separate doses as the syringe holds maximally 3.0 ml of solution.

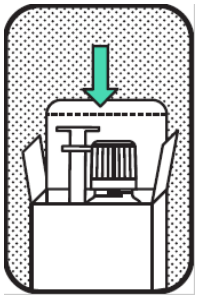
The accuracy of the syringe is demonstrated only for doses of 0.2 ml and higher. Dogs requiring doses lower than 0.2 ml can therefore not be treated.

Don’t leave the filled dosing syringe unattended while preparing the dog for administration.



4. GIVE DOSE

Gently place the syringe in the mouth of the dog and administer the dose to the base of the tongue by gradually pressing the plunger until the syringe is empty. Give the dog a small treat to ensure that the dog swallows the solution.



5. BACK TO PACKAGE

Replace the cap and rinse the syringe with water when finished. Put the syringe and bottle back to the secondary package and put them in the refrigerator.

Pack size:
Cardboard box containing one 15 ml bottle and an oral syringe.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Approved: 18 August 2023