PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Cardboard carton}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Atopease 3.6 mg film-coated tablets for dogs

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

3.6 mg oclacitinib per tablet (as oclacitinib maleate).

3. PACKAGE SIZE

100 tablets.

4. TARGET SPECIES

Dogs

5. INDICATION(S)

-

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

-

8. EXPIRY DATE

EXP {month/year}

9. SPECIAL STORAGE PRECAUTIONS

Store below 25°C.
Any remaining half tablet should be placed back in the opened blister and stored in the original cardboard carton (for a maximum of 3 days).

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 AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

14. MARKETING AUTHORISATION NUMBERS

Vm 42058/5093

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

-

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V

To be supplied only on veterinary prescription.

MINIMUM PARTICULARS TO APPEAR ON BLISTERS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Atopease 3.6 mg tablets for dogs

oclacitinib

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

3.6 mg tablets

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

EXP {month/year}

5. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis

6. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only

PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Atopease 3.6 mg film-coated tablets for dogs
Atopease 5.4 mg film-coated tablets for dogs
Atopease 16 mg film-coated tablets for dogs

2. COMPOSITION

Each film-coated tablet contains 3.6 mg, 5.4 mg or 16 mg oclacitinib (as oclacitinib maleate).

White to off-white, oblong shaped film-coated tablets with a score-line on both sides and marked with the letters "AQ" and "S", "M" or "L" on both sides. The letters "S", "M" and "L" refer to the different strengths of tablets: "S" is on the 3.6 mg tablets, "M" on the 5.4 mg tablets, and "L" on the 16 mg tablets.

The tablets can be divided into 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 cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in dogs less than 12 months of age or less than 3 kg bodyweight.
Do not use in dogs with evidence of immune suppression, such as hyperadrenocorticism, or with evidence of progressive malignant neoplasia as the active substance has not been evaluated in these cases.

6. SPECIAL WARNING(S)

For animal treatment only.

Special precautions for safe use in the target species:
Oclacitinib modulates the immune system and may increase susceptibility to infection and exacerbate neoplastic conditions. Dogs receiving Atopease tablets should therefore be monitored for the development of infections and neoplasia.

When treating pruritus associated with allergic dermatitis with oclacitinib, 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).

Given the potential for effects on certain clinicopathological parameters (see section 7), periodic monitoring with complete blood counts and serum biochemistry is recommended when dogs are on long-term treatment.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Wash hands after administration.

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

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation, or in breeding male dogs, therefore its use is not recommended during pregnancy, lactation or in dogs intended for breeding.

Interaction with other medicinal products and other forms of interaction:
No drug interactions were observed in field studies where oclacitinib was administered concomitantly with veterinary medicinal products such as endo- and ectoparasiticides, antimicrobials and anti-inflammatories.

The impact of oclacitinib administration on vaccination with modified live vaccines, canine parvovirus (CPV), canine distemper virus (CDV) and canine parainfluenza (CPI) and inactivated rabies vaccine (RV), on 16 week old vaccine naïve puppies has been studied. An adequate immune response (serology) to CDV and CPV vaccination was achieved when puppies were administered oclacitinib at 1.8 mg/kg bodyweight (bw) twice daily for 84 days. However, the findings of this study indicated a reduction in serological response to vaccination with CPI and RV in puppies being treated with oclacitinib compared to untreated controls. The clinical relevance of these observed effects for animals vaccinated while being administered oclacitinib (in accordance with the recommended dosing regimen) is unclear.

Overdose:
Oclacitinib tablets were administered to healthy, one year old Beagle dogs twice daily for 6 weeks, followed by once per day for 20 weeks, at 0.6 mg/kg bw, 1.8 mg/kg bw and 3.0 mg/kg bw for a total of 26 weeks. Clinical observations that were considered likely to be related to oclacitinib treatment included: alopecia (local), papilloma, dermatitis, erythema, abrasions and scabbing/crusts, interdigital "cysts", and oedema of the feet.

Dermatitis lesions were mostly secondary to the development of interdigital furunculosis on one or more feet during the study with the number and frequency of observations increasing with increasing dose. Lymphadenopathy of peripheral nodes

was noted in all groups, increasing in frequency with increasing dose, and was frequently associated with interdigital furunculosis.

Papilloma was considered treatment related, but not dose related.

