PARTICULARS TO APPEAR ON THE OUTER PACKAGE {NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Elanco JAK Inhibitor 4.8 mg Film-Coated Tablets for Dogs

2. STATEMENT OF ACTIVE SUBSTANCES

4.8 mg ilunocitinib

3. PACKAGE SIZE

10 tablets
30 tablets
90 tablets

4. TARGET SPECIES

Dogs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Any remaining half tablet should be stored in the blister and discarded if not used within 20 days.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco logo

14. MARKETING AUTHORISATION NUMBER

Vm 52127/5056

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {Blister}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Elanco JAK Inhibitor

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

4.8 mg ilunocitinib

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Elanco JAK Inhibitor 4.8 mg Film-Coated Tablets for Dogs
Elanco JAK Inhibitor 6.4 mg Film-Coated Tablets for Dogs
Elanco JAK Inhibitor 8.5 mg Film-Coated Tablets for Dogs
Elanco JAK Inhibitor 15 mg Film-Coated Tablets for Dogs

2. Composition

Each film-coated tablet contains:

Active substance:
4.8 mg, 6.4 mg, 8.5 mg or 15 mg ilunocitinib.

Yellow, oblong film-coated tablets with a score-line on both sides. The tablets can be divided into equal halves.

3. Target species

Dogs

4. Indications for use

Treatment of pruritus associated with allergic dermatitis in dogs.
Treatment of clinical manifestations of atopic dermatitis in dogs.

5. Contraindications

Do not use in dogs with evidence of immune suppression.
Do not use in dogs with evidence of progressive malignant neoplasia.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. Special warnings

Special warnings:
None

Special precautions for use in the target species:
Use of this veterinary medicinal product in dogs younger than 12 months of age is not recommended and should be based on a benefit-risk assessment by the responsible veterinary surgeon.

When dogs are to be administered long-term treatment, it is recommended that they are re-weighed on a regular basis so that the dose can be adjusted accordingly in the case of a significant change in bodyweight.

Use of the veterinary medicinal product has not been evaluated in dogs with hepatic or renal disease. Use of the product in these sub-populations should be according to a benefit:risk assessment by the responsible veterinary surgeon.

Ilunocitinib modulates the immune system and may increase susceptibility to opportunistic infection and exacerbate neoplastic conditions. Dogs receiving the veterinary medicinal product should therefore be monitored for the development of infections and neoplasia.

The veterinary medicinal product may cause a decrease in leukocyte (monocyte, eosinophil and neutrophil) counts and a reduction in red cell mass parameters (red blood cell count, haemoglobin and haematocrit) when initiating treatment. These changes typically remain within the laboratory reference range, stabilise within the first month of treatment and do not appear to be clinically relevant. However, periodic monitoring of complete blood counts and serum biochemistry is recommended when dogs are on long-term treatment.
Use of the product in dogs with anaemia has not been evaluated and should be according to a benefit:risk assessment by the responsible veterinary surgeon.

When treating pruritus associated with allergic dermatitis with ilunocitinib, investigate and treat any underlying causes (e.g. flea allergic dermatitis, contact dermatitis, food hypersensitivity). Furthermore, in cases of allergic dermatitis and atopic dermatitis, it is recommended to investigate and treat complicating factors, such as bacterial, fungal or parasitic infections/infestations (e.g. flea and mange).

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Accidental ingestion of the product may cause gastro-intestinal effects.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
Wash hands after administration.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy, lactation, or in breeding dogs. However, laboratory studies in rats have shown evidence of foetotoxic effects. Therefore, its use is not recommended during pregnancy, lactation or in dogs intended for breeding.

Interaction with other medicinal products and other forms of interaction:

Based on adverse event reporting, no known drug interactions were observed under field conditions following concomitant administration of ilunocitinib with other veterinary medicinal products such as endo- and ectoparasiticides, antimicrobials, vaccines or non-steroidal anti-inflammatories. However, during these clinical trials no specific investigation of the potential for drug interactions was conducted in animals receiving ilunocitinib with another veterinary medicinal product concomitantly.

Concurrent administration with other drugs with potential immunosuppressive effects (e.g. systemic glucocorticoids, cyclosporin A) must only be based on a benefit:risk assessment by the responsible veterinary surgeon.

The effect of ilunocitinib administration concomitantly with vaccines has only been evaluated in the laboratory using vaccines authorised in the USA. A similar serological response to vaccination was seen in Beagle dogs administered the vaccine concomitantly with ilunocitinib at 1x the recommended treatment dose (0.6-0.8 mg/kg bodyweight) compared to dogs administered the vaccine alone. The clinical relevance of these findings (correlate of protection) has not been established and infection challenge studies have not been conducted. The decision on whether to administer vaccines concomitantly with the veterinary medicinal product should be made according to a benefit:risk assessment by the responsible veterinary surgeon.

Ilunocitinib is a substrate for the P-glycoprotein transporter. Co-treatment with other drugs that are P-glycoprotein substrates, inhibitors or inducers could give rise to pharmacokinetic drug interactions. The potential clinical consequences of such interactions have not been investigated.

The use of gastric pH modifiers may affect the oral bioavailability of ilunocitinib. Therefore, such products should be used with caution.

