ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains:

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

Excipients:

Qualitative composition of excipients and other constituents
Tablet core:
Cellulose, microcrystalline
Lactose monohydrate
Magnesium stearate
Sodium starch glycolate
Tablet coating:
Lactose monohydrate
Hypromellose (E464)
Titanium dioxide (E171)
Macrogol 400 (E1521)

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 equal halves.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

Treatment of pruritus associated with allergic dermatitis in dogs.
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.
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.

3.4 Special warnings

None.

3.5 Special precautions for use

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 3.6 "Adverse events"), 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 the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

3.6 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

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 3.5 "Special precautions for use".

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 its local representative or the national competent authority via the national reporting system. See also section "Contact details" of the package leaflet.

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 male dogs, therefore its use is not recommended during pregnancy, lactation or in dogs intended for breeding.

3.8 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.

3.9 Administration routes and dosage

For oral use.

The recommended initial dose is 0.4 to 0.6 mg oclacitinib/kg bodyweight, administered orally, twice daily for up to 14 days.

For maintenance therapy, 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.

These tablets can be administered with or without food.

The dosing table below shows the number of tablets required. The tablets are breakable along the score line.

Bodyweight (kg) of dog	**Strength and number of tablets to be administered:**		
	Prolevare 3.6 mg tablets	**Prolevare 5.4 mg tablets**	**Prolevare 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

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

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.

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: QD11AH90.

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

Following oral administration in dogs, oclacitinib maleate is rapidly and well absorbed, with a time to peak plasma concentration (t_{max}) of less than 1 hour. The absolute bioavailability of oclacitinib maleate was 89%. The prandial state of the dog does not significantly affect the rate or extent of its absorption.

Total body oclacitinib clearance from plasma was low – 316 ml/h/kg bodyweight (5.3 ml/min/kg bodyweight), and the apparent volume of distribution at steady-state was 942 ml/kg bodyweight. Following intravenous and oral administration, the terminal $t_{1/2}$s were similar at 3.5 and 4.1 hours respectively. Oclacitinib exhibits low protein binding with 66.3% to 69.7% bound in fortified canine plasma at nominal concentrations ranging from 10 to 1,000 ng/ml.

Oclacitinib is metabolised in the dog to multiple metabolites. One major oxidative metabolite was identified in plasma and urine.

Overall the major clearance route is metabolism, with minor contributions from renal and biliary elimination. Inhibition of canine cytochrome P450s is minimal with IC_{50}s 50-fold greater than the observed mean C_{max} (333 ng/ml or 0.997 µM) following 0.6 mg/kg bw oral administration in the target animal safety study. Therefore, the risk of metabolic drug-drug interactions due to oclacitinib inhibition is very low. No accumulation was observed in the blood of dogs treated for 6 months with oclacitinib.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale in blisters: 2 years.
Any remaining half tablets should be discarded after 3 days.

5.3 Special precautions for storage

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).

5.4 Nature and composition of immediate packaging

All tablets strengths are packaged in either aluminium/PVC/Aclar or aluminium/PVC/PVDC blisters (each strip containing 10 film-coated tablets) packed into an outer cardboard box. Pack sizes of 100 tablets.

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

Zoetis Belgium

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/23/295/001–006

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 24 April 2023

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

None.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD CARTON FOR BLISTER

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prolevare 3.6 mg film-coated tablets.
Prolevare 5.4 mg film-coated tablets.
Prolevare 16 mg film-coated tablets.

2. STATEMENT OF ACTIVE SUBSTANCES

3.6 mg oclacitinib per tablet (as oclacitinib maleate).
5.4 mg oclacitinib per tablet (as oclacitinib maleate).
16 mg oclacitinib per tablet (as oclacitinib maleate).

3. PACKAGE SIZE

100 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

Store below 25 °C.
Any remaining half tablet should be stored in the blister and discarded if not used within 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 OF THE MARKETING AUTHORISATION HOLDER

Zoetis Belgium

14. MARKETING AUTHORISATION NUMBERS

EU/2/23/295/001 (10 x 10 tablets, 3.6 mg)
EU/2/23/295/002 (10 x 10 tablets, 3.6 mg)
EU/2/23/295/003 (10 x 10 tablets, 5.4 mg)
EU/2/23/295/004 (10 x 10 tablets, 5.4 mg)
EU/2/23/295/005 (10 x 10 tablets, 16 mg)
EU/2/23/295/006 (10 x 10 tablets, 16 mg)

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

BLISTER

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prolevare film-coated tablets.

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

3.6 mg
5.4 mg
16 mg
oclacitinib

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

Each film-coated tablet contains:

Active substance:
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 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 warnings

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.

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.

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

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 or the local representative of 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.

The recommended initial dose of Prolevare 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:		
	Prolevare 3.6 mg tablets	Prolevare 5.4 mg tablets	Prolevare 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 periods

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.

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 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

EU/2/23/295/001–006

All tablets strengths are packaged in either aluminium/PVC/Aclar or aluminium/PVC/PVDC blisters (each strip containing 10 film-coated tablets) packed into an outer cardboard box. Pack sizes of 100 tablets.

15. Date on which the package leaflet was last revised

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:
Zoetis Belgium
Rue Laid Burniat 1
1348 Louvain-La-Neuve
Belgium

Manufacturer responsible for batch release:
Pfizer Italia S.r.l.
Viale Del Commercio 25/27
Ascoli Piceno
63100
Italy

or

Zoetis Belgium
Rue Laid Burniat 1
1348 Louvain-La-Neuve
Belgium

Local representatives and contact details to report suspected adverse reactions:

België/Belgique/Belgien
Zoetis Belgium
Mercuriusstraat 20
BE-1930 Zaventem
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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.