Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

Veterinary medicine package leaflet

This medicine is dispensed with a veterinarian's prescription only

For use in animals only

1) Name, form and strength of the veterinary medicine:

Previcox 57 mg veterinary

Previcox 227 mg veterinary

Chewable tablets for dogs

2) Active ingredient and quantity in dose unit

Medicine name	Quantity of the active ingredient in each chewable tablet
Previcox 57 mg veterinary	Firocoxib 57 mg
Previcox 227 mg veterinary	Firocoxib 227 mg

Excipients with known effect: Iron oxide food colours (E172) and caramel (E150d).

For the list of all the inactive ingredients and allergens in the medicine – please see section 13.

Read the entire leaflet carefully before you start using this medicine.

This leaflet contains concise information about this medicine. If you have any further questions, consult the veterinarian or pharmacist.

3) What is this medicine intended for?

The medicine is intended for the treatment of pain and noninfectious inflammation caused by osteoarthritis (such as arthritis and the like) in dogs; for the treatment of post-operative pain and noninfectious inflammation following soft-tissue surgery, orthopaedic surgery and dental surgery (teeth and mouth).

Therapeutic group: The medicine belongs to the group of anti-inflammatory and anti-rheumatic products that are not steroids.

4) Contraindications:

Do not use this medicine:

- If the dog is sensitive (allergic) to the active ingredient or to any of the other ingredients in this medicine.
  The active ingredient appears in section 2, and the other ingredients are listed in section 13.
- When the bitch is pregnant or lactating, unless the bitch's condition requires treatment with the medicine.
- In dogs less than 10 weeks of age or that weigh less than 3 kg.
- If the dog suffers from gastrointestinal bleeding, blood dyscrasia or blood clotting problems.
- Concomitantly with steroids or other non-steroidal anti-inflammatory drugs (NSAID's).

5) Side effects:

Like all medicines, this medicine may cause side effects in some dogs. Do not be alarmed by this list of side effects. The dog may not experience any of them.

Side effects that have been observed: emesis and diarrhoea. These effects generally pass after adjusting to the medicine. These effects disappear when treatment with the medicine is stopped.

Rare side effects: Nervous system disorders.

Very rare side effects: Urinary tract and/or liver disorders.

If any of the side effects gets worse, or if the dog experiences a side effect not mentioned in this leaflet, consult your veterinarian.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: https://sideeffects.health.gov.il

6) Target animals:

The medicine is intended for use in dogs only.

7) Method of administration and dosage:

Always use according to the veterinarian's instructions. Check with the veterinarian or pharmacist if you are not sure. Only the veterinarian will determine the dose and how this medicine should be taken.

Consult the veterinarian to ensure the suitability of the medicine to the dog's medical diagnosis, prior to administration of the treatment.

Do not exceed the recommended dose.

Method of administration: Tablets to be chewed or swallowed. Tablets can be divided in half and into four parts.

Dose: Use this medicine at set intervals, as determined by the attending veterinarian, striving to treat the dog with the lowest possible dose that provides therapeutic efficacy.

- For treatment of osteoarthritis: Will be done according to a calculation of 5 mg firocoxib once daily per 1 kg bodyweight of the dog. Duration of treatment will be dependent on the dog's response and generally no longer than 90 days.
- For treatment of post-operative pain: Will be done according to a calculation of 5 mg firocoxib once daily per 1 kg bodyweight of the dog. Duration of treatment will generally be 3 days, with treatment starting approximately two hours prior to surgery.

The table below can be used to calculate the dose relative to the medicine tablet.

Dog's weight (kg)	Number of chewable tablets by strength		mg/kg range
	57 mg	227 mg	
3.0 - 5.5	0.5	- - - -	5.2 - 9.5
5.6 - 7.5	0.75	- - - -	5.7 - 7.6
7.6 - 10	1	0.25	5.7 - 7.5
10.1 - 13	1.25	- - - -	5.5 - 7.1
13.1 - 16	1.5	- - - -	5.3 - 6.5
16.1 - 18.5	1.75	- - - -	5.4 - 6.2
18.6 - 22.5	- - - -	0.5	5.0 - 6.1
22.6 - 34	- - - -	0.75	5.0 - 7.5
34.1 - 45	- - - -	1	5.0 - 6.7
45.1 - 56	- - - -	1.25	5.1 - 6.3
56.1 - 68	- - - -	1.5	5.0 - 6.1
68.1 - 79	- - - -	1.75	5.0 - 5.8
79.1 - 90	- - - -	2	5.0 - 5.7

The tablets can be divided in half to obtain half and quarter doses, in order to optimally adjust the dose to the weight of the dog.

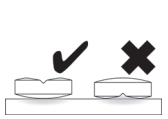
Complete the treatment of the dog as recommended by the veterinarian.

Administration to puppies: Treatment of puppies will be done at the discretion of the veterinarian, considering the risk-benefit data for use of the medicine in this age group. See chapter 4 (Contraindications).

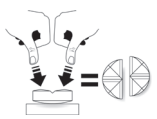
8) How to use the medicine:

- The tablet may be administered to the dog directly to be swallowed, without food or mixed with food.
- It is recommended to mix with a small serving of food such as meat, chicken, cold cuts or any other food (wet food is preferable to dry food).
- Wash hands after use.
- If only half or quarter of a tablet is administered, the remaining part should be returned to the plastic tray or the bottle of the product until the next use and at most for up to 1 month after the tablet is removed from the tray/bottle. See chapter 11 (Storage instructions).