Overdose:
A target species tolerance study was conducted in which ilunocitinib tablets (final marketed formulation) were administered orally to healthy 11-12 month old Beagle dogs once daily for 6 months at 0.8 mg/kg bw, 1.6 mg/kg bw, 2.4 mg/kg bw and 4.0 mg/kg bw (1, 2, 3 and 5x the recommended treatment dose, respectively). Prior to this, a similar target species tolerance pilot study was carried out with a near-final ilunocitinib tablet formulation. Clinical signs recorded in one or both of these studies that were likely to be related to ilunocitinib treatment included: generalised demodicosis, gum infections, interdigital cysts with or without discharge, papillomas, swollen feet (attributed to interstitial oedema), scabs on the paws and paw thickening and/or discolouration.

A mild-moderate reduction in red blood cell mass (mean haematocrit, haemoglobin and red blood cell count) was recorded in animals administered 2x to 5x the recommended treatment dose of ilunocitinib, with these parameters sometimes falling below the lower limit of the laboratory reference range. This was of no apparent clinical relevance in any of the treated animals.

In a separate study, seven of eight 10-month old vaccine-naïve Beagle dogs administered the veterinary medicinal product at 3x the recommended treatment dose (2.4 mg/kg/day) for up to 88 days developed clinical signs of coccidiosis (haemorrhagic diarrhoea, vomiting, weight loss and pale mucous membranes) due to *Isospora canis* infection, compared to 0/8 dogs administered placebo tablets. The origin of the parasite was unclear. Two of these eight dogs subsequently developed progressive severe clinical signs (haematemesis, lethargy, dehydration and depression) which were unresponsive to anticoccidial treatment and supportive therapy, necessitating early removal from the study and euthanasia. In these two dogs, clinical presentation and progression and post-mortem findings were consistent with environmentally-

acquired canine adenovirus-1 (CAV-1) infection which was potentially exacerbated by the immunosuppressive effects of ilunocitinib. Four of eight dogs in the ilunocitinib group developed thickening and crusting of the ear margins of unidentified aetiology compared to 0/8 dogs in the placebo group.

There is no specific antidote and in case of signs of overdose in dogs, the veterinary medicinal product should be withdrawn, and the signs should be treated symptomatically.

7. Adverse events

Dogs:

Common (1 to 10 animals / 100 animals treated):	Emesis, Diarrhoea
Undetermined frequency	Pododermatitis, Papilloma

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

For oral use.

The recommended dose is 0.6 to 0.8 mg ilunocitinib/kg bodyweight, administered once daily. Bodyweight must be determined as accurately as possible prior to commencing treatment.

The requirement for long-term therapy should be based on an individual benefit-risk assessment.

The dosing table below shows the number of tablets required. The tablets are breakable along a score-line allowing them to be divided into equal halves, if required.

Body weight (kg) of dog	Strength and number of tablets to be administered:			
	4.8 mg tablets	6.4 mg tablets	8.5 mg tablets	15 mg tablets
3.0 - 4.0	0.5			
4.1 - 5.3		0.5		
5.4 - 6.5			0.5	
6.6 - 8.0	1			
8.1 - 10.6		1		
10.7 - 14.1			1	
14.2 - 16.0		1.5		
16.1 - 19.5			1.5	
19.6 - 24.9				1
25.0 - 28.3			2	
28.4 - 37.4				1.5
37.5 - 49.9				2
50.0 - 62.4				2.5
62.5 - 74.9				3
≥ 75	Administer the appropriate combination of tablet strengths			

9. Advice on correct administration

The veterinary medicinal product can be given with or without food. However, it is recommended that you administer this product in a consistent manner in relation to feeding since administering the product on an empty stomach may reduce absorption of the active substance responsible for the product's effect.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.

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

Any remaining half tablet should be stored in the blister and discarded if not used within 20 days.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Elanco JAK Inhibitor 4.8 mg – Vm 52127/5056
Elanco JAK Inhibitor 6.4 mg – Vm 52127/5057
Elanco JAK Inhibitor 8.5 mg - Vm 52127/5058
Elanco JAK Inhibitor 15 mg – Vm 52127/5059

All tablet strengths are packaged in aluminium/ aluminium blisters, with a single film-coated tablet per blister. Each strip contains 10 blisters and are packed into an outer cardboard box. Pack sizes of 10, 30 or 90 film-coated tablets.
Not all pack sizes may be marketed.

15. PID link (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:
Elanco GmbH
Heinz-Lohmann Strasse 4
Groden
27472 Cuxhaven
Germany

Tel: +44 3308221732
PV.GBR@elancoah.com

Manufacturer responsible for batch release:
Elanco France S.A.S., 26 rue de la Chapelle, 68330 Huningue, France

17. Other information

Ilunocitinib is a non-selective Janus kinase (JAK) inhibitor. It inhibits the function of a variety of pruritogenic and pro-inflammatory cytokines, as well as cytokines involved in allergy which are dependent on JAK enzyme activity. Ilunocitinib has also been demonstrated to exert effects on the function of several cytokines involved in haematopoiesis and the innate immune response.

POM-V

Gavin Hall
Approved: 21 August 2025