



EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

PRUBAN

EPAR summary for the public

This document is a summary of the European Public Assessment Report. Its purpose is to explain how the assessment done by the Committee for Medicinal Products for Veterinary Use (CVMP) on the basis of the documentation provided, led to the recommendations on the conditions of use. This document cannot replace a face-to-face discussion with your veterinarian. If you need more information about your animal's medical condition or treatment, contact your veterinarian. If you want more information on the basis of the CVMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is Pruban?

Pruban is a white to off-white cream containing resocortol butyrate as the active substance. Resocortol butyrate is a corticosteroid.

What is Pruban used for?

Pruban is applied to the skin for the treatment of small areas of sudden onset moist irritated skin (acute moist dermatitis in dogs). The cream should be applied to the area twice daily for 7-14 days. For details on dosing, please see the Package Leaflet.

How does Pruban work?

Most cases of acute moist dermatitis are due to complications of flea bite hypersensitivity, although they may also be caused by other ectoparasites, allergic skin diseases, anal sac problems or foreign bodies (such as grass awns). Once the skin is irritated, an itch-scratch cycle starts and this may lead to lesions that are quite severe in appearance within a few hours. Resocortol butyrate belongs to the group of glucocorticosteroids which have anti-inflammatory effects. Pruban reduces the inflammation of the skin locally.

How has Pruban been studied?

Several studies were performed in rats, rabbits and dogs to examine the safety of Pruban. A trial in humans had also been conducted. The trial showed low level irritation, but no toxicity. The results of these studies are reflected in the contraindications.

What benefit has Pruban shown during the studies?

In the studies of dogs suffering from acute moist dermatitis almost 80% of cases were cured or improved following treatment for 7 to 14 days.

What is the risk associated with Pruban?

Pruban should not be used in dogs with extensive, infected or ulcerated skin lesions or in animals suffering from Cushing's syndrome (hyperadrenocorticism).

Pruban should not be used in puppies under 6 months of age. Since glucocorticosteroids can slow growth, the use of the product in young, growing animals should be well controlled and large lesions should not be treated.

Lesions should be monitored closely for signs of infection. In case of diabetes mellitus, the potential systemic effects of the product may influence blood glucose concentrations.

On rare occasions, hyperaemia of the treated area has been observed. Do not use in dogs for breeding or in pregnant or lactating bitches.

What are the precautions for the person who gives the medicine or comes into contact with the animal?

The therapeutic use of these substances in humans has been recognised to induce local side effects such as skin thinning, skin weakness, delayed healing and secondary infections.

Why has Pruban been approved?

The Committee for Medicinal Products for Veterinary Use (CVMP) concluded that the benefits of Pruban exceeded the risks for the treatment of acute localised moist dermatitis in dogs, and recommended that Pruban be granted a market authorisation.

Other information about Pruban:

The European Commission granted a marketing authorisation valid throughout the European Union, for Pruban to Intervet International B.V. on 16 November 2000. The authorisation was subsequently renewed. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated in August 2008.