ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Numelvi 4.8 mg tablets for dogs
Numelvi 7.2 mg tablets for dogs
Numelvi 21.6 mg tablets for dogs
Numelvi 31.6 mg tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substances:
Atinvicitinib 4.8 mg
Atinvicitinib 7.2 mg
Atinvicitinib 21.6 mg
Atinvicitinib 31.6 mg

Excipients:

Qualitative composition of excipients and other constituents
Cellulose, microcrystalline
Lactose monohydrate
Sodium starch glycolate (type A)
Tocofersolan
Hydroxypropylcellulose
Silica, colloidal anhydrous
Magnesium stearate

White to off-white, oblong shaped tablets with one score-line on each side and marked with "S" (on the 4.8 mg tablets), "M" (on the 7.2 mg tablets), "L" (on the 21.6 mg tablets) or “XL” (on the 31.6 mg tablets) on each half of the top side.

The tablets can be divided into two equal halves.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

For the treatment of pruritus associated with allergic dermatitis including atopic dermatitis in dogs.
For the treatment of clinical manifestations of atopic dermatitis in dogs.

3.3 Contraindications

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 6 months of age or weighing less than 3 kg bodyweight. Use of the veterinary medicinal product in younger animals or animals with a lower bodyweight should be based on a benefit-risk assessment by the responsible veterinarian.
It is recommended to investigate and treat complicating factors, such as bacterial, fungal or parasitic infections (e.g., flea, *Demodex* mites), as well as any underlying causes (e.g., flea allergy, contact allergy, food allergy) of allergic and atopic dermatitis.
The safety of the veterinary medicinal product has not been investigated in dogs with evidence of immune suppression, such as uncontrolled primary hypothyroidism or rickettsial disease, or with evidence of progressive malignant neoplasia.
Therefore, the use in such cases should be based on a benefit-risk assessment by the responsible veterinarian.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Wash hands thoroughly with soap and water immediately after use of 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, Anorexia

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 and lactation or in breeding dogs.

Pregnancy and lactation:
The use is not recommended during pregnancy and lactation.
Laboratory studies in rats and rabbits have shown effects on prenatal development, inherent to the class of JAK inhibitors.

Fertility:
The use is not recommended in breeding animals.
Laboratory studies in male rats showed an effect on sperm counts and sperm motility.

3.8 Interaction with other medicinal products and other forms of interaction

None known. No drug interactions were observed in field studies where the veterinary medicinal product was administered concomitantly with other veterinary medicinal products such as antimicrobials (including topicals), ecto- and endoparasiticides (isoxazolines, milbemycins,

avermectins, pyrethrins and pyrethroids), nutritional supplements, topical skin and ear cleansers that did not contain glucocorticoids, as well as medicated shampoos.

There was no impact on immune response to vaccination. The veterinary medicinal product was well-tolerated with no adverse clinical effects related to treatment when used concomitantly with vaccination. An adequate immune response (serology) to modified live Canine Adenovirus type-2 (CAV), modified live Canine Distemper Virus (CDV), modified live Canine Parvovirus (CPV), and inactivated Rabies Virus (RV) vaccination was achieved when 6-month-old vaccine naïve puppies were administered the veterinary medicinal product at 3.6 mg/kg atinvicitinib (3 times the maximum recommended dose) once daily for 84 days.

3.9 Administration routes and dosage

Oral use.

The veterinary medicinal product should be administered once daily, at or around the time of feeding, in accordance with the following dosing table (corresponding to a dose of 0.8 - 1.2 mg atinvicitinib/kg bodyweight within one weight band):

	Strength and number of tablets to be administered			
Bodyweight of dog (kg)	**Numelvi 4.8 mg**	**Numelvi 7.2 mg**	**Numelvi 21.6 mg**	**Numelvi 31.6 mg**
3.0-4.3		½		
4.4-6.0	1			
6.1-9.0		1		
9.1-13.5			½	
13.6-19.3				½
19.4-26.5			1	
26.6-39.5				1
39.6-54.0				1 ½
54.1-79.0				2

The tablets are breakable along the score line.
Dogs outside the listed weight bands (see section 3.5) can be dosed with a combination of full and/or half tablets of appropriate tablet strengths to achieve a target dose of 0.8 - 1.2 mg atinvicitinib/kg bodyweight.
The available tablet strengths do not allow for accurate dosing of dogs weighing less than 2 kg bodyweight.

The intensity and duration of signs of allergic dermatitis including atopic dermatitis are variable. The need for long-term treatment should be based on an individual benefit-risk assessment.

