

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Numelvi 4.8 mg tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:

Atinvcitinib 4.8 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 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 in dogs.

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

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. 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.

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.
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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 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.

3.8 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 3.5 of the SPC (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 atinivicitinib (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.

3.9 Administration routes and dosage

Oral use.

The veterinary medicinal product should be administered once daily at the recommended dose of 0.8 to 1.2 mg atinivicitinib/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 atinivicitinib 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 atinicitinib/kg bodyweight (see SPC section 3.5). 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.

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

For atinicitinib, 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.

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

Atinicitinib is a selective Janus kinase (JAK) inhibitor, highly selective for JAK1. It inhibits the function of a variety of cytokines involved in pruritus 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). Atinicitinib did not lead to immunosuppressive effects at the target dose. Atinicitinib 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 defence that are dependent on JAK2 or the other JAK family members.

4.3 Pharmacokinetics

Following oral administration, atinivicitinib 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 atinivicitinib after administration once daily for four days was approximately 65%. Bioavailability was higher in fed dogs.

Total atinivicitinib 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 1.65 L/kg bodyweight. Following oral administration, the terminal half-life ($t_{1/2}$) was 2 hours.

In a six-month study conducted in dogs (see section 3.10), mild accumulation that was not considered clinically relevant was observed in some individuals; steady state was reached after 7 weeks.

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

Atinivicitinib is metabolised in the dog to multiple metabolites and, although the extent of any hepatic metabolism has not been definitively determined, its main clearance route is metabolism with excretion in the faeces. Renal elimination, with excretion in the urine, is considered a minor route.

Dogs with hepatic impairment were not excluded from the clinical field trials conducted with this veterinary medicinal product. However, it was not specifically tested in patients with confirmed hepatic impairment and any impact of hepatic impairment on the pharmacokinetics of atinivicitinib remains uncertain.

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.
Cardboard box with 1 or 3 blister strips equivalent to 30 or 90 tablets.
Cardboard box with HDPE bottle 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.

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

MSD Animal Health UK Limited

7. MARKETING AUTHORISATION NUMBER

Vm 01708/5134

8. DATE OF FIRST AUTHORISATION

20 January 2026

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

January 2026

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: 23 February 2026