Attachment

SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the product:

   RAPROS®

2. Approval No.:

   1-douyaku No.176

3. Dosage form:

   Oral tablet

4. Active substance:

   Each tablet contains beraprost sodium 55 μg.

5. Target animal:

   Cat

6. Therapeutical indications:

   Suppression of deterioration of renal function and improvement of clinical signs in cats having chronic kidney disease with International Renal Interest Society (IRIS) stage 2 to 3

7. Dosage and method of administration:

   1 tablet per cat, twice a day after feeding

8. Withdrawal time:

   Not applicable

9. Storage:

   Keep sealed and protected from light.

   Store at 1-30 ℃.

10. Capacity specification:

    10 tablets per blister. Cardboard box with 100 tablets

11. Shelf life:

5 years

12. Precautions:

(1) Contraindications:

Do not administer to cats with haemorrhage or bleeding tendency predicted by medical history, surgical history, current symptoms, or abnormal platelet count, as RAPROS® may increase bleeding tendency.

(2) Special precautions for use in animals:

Efficacy and safety of RAPROS® in cats having chronic kidney disease with International Renal Interest Society (IRIS) stage 2 to 3 has been tested in the pivotal clinical trial for regulatory approval. None of the cats tested in the trial were in acute exacerbation period.

RAPROS® should only be administered to suppress deterioration of renal function and improve clinical signs in cats having chronic kidney disease with IRIS stage 2 to 3.

The safety of RAPROS® has not been tested in cats under the age of 10 months. Do not administer RAPROS® to cats under the age of 10 months.

The safety of RAPROS® has not been tested in cats with severe hepatic disorders or cats with thyroid dysfunction. Pay particular attention in case of administration to cats with severe hepatic disorders and cats with thyroid dysfunction.

The efficacy of RAPROS® has not been tested in cats with IRIS stage 4 or in cats weighing over 7 kg.

(3) Special precautions to be taken by the person administrating the veterinary medicinal product to animals:

RAPROS® is a prescription drug. Administer according to prescription and

instructions from a veterinarian.

In case of accidental ingestion, seek medical advice immediately. There was one adult human who ingested 7240 μg of beraprost sodium. The incident resulted in recovery following gastric lavage employment and activated carbon administration.

(4) Adverse reactions:

Heart rate may increase within 1 hour after administration of RAPROS®.

Anorexia may be observed after administration of RAPROS®.

In the event of adverse reaction, seek veterinary advice immediately.

(5) Use during pregnancy, lactation or lay:

The safety of RAPROS® has not been tested in pregnant cats. Do not administer RAPROS® to pregnant cats or cats that may be pregnant.

(6) Interaction with other medicinal products and other forms of interaction:

Concomitant use of RAPROS® with anticoagulant, antiplatelet, and thrombolytic agents may increase bleeding tendency. Pay particular attention before administering RAPROS® with these drugs. In case of adverse reaction, take appropriate measures such as reducing the dose or deprescribing one of the drugs.

Concomitant use of RAPROS® with other prostacyclin agonists or endothelin receptor antagonists may reduce blood pressure. It is advised to monitor blood pressure when administering RAPROS® with these agents.

(7) Amount to be administered and administration route:

Oral use

Administer 1 tablet of RAPROS® in the morning and in the evening after meals.

(8) Special precautions for storage:

Keep out of reach of children.

Store the blisters in cardboard boxes to avoid direct sunlight. Avoid high

temperature and high humidity.

Remove RAPROS® from the blister before administration and do not store in packaging or container other than the packaging provided by the manufacturer.

Do not use after expiration.

(9) Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products:

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements to avoid polluting the water and to protect the environment.

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