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

For atinvicitinib a high selectivity of JAK1 was shown, limiting the potential for adverse effects mediated via other JAK family enzymes.
Consequently, the veterinary medicinal product was well tolerated when administered orally to healthy 6-months-old puppies treated with overdoses of up to 5 times the maximum recommended dose once daily over a period of 6 months.
At significant overdoses, treatment with the veterinary medicinal product may lead to a higher susceptibility of dogs for development of bacterial, fungal and/or parasitic skin disease.

In case of adverse effects following an 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: QD11AH93

4.2 Pharmacodynamics

Atinvicitinib is a selective Janus kinase (JAK) inhibitor, highly selective for JAK1. It inhibits the function of a variety of cytokines involved in itch and inflammation, as well as cytokines involved in allergy, that are dependent on JAK1 enzyme activity. Reduction of allergy mediated inflammation, which is dependent on JAK1 enzyme activity, leads to a reduction of inflammation associated white blood cell counts (within the reference range). Atinvicitinib did not lead to immunosuppressive effects at the target dose.
Atinvicitinib is at least 10 times more selective for JAK1 compared to the other JAK family members (JAK2, JAK3, Tyrosine Kinase (TYK)2). Thus, it has very little to no effect on cytokines involved in haematopoiesis or host defense that are dependent on JAK2 or the other JAK family members.

4.3 Pharmacokinetics

Following oral administration, atinvicitinib was rapidly and well absorbed with an observed mean C_{max} of 190 ng/ml, which occurred at approximately 1 hour (t_{max}) post dosing. The absolute bioavailability of atinvicitinib after administration once daily for four days was approximately 65%. Bioavailability was higher in fed dogs. Total body atinvicitinib clearance from plasma was 1074 ml/h/kg bodyweight (17.9 ml/min/kg bodyweight), and the apparent volume of distribution at steady state was 1651 ml/kg bodyweight. Following oral administration, the terminal half-life ($t_{1/2}$) was 2 hours. In a six-month study conducted in dogs with up to 5 times the maximum recommended dose (see section 3.10), mild accumulation was observed in some individuals; steady state was reached after 7 weeks.

Atinvicitinib has moderate protein binding with 82.3% bound in fortified canine plasma at concentrations of 1802 ng/ml (5 µM).

Atinvicitinib is metabolized in the dog to multiple metabolites. Overall clearance route is metabolism with excretion in the faeces while renal elimination with excretion in urine is a minor route.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.
Any remaining half tablet should be placed back into the opened blister or into the bottle.

5.4 Nature and composition of immediate packaging

Aluminium/PVC/ polychlorotrifluoroethylene blisters containing 30 tablets per strip. Blister strips are packaged in a cardboard box containing either 1 or 3 blister strips equivalent to 30 or 90 tablets.

HDPE bottles containing 30 or 90 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

Intervet International B.V.

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/25/351/001-016

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

Numelvi 4.8 mg tablets
Numelvi 7.2 mg tablets
Numelvi 21.6 mg tablets
Numelvi 31.6 mg tablets

2. STATEMENT OF ACTIVE SUBSTANCES

4.8 mg atinvicitinib
7.2 mg atinvicitinib
21.6 mg atinvicitinib
31.6 mg atinvicitinib

3. PACKAGE SIZE

30 tablets
90 tablets

4. TARGET SPECIES

For dogs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

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

Intervet International B.V.

14. MARKETING AUTHORISATION NUMBERS

EU/2/25/351/001 (1 x 30 tablets, 4.8 mg, blister)
EU/2/25/351/002 (3 x 30 tablets, 4.8 mg blister)
EU/2/25/351/003 (1 x 30 tablets, 7.2 mg, blister)
EU/2/25/351/004 (3 x 30 tablets, 7.2 mg blister)
EU/2/25/351/005 (1 x 30 tablets, 21.6 mg, blister)
EU/2/25/351/006 (3 x 30 tablets, 21.6 mg blister)
EU/2/25/351/007 (1 x 30 tablets, 31.6 mg, blister)
EU/2/25/351/008 (3 x 30 tablets, 31.6 mg blister)
EU/2/25/351/009 (30 tablets, 4.8 mg, bottle)
EU/2/25/351/010 (90 tablets, 4.8 mg, bottle)
EU/2/25/351/011 (30 tablets, 7.2 mg, bottle)
EU/2/25/351/012 (90 tablets, 7.2 mg bottle)
EU/2/25/351/013 (30 tablets, 21.6 mg, bottle)
EU/2/25/351/014 (90 tablets, 21.6 mg bottle)
EU/2/25/351/015 (30 tablets, 31.6 mg, bottle)
EU/2/25/351/016 (90 tablets, 31.6 mg bottle)

