PARTICULARS TO APPEAR ON THE OUTER PACKAGE {CARDBOARD CARTON}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Apoquel 16 mg chewable tablets.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

16 mg oclacitinib per tablet (as oclacitinib maleate).

3. PACKAGE SIZE

20 tablets
50 tablets
100 tablets

4. TARGET SPECIES

Dogs.

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Store in the original package in order to protect from moisture.
Remaining tablet parts should be stored in the blister and be given 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 AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

14. MARKETING AUTHORISATION NUMBER

Vm 42058/5002

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

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

Disposal: read the package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

[Distribution category]

POM-V

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS {BLISTER}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Apoquel chewable tablets.

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

16 mg oclacitinib

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

5. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited

6. THE WORDS “FOR ANIMAL TREATMENT ONLY”

PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Apoquel 3.6 mg chewable tablets for dogs
Apoquel 5.4 mg chewable tablets for dogs
Apoquel 16 mg chewable tablets for dogs

2. COMPOSITION

Each chewable tablet contains:

Active substance:
3.6 mg, 5.4 mg or 16 mg oclacitinib (as oclacitinib maleate).

Light to dark brown pentagon shaped mottled chewable tablets with score lines on both sides. The tablets are debossed with the corresponding strength (“S S” for 3.6 mg, “M M” for 5.4 mg and “L L” for 16 mg).

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 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)

Special warnings:
None.

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 the veterinary medicinal

product 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 “Adverse events”), periodic monitoring with complete blood counts and serum biochemistry is recommended when dogs are on long-term treatment.

The tablets are flavoured. In order to avoid accidental ingestion, store tablets in a safe place out of reach of animals.

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 the label to the physician.

Ingestion of this product may be harmful for children. To avoid accidental ingestion, administer the tablet(s) to the dog immediately after removal from the blister packaging.

Special precautions for the protection of the environment:
Not applicable.

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 naive 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.

Special restrictions for use and special conditions for use:
Not applicable.

Major incompatibilities:
Not applicable.

7. ADVERSE EVENTS

Dogs:

Very common (>1 animal / 10 animals treated):
pyoderma, skin lump, papilloma
Common (1 to 10 animals / 100 animals treated):
lethargy, lipoma, polydipsia, increased appetite nausea, vomiting, diarrhoea, anorexia histiocytoma, fungal skin infection, pododermatitis otitis lymphadenopathy cystitis aggression
Very rare (<1 animal / 10,000 animals treated, including isolated reports):
anaemia, lymphoma, convulsion

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.

Regarding susceptibility to infection and neoplastic conditions, see section 6 “Special warnings”.

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.

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

For oral use.

The recommended initial dose of Apoquel 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.

Apoquel tablets are chewable, palatable and readily consumed by the majority of dogs.

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:		
	Apoquel 3.6 mg tablets	Apoquel 5.4 mg tablets	Apoquel 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
20.0–22.7*	½		½
22.8–26.7*		½	½
26.8–39.9			1
40.0–54.9			1½
55.0–80.0			2

*Alternatively, two 5.4 mg tablets can be administered.

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 in the original package in order to protect from moisture.
Remaining tablet parts should be stored in the blister and be given at the next administration.
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.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 42058/5000
Vm 42058/5001
Vm 42058/5002

Aluminium/PVC/Aclar blisters (each strip containing 10 chewable tablets) packed into an outer cardboard box. Pack sizes of 20, 50 or 100 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:
Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP
Tel: +44 (0) 345 300 8034

Manufacturer responsible for batch release:
Zoetis Belgium
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 13 May 2026
Gavin Hall