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

7. ADVERSE EVENTS

The common adverse reactions seen up to day 16 of the field trials are listed in the following table:

	Adverse reactions observed in atopic dermatitis study up to day 16		Adverse reactions observed in pruritus study up to day 7	
	Atopease (n=152)	Placebo (n=147)	Atopease (n=216)	Placebo (n=220)
Diarrhoea	4.6%	3.4%	2.3%	0.9%
Vomiting	3.9%	4.1%	2.3%	1.8%
Anorexia	2.6%	0%	1.4%	0%
New cutaneous or subcutaneous lumps	2.6%	2.7%	1.0%	0%
Lethargy	2.0%	1.4%	1.8%	1.4%
Polydipsia	0.7%	1.4%	1.4%	0%

After day 16, the following adverse reactions have been observed:
- pyoderma and non-specified dermal lumps have been observed very commonly;
- otitis, vomiting, diarrhoea, histiocytoma, cystitis, yeast skin infections, pododermatitis, lipoma, polydipsia, lymphadenopathy, nausea, increased appetite and aggression have been observed commonly.

Treatment-related clinical pathology changes were restricted to an increase in mean serum cholesterol and a decrease in mean leukocyte count, however, all mean values remained within the laboratory reference range. The decrease in mean leukocyte count observed in oclacitinib-treated dogs was not progressive, and affected all white blood cell counts (neutrophil, eosinophil and monocyte counts) except lymphocyte counts. Neither of these clinical pathology changes appeared clinically significant.

The development of papillomas was noted in a number of dogs in a laboratory study.

Anaemia and lymphoma have been reported very rarely in spontaneous reports.

Regarding susceptibility to infection and neoplastic conditions, see section 6.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))

- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For oral use.

Dosage and treatment schedule:

The recommended initial dose of Atopease tablets to be given to the dog is to achieve 0.4 to 0.6 mg oclacitinib/kg bodyweight, administered orally, twice daily for up to 14 days.

For maintenance therapy (after the initial 14 days of treatment), the same dose (0.4 to 0.6 mg oclacitinib/kg bodyweight) should then be administered only once a day. The requirement for long-term maintenance therapy should be based on an individual benefit-risk assessment by the responsible veterinarian.

These tablets can be administered with or without food.

Please see dosing table below for the number of tablets required to achieve the recommended dose. The tablets are breakable along the score line.

Bodyweight (kg) of dog	**Strength and number of tablets to be administered:**		
	Atopease 3.6 mg tablets	**Atopease 5.4 mg tablets**	**Atopease 16 mg tablets**
3.0–4.4	½		
4.5–5.9		½	
6.0–8.9	1		
9.0–13.4		1	
13.5–19.9			½
20.0–26.9		2	
27.0–39.9			1
40.0–54.9			1½
55.0–80.0			2

9. ADVICE ON CORRECT ADMINISTRATION

Dogs should be carefully observed following administration to ensure that each tablet is swallowed.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store below 25°C.
Any remaining half tablet should be placed back in the opened blister and stored in the original cardboard carton (for a maximum of 3 days).
Do not use this veterinary medicinal product after the expiry date which is stated on the blister after EXP.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

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

Ask your veterinary surgeon how to dispose of medicines no longer required. 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

Atopease 3.6 mg x 100 tablets	Vm 42058/5093
Atopease 5.4 mg x 100 tablets	Vm 42058/5094
Atopease 16 mg x 100 tablets	Vm 42058/5095

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

Find more product information by searching for the ‘Product Information Database’ or ‘PID’ on www.gov.uk.

16. CONTACT DETAILS

To include: Name and address of the marketing authorisation holder and of the manufacturing authorisation holder responsible for batch release, if different

Marketing authorisation holder:
Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

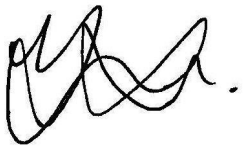
Manufacturer responsible for batch release:
Pfizer Italia S.R.L.
Via del Commercio 25/27
63100 Marino Del Tronto (AP)
Italy

or

Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-la-Neuve
BELGIUM

17. OTHER INFORMATION

Oclacitinib is a Janus kinase (JAK) inhibitor. It can inhibit the function of a variety of cytokines dependent on JAK enzyme activity. For oclacitinib, the target cytokines are those that are proinflammatory or have a role in allergic responses/pruritis. However, oclacitinib may also exert effects on other cytokines (for example, those involved in host defence or haematopoiesis) with the potential for unwanted effects.



Approved: 10 January 2023