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Bottle label (volume 60 and 100 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Numelvi 4.8 mg tablets
Numelvi 7.2 mg tablets
Numelvi 21.6 mg tablets
Numelvi 31.6 mg tablets

2. STATEMENT OF ACTIVE SUBSTANCES

4.8 mg atinvicitinib
7.2 mg atinvicitinib
21.6 mg atinvicitinib
31.6 mg atinvicitinib

3. TARGET SPECIES

For dogs.

4. ROUTES OF ADMINISTRATION

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

6. EXPIRY DATE

Exp. {mm/yyyy}

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Bottle label (volume 15 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Numelvi

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

4.8 mg atinvicitinib
7.2 mg atinvicitinib
21.6 mg atinvicitinib
31.6 mg atinvicitinib

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Numelvi

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

4.8 mg atinvicitinib
7.2 mg atinvicitinib
21.6 mg atinvicitinib
31.6 mg atinvicitinib

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Numelvi 4.8 mg tablets for dogs
Numelvi 7.2 mg tablets for dogs
Numelvi 21.6 mg tablets for dogs
Numelvi 31.6 mg tablets for dogs

2. Composition

Each tablet contains:

Active substance:
4.8 mg, 7.2 mg, 21.6 mg or 31.6 mg atinvicitinib.

White to off-white, oblong shaped tablets with one score-line on each side and marked with "S" (on the 4.8 mg tablets), "M" (on the 7.2 mg tablets), "L" (on the 21.6 mg tablets) or “XL” (on the 31.6 mg tablets) on each half of the top side.
The tablets can be divided into two equal halves.

3. Target species

Dogs.

4. Indications for use

For the treatment of pruritus associated with allergic dermatitis including atopic dermatitis in dogs.
For the treatment of clinical manifestations of atopic dermatitis in dogs.

5. Contraindications

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 6 months of age or weighing less than 3 kg bodyweight. Use of the veterinary medicinal product in younger animals or animals with a lower bodyweight should be based on a benefit-risk assessment by the responsible veterinarian.
It is recommended to investigate and treat complicating factors, such as bacterial, fungal or parasitic infections (e.g., flea, *Demodex* mites), as well as any underlying causes (e.g., flea allergy, contact allergy, food allergy) of allergic and atopic dermatitis.

The safety of the veterinary medicinal product has not been investigated in dogs with evidence of immune suppression, such as uncontrolled primary hypothyroidism or rickettsial disease, or with evidence of progressive malignant neoplasia.
Therefore, the use in such cases should be based on a benefit-risk assessment by the responsible veterinarian.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Wash hands thoroughly with soap and water immediately after use of the veterinary medicinal product.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation or in breeding dogs. The use is not recommended during pregnancy and lactation.
Laboratory studies in rats and rabbits have shown effects on prenatal development, inherent for the class of JAK inhibitors.

Fertility:
The use is not recommended in breeding animals. Laboratory studies in male rats showed an effect on sperm counts and sperm motility.

Interaction with other medicinal products and other forms of interaction:
None known. No drug interactions were observed in field studies where the veterinary medicinal product was administered concomitantly with other veterinary medicinal products such as antimicrobials (including topicals), ecto- and endoparasiticides (isoxazolines, milbemycins, avermectins, pyrethrins and pyrethroids), nutritional supplements, topical skin and ear cleansers that did not contain glucocorticoids, as well as medicated shampoos.
There was no impact on immune response to vaccination. The veterinary medicinal product was well-tolerated with no adverse clinical effects related to treatment when used concomitantly with vaccination. An adequate immune response (serology) to modified live Canine Adenovirus type-2 (CAV), modified live Canine Distemper Virus (CDV), modified live Canine Parvovirus (CPV), and inactivated Rabies Virus (RV) vaccination was achieved when 6-month-old vaccine naïve puppies were administered the veterinary medicinal product at 3.6 mg/kg atinvicitinib (3X the maximum labelled dose) once daily for 84 days.

Overdose:
For atinvicitinib a high selectivity of JAK1 was shown, limiting the potential for adverse effects mediated via other JAK family enzymes.
Consequently, the veterinary medicinal product was well tolerated when administered orally to healthy 6-months-old puppies treated with overdoses of up to 5 times the maximum recommended dose once daily over a period of 6 months.
At significant overdoses, treatment with the veterinary medicinal product may lead to a higher susceptibility of dogs for development of bacterial, fungal and/or parasitic skin disease.
In case of adverse effects following an overdose, the dog should be treated symptomatically.

