PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Cardboard box (blisters and bottles)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Numelvi 4.8 mg tablets for dogs

2. STATEMENT OF ACTIVE SUBSTANCES

4.8 mg atinvicitinib

3. PACKAGE SIZE

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 placed back into the opened blister.
Any remaining half tablet should be placed back into the opened bottle.

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

MSD Animal Health UK Ltd.

14. MARKETING AUTHORISATION NUMBERS

Vm 01708/5134

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
Bottle label (volume 60 ml and 100 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Numelvi 4.8 mg tablets for dogs

2. STATEMENT OF ACTIVE SUBSTANCES

4.8 mg atinvicitinib

3. TARGET SPECIES

Dogs.

4. ROUTES OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

6. EXPIRY DATE

Exp. {mm/yyyy}

7. SPECIAL STORAGE PRECAUTIONS

Any remaining half tablet should be placed back into the opened bottle.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Ltd.

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

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

5. ROUTE OF ADMINISTRATION

Oral use.

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

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

5. ROUTE OF ADMINISTRATION

Oral use.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET
(Combined 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:
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 in dogs.
For the treatment of the clinical manifestations associated with atopic dermatitis in dogs, including pruritus.

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. 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.

Complicating factors such as bacterial, fungal or parasitic infections (e.g., fleas, *Demodex* mites), in addition to any underlying causes of allergic and atopic dermatitis (e.g., flea allergy, contact allergy, food allergy) should be investigated and treated.

Use of the veterinary medicinal product has not been evaluated in combination with systemic immunosuppressive agents such as glucocorticoids, cyclosporine or other immunosuppressive agents. Furthermore, the safety of the veterinary medicinal product has not been investigated in dogs with evidence of immunosuppression (for example, uncontrolled primary hypothyroidism, rickettsial disease) or dogs with evidence of progressive malignant neoplasia. 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 of the veterinary medicinal product during pregnancy and lactation is not recommended. Laboratory studies in rats and rabbits have shown effects on prenatal development inherent to the class of JAK inhibitors.

Fertility:
The use of the veterinary medicinal product 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:
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 topical preparations), ecto- and endoparasiticides (isoxazolines, milbemycins, avermectins, pyrethrins and pyrethroids), nutritional supplements, topical skin and ear cleansers that did not contain glucocorticoids, and medicated shampoos.
The user is also referred to section 'Special precautions for safe use in the target species' for additional guidance.

In a controlled laboratory study, a similar serological response to vaccination with modified live canine adenovirus type-2 (CAV), canine distemper virus (CDV), canine parvovirus (CPV) and inactivated rabies virus (RV) was observed when 6-month-old vaccine naïve puppies were administered the veterinary medicinal product at 3.6 mg/kg atinvicitinib (3 times the maximum labelled dose) once daily for 84 days, compared to dogs receiving the vaccines alone. The veterinary medicinal product

was well-tolerated with no adverse clinical effects related to treatment when used concomitantly with vaccination.

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

7. Adverse events

Dogs:

Common (1 to 10 animals / 100 animals treated):	Emesis (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 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

Oral use.

The veterinary medicinal product should be administered once daily at the recommended dose of 0.8 to 1.2 mg atinvicitinib/kg bodyweight at or around the time of feeding, in accordance with the following dosing table. Doses in the table, achieved within each weight band, correspond to the recommended dose of atinvicitinib in milligrams per kilogram bodyweight:

	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, for example dogs above 79 kg bodyweight, can be dosed with a combination of full and/or half tablets of the appropriate tablet strengths to achieve a target dose of 0.8 to 1.2 mg atinvicitinib/kg bodyweight (also see section 'Special precautions for safe use in the target species'). However, the available tablet strengths do not allow for accurate dosing of dogs weighing less than 2 kg bodyweight.

The intensity and duration of pruritus associated with allergic dermatitis and the clinical manifestations of atopic dermatitis are variable. The need for long-term treatment of dogs receiving the veterinary medicinal product 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.

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

Numelvi 4.8 mg tablets for dogs: Vm 01708/5134
Numelvi 7.2 mg tablets for dogs: Vm 01708/5135
Numelvi 21.6 mg tablets for dogs: Vm 01708/5136
Numelvi 31.6 mg tablets for dogs: Vm 01708/5137

Cardboard box with 1 or 3 blister strips, 30 tablets per strip, equivalent to 30 or 90 tablets.
Cardboard box with HDPE plastic bottle containing 30 or 90 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:
MSD Animal Health UK Limited
Walton Manor, Walton
Milton Keynes
MK7 7AJ, UK
Tel.: +44 (0)1908 685685

Manufacturers responsible for batch release:
Intervet GesmbH
Siemensstrasse 107
1210 Vienna
Austria

17. Other information

POM-V

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

Inhibition of JAK1 enzyme activity leads to a reduction of inflammation-associated white blood cell counts (mean absolute counts were within the reference range in field trials). 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.

Gavin Hall

Approved: 23 February 2026