

Skyloalm[®] film-coated tablets for dogs

PRESENTATION

Skyloalm tablets contain 3.6, 5.4 or 16 mg oclacitinib (as oclacitinib maleate). Each tablet is marked with “AQ” on one side, with “S”, “M” or “L” on the other side referring to the tablet strengths.

USES

Indicated for the treatment of pruritus associated with allergic dermatitis and the clinical manifestations of atopic dermatitis in dogs.

DOSAGE AND ADMINISTRATION

For oral use.

Dosage and treatment schedule:

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.

Skyloalm 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	Number and strength of tablets to be administered. Initial dose (twice daily) / Maintenance therapy (once daily)		
	3.6 mg	5.4 mg	16 mg
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			1 ½
55.0 – 80.0			2

CONTRA-INDICATIONS, WARNINGS, ETC

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.

The safety of Skyloalm 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.

Oclacitinib modulates the immune system and may increase susceptibility to infection and exacerbate neoplastic conditions. Dogs receiving Skyloalm 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 below), periodic monitoring with complete blood counts and serum biochemistry is recommended when dogs are on long-term treatment.

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.

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.

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 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.

Oclacitinib tablets were administered to healthy, one year old Beagle dogs twice daily for 6 weeks, followed by once daily 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 increased with increasing dose. Lymphadenopathy of peripheral nodes was noted in all groups, increasing in frequency with increased 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.

User warnings:

Wash hands after administration.

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

PHARMACEUTICAL PRECAUTIONS

Store below 25 °C.

Any remaining half tablet should be placed back in the opened blister and stored in the original cardboard carton or in the HDPE bottle (for a maximum of 3 days).

Do not use after the expiry date which is stated on the blister or carton.

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

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

Keep out of the sight and reach of children.

For animal treatment only.

LEGAL CATEGORY

POM-V

PACKAGING QUANTITIES

Supplied in blister strips (each strip containing 10 film-coated tablets) or HDPE plastic bottles. Pack sizes of 20, 50 or 100 tablets. Not all pack sizes may be marketed.

FURTHER 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.

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%.

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 half-lives were similar at 3.5 and 4.1 hours respectively. Oclacitinib exhibits low protein binding.

Overall the major clearance route is metabolism, with minor contributions from renal and biliary elimination. Inhibition of canine cytochrome P450s is minimal. 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.

MARKETING AUTHORISATION NUMBER

UK(GB): Vm 42058/5096-5098