EMA/234177/2018
EMEA/H/C/000326

Targretin (*bexarotene*)

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

What is Targretin and what is it used for?

Targretin is a cancer medicine used for the treatment of the visible signs on the skin of cutaneous T-cell lymphoma (CTCL). CTCL is a rare type of lymphoma (cancer of the lymph tissue) where some white blood cells (T-cells) grow in the skin. Targretin is used in patients who have an advanced disease and have had at least one other treatment.

How is Targretin used?

Targretin can only be obtained with a prescription and treatment should only be initiated and maintained by a doctor who has experience in the treatment of patients with CTCL.

Targretin is available as capsules (75 mg). The dose of Targretin is based on the patient's body surface area in square metres (m^2). The recommended starting dose is 300 mg/m^2/day, taken as a single dose once a day with a meal. The dose is adjusted depending on the patient's response to treatment or side effects. Treatment should continue as long as the patient benefits from it.

For more information about using Targretin, see the package leaflet or contact your doctor or pharmacist.

How does Targretin work?

The active substance in Targretin, bexarotene, belongs to the group of retinoids, substances that are derived from vitamin A. The exact way bexarotene works in CTCL is not known.

What benefit of Targretin have been shown in studies?

The effectiveness of Targretin has been examined in two studies involving a total of 193 patients with CTCL who received at least two previous treatments. Targretin was not compared with another medicine. Ninety-three of these patients had advanced disease that had not responded to other treatment. Sixty-one patients were treated at the starting dose of 300 mg/m^2/day. The main measure of effectiveness was the response to treatment after 16 weeks. This was measured by the doctor's

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

grading of improvement, as well as by a score of 5 clinical signs (area of skin affected, redness, raised areas, scale-like skin and colour).

Across the two studies, among the patients who received 300 mg/m^2, about half of them responded to treatment, according the doctor's grading. The response rates according to the 5 skin scores were 36% and 27%, respectively.

What are the risks associated with Targretin?

The most common side effects with Targretin (which may affect more than 1 patient in 10) are leucopenia (reduced white cell count), hypothyroidism (underactive thyroid gland), hyperlipaemia (high levels of fats in the blood), hypercholesterolaemia (high blood cholesterol), exfoliative dermatitis (skin peeling), pruritus (itching), rash, pain, headache and weakness. For the full list of side effects reported with Targretin, see the package leaflet.

Targretin must not be used in women who are pregnant or breast-feeding, or women who could become pregnant and who are not using effective contraception; patients who have had pancreatitis (inflammation of the pancreas); patients with uncontrolled hypercholesterolaemia (high blood cholesterol), hypertriglyceridaemia (high blood triglycerides [fat]) or thyroid disease; patients with hypervitaminosis A (high levels of vitamin A); patients with liver disease; patients with an ongoing body infection. For the full list of restrictions, see the package leaflet.

Why is Targretin authorised in the EU?

The European Medicines Agency decided that Targretin's benefits are greater than its risks for the treatment of the skin manifestations of advanced-stage CTCL patients refractory to at least one treatment. The Agency recommended that Targretin be given marketing authorisation.

What measures are being taken to ensure the safe and effective use of Targretin?

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

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

Other information about Targretin

Targretin received a marketing authorisation valid throughout the EU on 29 March 2001.

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

This overview was last updated in 04-2018.