EMA/337501/2017
EMEA/H/C/002157

EPAR summary for the public

Skilarence

dimethyl fumarate

This is a summary of the European public assessment report (EPAR) for Skilarence. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Skilarence.

For practical information about using Skilarence, patients should read the package leaflet or contact their doctor or pharmacist.

What is Skilarence and what is it used for?

Skilarence is a medicine used to treat plaque psoriasis, a disease that causes thickened, red and inflamed areas of skin with scaly patches. It is used in patients with moderate or severe disease for whom treatments applied direct to the skin do not work well enough.

Skilarence contains the active substance dimethyl fumarate.

How is Skilarence used?

Skilarence can only be obtained with a prescription and it should be used under the supervision of a doctor who has experience in diagnosing and treating psoriasis.

Skilarence is available as tablets (30 and 120 mg). The starting dose is 30 mg once a day and the dose is increased every week according to the schedule shown in the package leaflet until the psoriasis starts improving or until the patient is taking the maximum dose of 240 mg three times a day. Tablets should be swallowed whole during or immediately after a meal. The doctor may reduce the dose when the psoriasis has been brought under control.

For further information, see the package leaflet.

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

How does Skilarence work?

Psoriasis results from over-activity of the body's immune (defence) system. The active substance in Skilarence, dimethyl fumarate, reduces the activity of the immune system. It is thought to act on T cells (a type of white blood cell that forms part of the immune system) to prevent the cells from producing substances that cause inflammation and lead to psoriasis.

What benefits of Skilarence have been shown in studies?

A main study involving 704 patients with moderate to severe plaque psoriasis found that Skilarence was more effective than placebo (dummy treatment) at treating the disease and as effective as Fumaderm (a psoriasis medicine that contains dimethyl fumarate and monoethyl fumarate). The main measure of effectiveness was the proportion of patients who achieved a 75% reduction in their score for disease severity. After 16 weeks of treatment, 37% of patients taking Skilarence achieved this reduction, compared with 15% taking placebo and 40% taking Fumaderm .

What are the risks associated with Skilarence?

The most common side effects with Skilarence (which may affect more than 1 in 10 people) are effects on the digestive system (diarrhoea, bloating, belly ache and nausea), flushing (reddening of the skin) and low levels of lymphocytes (type of white blood cells) or of white blood cells in general. For the full list of all side effects reported with Skilarence, see the package leaflet.

Skilarence must not be used in patients who have severe problems of the digestive system, liver or kidneys. It must also not be used by women during pregnancy or if breast-feeding.

Why is Skilarence approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Skilarence's benefits are greater than its risks and recommended that it be approved for use in the EU. The CHMP considered that the main study has shown Skilarence's short-term effectiveness, and published studies with similar medicines show that the effectiveness is maintained with continued use. Most side effects are mild or moderate. Because Skilarence reduces the activity of the immune system, there is a risk of serious infections, including progressive multifocal leukoencephalopathy (PML, a brain infection), but the risk can be minimised by regular tests for white blood cell counts and stopping treatment if necessary.

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

The company that markets Skilarence will supply educational materials to healthcare professionals about the risk of serious infections, including PML, and how to minimise this risk.

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

Other information about Skilarence

The European Commission granted a marketing authorisation valid throughout the European Union for Skilarence on 23 June 2017.

The full EPAR for Skilarence can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Skilarence, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 06-2017.