ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zenrelia 4.8 mg film-coated tablets for dogs
Zenrelia 6.4 mg film-coated tablets for dogs
Zenrelia 8.5 mg film-coated tablets for dogs
Zenrelia 15 mg film-coated tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains:

Active substance:

4.8 mg ilunocitinib
6.4 mg ilunocitinib
8.5 mg ilunocitinib
15 mg ilunocitinib

Excipients:

Qualitative composition of excipients and other constituents
Tablet core:
Cellulose, microcrystalline 302
Calcium hydrogen phosphate dihydrate
Starch, pregelatinized
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 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:

Safety of this veterinary medicinal product has not been investigated in dogs younger than 12 months of age or weighing less than 3 kg. Therefore, its use in such cases should be based on a benefit-risk assessment by the responsible veterinarian.

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

Do not use in dogs with evidence of malignant neoplasia, demodicosis or immune suppression such as hyperadrenocorticism, as the active substance has not been evaluated in these cases.

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:

Wash hands after administration.

Accidental ingestion may be harmful.

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Keep tablets and unused half tablets in the original packaging until next administration, in order to prevent children from getting direct access to the veterinary medicinal product.

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, Lethargy
Uncommon (1 to 10 animals / 1 000 animals treated):	Papilloma, Interdigital Cyst

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.

Pregnancy and lactation:
The use is not recommended during pregnancy and lactation.
Laboratory studies in rats have shown evidence of teratogenic, and foetotoxic effects.

Fertility:
The use is not recommended in breeding animals.

3.8 Interaction with other medicinal products and other forms of interaction

No drug interactions were observed in field studies where ilunocitinib was administered concomitantly with veterinary medicinal products such as endo- and ectoparasiticides, antimicrobials, vaccines and non-steroidal anti-inflammatory drugs.

The effect of ilunocitinib administration on vaccination with canine parvovirus (CPV), canine distemper virus (CDV), canine adenovirus-2 (CAV-2), canine parainfluenza (CPiV) and inactivated rabies vaccine (RV), has been studied in 10-month-old vaccine naïve dogs, receiving 2.4 mg/kg (3X the maximum recommended label dose) for 89 days. Based on assessment of serological antibody titres, an adequate immune response to canine core Modified Live Vaccines (CAV-2, CDV and CPV) was observed following primary vaccination on Day 28. Response to primary CPiV (non-core vaccine) vaccination in treated animals was 4 of 6 above threshold vs 6 of 8 controls above threshold following primary vaccination. A delayed or reduced response to RV was observed. The clinical relevance of these observed effects in animals vaccinated while being administered ilunocitinib in accordance with the recommended dosing regimen is unclear. The effect of ilunocitinib on response to booster vaccinations has been studied in 10-month-old previously vaccinated dogs receiving 1X or 3X the recommended label dose (0.6 -0.8 or 1.8 -2.4 mg/kg, respectively) for 56 days and showed no difference in booster vaccination response between control and 1X or 3X ilunocitinib treated groups.

3.9 Administration routes and dosage

Oral use.

The recommended dose is 0.6 to 0.8 mg ilunocitinib/kg bodyweight, administered once daily.

The requirement for long-term maintenance therapy should be based on an individual benefit-risk assessment by the responsible veterinarian.

The tablets can be administered with or without food.

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

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)

Ilunocitinib tablets were administered orally to healthy 11-12 month old Beagle dogs once daily for 6 months at 0.8 mg/kg body weight (bw), 1.6 mg/kg bw, 2.4 mg/kg bw and 4.0 mg/kg bw. Clinical signs that were likely to be related to ilunocitinib treatment included: interdigital cysts, with or without discharge, swollen and/or scabs on the paws and paw thickening and/or discoloration. More commonly in males, a mild reduction in red blood cell mass was noted in some animals at 3X dose after 8 weeks of use. This reduction was self-limiting, with gradual recovery to pre-treatment measurements.

There is no specific antidote and in case of signs of overdose the dog 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 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 minimal impact on other protein and lipid kinases and has therefore limited risk of off-target effects. Ilunocitinib may also exert effects on other cytokines (for example, those involved in immune defense or haematopoiesis), which may have the potential for unwanted effects.

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 %. 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). Time to peak plasma concentrations (t_{max}) was between 1 to 4 hours.

After repeated oral administration there was no significant accumulation.

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

After intravenous 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.

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 used at the next administration.

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

PA-alu-PVC/alu-PET-paper unit-dose blisters. Each blister pack contains 10 film-coated tablets. Cardboard box containing 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 products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

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(S)

EU/2/25/349/001-012

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 24/07/2025

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

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (*https://medicines.health.europa.eu/veterinary*).

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

SPECIFIC PHARMACOVIGILANCE REQUIREMENTS:

The MAH shall record in the pharmacovigilance database all results and outcomes of the signal management process, including a conclusion on the benefit-risk balance, according to the following frequency: annually.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zenrelia 4.8 mg film-coated tablets
Zenrelia 6.4 mg film-coated tablets
Zenrelia 8.5 mg film-coated tablets
Zenrelia 15 mg film-coated tablets

2. STATEMENT OF ACTIVE SUBSTANCES

4.8 mg ilunocitinib/tablet
6.4 mg ilunocitinib/tablet
8.5 mg ilunocitinib/tablet
15 mg ilunocitinib/tablet

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 used at the next administration.

