SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Elanco JAK Inhibitor 15 mg Film-Coated Tablets for Dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains:

Active substance:
15 mg ilunocitinib

Excipients:

Qualitative composition of excipients and other constituents
Tablet core:
Cellulose, microcrystalline 302
Calcium hydrogen phosphate dihydrate
Starch, pregelatinised
Povidone K30
Magnesium stearate
Tablet coating:
Opadry QX 321A220011 yellow
Macrogol poly(vinyl alcohol) grafted copolymer (E1209)
Talc (E553b)
Titanium dioxide (E171)
Glycerol monocaprylocaprate (E471)
Poly(vinyl alcohol) (E1203)
Iron oxide yellow (E172)
Iron oxide red (E172)
Iron oxide black (E172

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

3. CLINICAL INFORMATION

3.1 Target species

Dogs

3.2 Indications for use for each target species

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

3.3 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.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe 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.

Special precautions for the protection of the environment:

Not applicable.

3.6 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 veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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.

3.8 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.

3.9 Administration routes and dosage

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 tablets can be administered with or without food. However, it is recommended that the veterinary medicinal product is administered in a consistent manner in relation to feeding since its bioavailability is increased by administering the product with food.

The dosing table below shows the number of tablets required. The tablets are breakable along the 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			

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QD11AH92

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

Ilunocitinib is rapidly and well absorbed after oral administration in dogs. After oral administration of the tablet at 0.8 mg/kg ilunocitinib in fed dogs, the absolute bioavailability was 80%, C_{max} was 268 ng/mL, and AUC_{inf} was 1330 h*ng/mL. The elimination half-life was 5.0 hours. In fasted dogs, oral bioavailability was 58% showing a similar elimination half-life as observed in fed dogs (5.4 hours), C_{max} was 122 ng/mL, and AUC_{inf} was 869 h*ng/mL. Time to peak plasma concentrations (T_{max}) was between 1 to 4 hours.

After IV administration of 0.8 mg/kg, ilunocitinib had a low plasma clearance of 437 mL/h/kg. The volume of distribution was 1.58 L/kg and terminal half-life was 4.4 hours.

Ilunocitinib exhibits low and consistent protein binding with approximatively 50% bound in fortified dog plasma.

Ilunocitinib is metabolised in dogs to several metabolites. In both urine and faeces, the parent drug remains the predominant component, with a combination of di-hydroxylation and reduction processes giving rise to a few minor metabolites.

The route of elimination of ilunocitinib is balanced between the faecal and urinary routes.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Any remaining half tablet should be stored in the blister and discarded if not used within 20 days.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

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.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco GmbH

7. MARKETING AUTHORISATION NUMBER

Vm 52127/5059

8. DATE OF FIRST AUTHORISATION

07 July 2025

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

July 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

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

Gavin Hall
Approved: 21 August 2025