7. Adverse events

Dogs:

Common (1 to 10 animals / 100 animals treated):
Vomiting, Diarrhoea, Lethargy, Anorexia (Decreased appetite)

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

For oral use in dogs.

Dosing table (corresponding to a dose of 0.8 - 1.2 mg atinvicitinib/kg bodyweight within one weight band):

Strength and number of tablets to be administered				
	Strength and number of tablets to be administered			
Bodyweight of dog (kg)	**Numelvi 4.8 mg**	**Numelvi 7.2 mg**	**Numelvi 21.6 mg**	**Numelvi 31.6 mg**
3.0-4.3		½		
4.4-6.0	1			
6.1-9.0		1		
9.1-13.5			½	
13.6-19.3				½
19.4-26.5			1	
26.6-39.5				1
39.6-54.0				1 ½
54.1-79.0				2

The tablets are breakable along the score line.
Dogs outside the listed weight bands (see section 6) can be dosed with a combination of full and/or half tablets of appropriate tablet strengths to achieve a target dose of 0.8 - 1.2 mg atinvicitinib/kg bodyweight.
The available tablet strengths do not allow for accurate dosing of dogs weighing less than 2 kg bodyweight.

The intensity and duration of signs of allergic dermatitis including atopic dermatitis are variable. The need for long-term treatment should be based on an individual benefit-risk assessment.

9. Advice on correct administration

The veterinary medicinal product should be administered once daily, at or around the time of feeding,

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.
Any remaining half tablet should be placed back into the opened blister or into the bottle.
Do not use this veterinary medicinal product after the expiry date which is stated on the blister or bottle after Exp. The expiry date refers to the last day of that month.

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/2/25/351/001-016

Each cardboard box with blisters or each HDPE plastic bottle contains 30 or 90 tablets.
Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{DD/MM/YYYY}

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:
Intervet International B.V., Wim de Körverstraat 35, 5831 AN Boxmeer, The Netherlands

België/Belgique/Belgien
Tél/Tel: + 32 (0)2 370 94 01

Република България
Тел: + 359 28193749

Česká republika
Tel: + 420 233 010 242

Danmark
Tlf: + 45 44 82 42 00

Deutschland
Tel: + 49 (0)8945614100

Eesti
Tel: + 37052196111

Ελλάδα
Τηλ: + 30 210 989 7452

España
Tel: + 34 923 19 03 45

Lietuva
Tel: + 37052196111

Luxembourg/Luxemburg
Tél/Tel: + 32 (0)2 370 94 01

Magyarország
Tel.: + 36 1 439 4597

Malta
Tel: + 39 02 516861

Nederland
Tel: + 32 (0)2 370 94 01

Norge
Tlf: + 47 55 54 37 35

Österreich
Tel: + 43 (1) 256 87 87

Polska
Tel.: + 48 22 18 32 200

France
Tél: + 33 (0)241228383

Hrvatska
Tel: + 385 1 6611339

Ireland
Tel: + 353 (0) 1 2970220

Ísland
Sími: + 354 535 7000

Italia
Tel: + 39 02 516861

Κύπρος
Τηλ: + 30 210 989 7452

Latvija
Tel: + 37052196111

Portugal
Tel: + 351 214 465 700

România
Tel: + 40 21 311 83 11

Slovenija
Tel: + 385 1 6611339

Slovenská republika
Tel: + 420 233 010 242

Suomi/Finland
Puh/Tel: + 358 10 2310 750

Sverige
Tel: + 46 (0)8 522 216 60

United Kingdom (Northern Ireland)
Tel: + 353 (0) 1 2970220

Manufacturer responsible for batch release:
Intervet Ges.m.b.H., Siemensstrasse 107, 1210 Vienna, Austria

17. Other information

Atinvicitinib is a selective Janus kinase (JAK) inhibitor, highly selective for JAK1. It inhibits the function of a variety of cytokines involved in itch and inflammation, as well as cytokines involved in allergy, that are dependent on JAK1 enzyme activity.

Atinvicitinib is at least ten-times more selective for JAK1 compared to the other JAK family members (JAK2, JAK3, Tyrosine Kinase (TYK) 2). Thus, it has very little to no effect on cytokines involved in haematopoiesis or host defense that are dependent on JAK2 or the other JAK family members.