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 NUMBERS

EU/2/25/349/001 (10 tablets, 4.8 mg)
EU/2/25/349/002 (30 tablets, 4.8 mg)
EU/2/25/349/003 (90 tablets, 4.8 mg)
EU/2/25/349/004 (10 tablets, 6.4 mg)
EU/2/25/349/005 (30 tablets, 6.4 mg)
EU/2/25/349/006 (90 tablets, 6.4 mg)
EU/2/25/349/007 (10 tablets, 8.5 mg)
EU/2/25/349/008 (30 tablets, 8.5 mg)
EU/2/25/349/009 (90 tablets, 8.5 mg)
EU/2/25/349/010 (10 tablets, 15 mg)
EU/2/25/349/011 (30 tablets, 15 mg)
EU/2/25/349/012 (90 tablets, 15 mg)

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Blisters

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zenrelia

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

4.8 mg ilunocitinib
6.4 mg ilunocitinib
8.5 mg ilunocitinib
15 mg ilunocitinib

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Zenrelia 4.8 mg film-coated tablets for dogs
Zenrelia 6.4 mg film-coated tablets for dogs
Zenrelia 8.5 mg film-coated tablets for dogs
Zenrelia 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 cases of hypersensitivity to the active substance or to any of the excipients.

6. Special warnings

Special warnings:
None.

Special precautions for safe use in the target species:

Safety of this veterinary medicinal product has not been investigated in dogs younger than 12 months of age or weighing less than 3 kg. Therefore, its use in such cases should be based on a benefit-risk assessment by the responsible veterinarian.

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

Do not use in dogs with evidence of malignant neoplasia, demodicosis or immune suppression such as hyperadrenocorticism, as the active substance has not been evaluated in these cases.

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:

Wash hands after administration.
Accidental ingestion may be harmful.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
Keep tablets and unused half tablets in the original packaging until next administration, in order to prevent children from getting direct access to the veterinary medicinal product.

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established during pregnancy and lactation. The use is not recommended during pregnancy and lactation.
Laboratory studies in rats have shown evidence of teratogenic, and foetotoxic effects.

Fertility:

The safety of the veterinary medicinal product has not been established in breeding dogs. The use is not recommended in breeding animals.

Interaction with other medicinal products and other forms of interaction:

No drug interactions were observed in field studies where ilunocitinib was administered concomitantly with veterinary medicinal products such as endo- and ectoparasiticides, antimicrobials, vaccines and non-steroidal anti-inflammatory drugs.

The effect of ilunocitinib administration on vaccination with canine parvovirus (CPV), canine distemper virus (CDV), canine adenovirus-2 (CAV-2), canine parainfluenza (CPiV) and inactivated rabies vaccine (RV), has been studied in 10-month-old vaccine naïve dogs, receiving 2.4 mg/kg (3X the maximum recommended label dose) for 89 days. Based on assessment of serological antibody titres, an adequate immune response to canine core Modified Live Vaccines (CAV-2, CDV and CPV) was observed following primary vaccination on Day 28. Response to primary CPiV (non-core vaccine) vaccination in treated animals was 4 of 6 above threshold vs 6 of 8 controls above threshold following primary vaccination. A delayed or reduced response to RV was observed. The clinical relevance of these observed effects in animals vaccinated while being administered ilunocitinib in accordance with the recommended dosing regimen is unclear. The effect of ilunocitinib on response to booster vaccinations has been studied in 10-month-old previously vaccinated dogs receiving 1X or 3X the recommended label dose (0.6-0.8 or 1.8-2.4 mg/kg, respectively) for 56 days and showed no difference in booster vaccination response between control and 1X or 3X ilunocitinib treated groups.

Overdose:

Ilunocitinib tablets were administered orally to healthy 11-12 month old Beagle dogs once daily for 6 months at 0.8 mg/kg body weight (bw), 1.6 mg/kg bw, 2.4 mg/kg bw and 4.0 mg/kg bw. Clinical signs that were likely to be related to ilunocitinib treatment included: interdigital cysts, with or without discharge, swollen and/or scabs on the paws and paw thickening and/or discoloration. More commonly in males, a mild reduction in red blood cell mass was noted in some animals at 3X dose

after 8 weeks of use. This reduction was self-limiting, with gradual recovery to pre-treatment measurements.

There is no specific antidote and in case of signs of overdose the dog should be treated symptomatically.

7. Adverse events

Dogs:

Common (1 to 10 animals / 100 animals treated):
Emesis, Diarrhoea, Lethargy
Uncommon (1 to 10 animals / 1 000 animals treated):
Papilloma, Interdigital Cyst

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: {national system details}.

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

Oral use.

The recommended dose is 0.6 to 0.8 mg ilunocitinib/kg bodyweight, administered once daily.

The requirement for long-term maintenance therapy should be based on an individual benefit-risk assessment by the responsible veterinarian.

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

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.

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 used at the next administration.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

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.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

EU/2/25/349/001-012

PA-alu-PVC/alu-PET-paper unit-dose blisters. Each blister pack contains 10 film-coated tablets. Cardboardbox containing 10, 30 or 90 film-coated tablets.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

Detailed information on this veterinary medicinal product is available in the Union Product Database (*https://medicines.health.europa.eu/veterinary*).

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse events:

Elanco GmbH, Heinz-Lohmann-Str. 4, 27472 Cuxhaven, Germany

België/Belgique/Belgien
Tél/Tel: +32 33000338
PV.BEL@elancoah.com

Република България
Тел: +48 221047815
PV.BGR@elancoah.com

Česká republika
Tel: +420 228880231
PV.CZE@elancoah.com

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PV.LVA@elancoah.com

PV.SWE@elancoah.com

United Kingdom (Northern Ireland)
Tel: +44 3308221732
PV.XXI@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 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 minimal impact on other protein and lipid kinases and has therefore limited risk of off-target effects. Ilunocitinib may also exert effects on other cytokines (for example, those involved in immune defense or haematopoiesis), which may have the potential for unwanted effects.