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Panretin (*alitretinoin*)

An overview of Panretin and why it is authorised in the EU

What is Panretin and what is it used for?

Panretin is a medicine used to treat the skin lesions seen in AIDS patients with Kaposi's sarcoma (a type of skin cancer). 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.

How is Panretin used?

Panretin can only be obtained with a prescription and treatment should be started and maintained by a doctor with experience in treating Kaposi's sarcoma. Panretin is available as a gel to be applied to the skin lesions twice a day, 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.

For more information about using Panretin, see the package leaflet or contact a doctor or pharmacist.

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.

What benefits of Panretin have been shown in studies?

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

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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.

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 are the risks associated with Panretin?

The most common side effects with Panretin (which may affect 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 must 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 who are planning a pregnancy, or who are breast-feeding. It must not be used to treat lesions that are close to areas affected by other skin disorders.

Why is Panretin authorised in the EU?

The European Medicines Agency decided that Panretin's benefits are greater than its risks and recommended that it be given marketing authorisation.

What measures are being taken to ensure the safe use of Panretin?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Panretin have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Panretin are continuously monitored. Side effects reported with Panretin are carefully evaluated and any necessary action taken to protect patients.

Other information about Panretin

Panretin received a marketing authorisation valid throughout the EU on 11 October 2000. The marketing authorisation holder is Eisai Ltd.

Further information on Panretin can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports.

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