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EPAR summary for the public

Panretin
alitretinoin

This document is a summary of the European public assessment report (EPAR) for Panretin. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Panretin.

What is Panretin?

Panretin is a gel that contains the active substance alitretinoin.

What is Panretin used for?

Panretin gel is used to treat the skin lesions seen in patients with Kaposi’s sarcoma (a type of skin cancer) in AIDS patients. Panretin is used when:

- the skin is not broken and the lesions are not swollen,
- the lesions have not responded to HIV treatment,
- other treatments (radiotherapy or chemotherapy) are not suitable, and
- treatment for visceral (internal) Kaposi’s sarcoma is not needed.

The medicine can only be obtained with a prescription.

How is Panretin used?

Panretin treatment should be started and maintained by a doctor with experience in treating Kaposi’s sarcoma. Panretin is applied twice a day to the skin lesions, using enough gel to cover each lesion with a generous coating and then leaving it to dry for three to five minutes before covering with clothing. Healthy skin around the lesion should be avoided. Depending on each lesion’s response to treatment,
the number of applications can be increased to three or four times a day. Panretin should be used for up to 12 weeks. It may be used after this period but only on lesions that are responding to treatment.

**How does Panretin work?**

The active substance in Panretin, alitretinoin, is an anticancer agent that belongs to the group ‘retinoids’, substances that are derived from vitamin A. The exact way alitretinoin works in Kaposi’s sarcoma is unknown.

**How has Panretin been studied?**

Panretin was compared with placebo (a dummy treatment) in two 12-week studies involving a total of 402 patients with Kaposi’s sarcoma. The main measure of effectiveness was the proportion of patients who responded to treatment. A patient was considered to have responded to treatment if their lesions reduced in area or flattened by a certain amount depending on the type of lesions.

**What benefit has Panretin shown during the studies?**

Panretin was more effective than placebo at treating Kaposi’s sarcoma. Around 35% and 37% of the patients using Panretin responded to treatment compared with 18% and 7% of the patients using placebo.

**What is the risk associated with Panretin?**

The most common side effects with Panretin (seen in more than 1 patient in 10) are rash, pruritus (itching), skin disorders (cracking, scabbing, crusting, draining, oozing) and pain (burning, soreness). For the full list of all side effects reported with Panretin, see the package leaflet.

Panretin should not be used in people who may be hypersensitive (allergic) to retinoids in general, alitretinoin, or any of the other ingredients. Panretin must also not be used in women who are pregnant or breast-feeding and must not be used to treat lesions that are close to other skin disorders.

**Why has Panretin been approved?**

The CHMP decided that Panretin’s benefits are greater than its risks and recommended that it be given marketing authorisation.

**Other information about Panretin:**

The European Commission granted a marketing authorisation valid throughout the European Union for Panretin on 11 October 2000. The marketing authorisation holder is Eisai Ltd. The marketing authorisation is valid for an unlimited period.

The full EPAR for Panretin can be found [here](#). For more information about treatment with Panretin, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 08-2010.