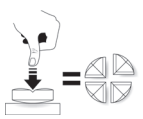
How to split the tablet: The tablet will be split in half or into quarters by breaking it down the score lines, which are on one side of the table.



Place the tablet on a flat surface, with the score lines facing up and the convex side facing the surface.



To split the tablet into two equal parts, press both your thumbs down on both sides of the tablet at the same time.



To split the tablet into four equal parts, press your thumb down in the middle of the tablet.

9) Waiting time:

Waiting times before slaughtering: Not applicable. The medicine is intended for dogs only.

10) Warnings:

- **Special warnings about use in target animal:** Do not use this medicine frequently or for a prolonged period without consulting a veterinarian. If the dog is sensitive to any food or any medicine, you should inform the veterinarian before the medicine is administered to the dog.
  If the dog suffers from problems of the urinary tract/kidney, heart, liver or if the dog is very young - the treatment requires close veterinary monitoring.
  Use of the medicine in dogs that are dehydrated or have hypotension may cause renal toxicity.
- **Special warnings about the safety of using this medicine in animals:** Follow all the veterinarian's instructions carefully. Treatment with the medicine should be discontinued and the veterinarian consulted if any of the following signs appears: vomiting, repeated diarrhoea, faecal occult blood, sudden weight loss, anorexia, lethargy, degradation of urinary/kidney function (according to laboratory tests).
  The tablets contain flavours. Keep them out of the reach of animals in order to prevent them from being swallowed accidentally.
- **Special safety precautions for the person administering the medicine:** Only remove the quantity of the tablet/s required from the package each time. For plastic (blister) packs: after removal of the tablet, return the plastic tray with the remaining tablets to the cardboard box. Wash hands after use of the medicine.
  If a person has accidentally swallowed some medicine, and particularly if it is a child, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.
- **Pregnancy and lactation in the treated animal:** Do not use in pregnant or lactating bitches. Laboratory studies have shown maternotoxic and foetotoxic effects at the dose rates required for treatment.
- **Interactions with other medicines and other forms of interaction:** If the dog receives or if the dog recently received other medicines and substances, inform the veterinarian or pharmacist to avoid risks or inefficacy due to drug interactions. In particular, inform the veterinarian or pharmacist if the dog receives: steroids and other anti-inflammatory drugs (recommended to wait at least 24 hours between the end of the previous treatment and commencement of treatment with Previcox), medicines that affect the urinary tract/kidney (e.g. diuretics, ACE inhibitors, anaesthetic drugs), medicines that bind to blood proteins. Refrain from concurrent administration of medicines known as being dangerous to the kidneys.
- **Overdose:** Administration of an overdose of the medicine may cause weight loss, poor appetite, changes in the liver (accumulation of lipid), brain damage, duodenum ulcer, vomiting and death. Some of these symptoms are reversible after administration of the medicine is discontinued. If a sign/signs of overdose appear, discontinue administration of the medicine immediately and immediately consult the veterinarian.
- **Incompatibility:** Unknown.

11) Storage instructions

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants.
- Do not use the medicine after the expiry date (Exp. Date) which is stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** Store at a temperature below 30°C.
- **Shelf life of the divided tablet:** Half and quarter tablets that remain should be returned to the product package (the plastic tray or bottle) until the next use, and they may be kept for up to one month after removal of the tablet from the plastic tray/bottle.
- **For bottle packaging - the shelf life after first opening of the bottle:** After first opening of the bottle, the tablets may be used for 3 months, but no later than the medicine's expiry date.

12) Instructions for the disposal of unused product or waste materials, if any:

- Do not throw away medicines in the toilet or with household waste.
- Ask your pharmacist or veterinarian how to dispose of medicines that have expired or are no longer required. These steps will help protect the environment.

13) Additional information:

- **In addition to the active ingredient, the medicine also contains the following inactive ingredients:**
  Lactose Monohydrate, Microcrystalline Cellulose, Chartor Hickory Smoke Flavor, Hydroxypropyl Cellulose, Croscarmellose Sodium, Magnesium Stearate, Caramel (E150d), Colloidal Silicone Dioxide, Yellow Iron Oxide (E172), Red Iron Oxide (E172).
- **What the medicine looks like and contents of the pack:** The medicine looks like a brown or brown-yellowish round, convex tablet with a cross-shaped break line on one side. The break line is used to split the tablet into two equal parts or four equal parts.
- The tablets are packaged in plastic trays (blisters), which are packed in cardboard boxes or plastic bottles closed with a twist cap, packaged in a cardboard box.
- **Pack size:** Plastic tray/s with 10 tablets in each tray. The number of plastic trays in each cardboard package may change according to the size of the pack. Plastic bottles with 60 tablets.
- The number of tablets in the pack appears on the cardboard package.
- Not all pack sizes may be marketed.
- **Registration holder:** Beit Erez Havat Milatin Ltd., P.C. 511088106, POB 209, Mishmar Hashiva 50297.
- **Manufacturer:** Boehringer Ingelheim Vetmedica, Ingelheim am Rhein, Germany (by Boehringer Ingelheim Animal Health France, Toulouse, France).

The medicines are intended for dogs and bitches.

Registration number of the medicine in the Ministry of Health's National Drug Registry:

Previcox 57 mg veterinary: 144-68-92443-00

Previcox 227 mg veterinary: 144-69-92444-00

Revised in 06/2021 according to MOH guidelines.