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EPAR summary for the public

Scenesse

afamelanotide

This is a summary of the European public assessment report (EPAR) for Scenesse. 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 Scenesse.

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

What is Scenesse and what is it used for?

Scenesse is an implant used to treat patients with erythropoietic protoporphyria (EPP), a rare disease that causes intolerance to light.

In patients with EPP, exposure to light can lead to symptoms such as pain and swelling of the skin, which prevent patients from being able to spend time outdoors or in places with bright light. Scenesse is used to help prevent or reduce these symptoms so that these patients can lead more normal lives.

Because the number of patients with EPP is low, the disease is considered 'rare', and Scenesse was designated an 'orphan medicine' (a medicine used in rare diseases) on 8 May 2008.

Scenesse contains the active substance afamelanotide.

How is Scenesse used?

Scenesse is only prescribed by specialist doctors in recognised centres for treating EPP and should only be used by doctors who have been properly trained.

One Scenesse implant is injected under the patient's skin once every 2 months, before and during periods of high sunlight exposure, e.g. from spring to autumn. The number of implants per year depends on how much protection from the sun is needed. Three implants per year are recommended;

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the maximum number is 4. Patients should be observed for allergic reactions for 30 minutes after the injection of each implant.

For more information on how to use Scenesse, see the summary of product characteristics (also part of the EPAR).

How does Scenesse work?

The active substance in Scenesse, afamelanotide, is similar to a hormone in the body known as alpha-melanocyte stimulating hormone, which stimulates the production of a brown-black pigment in the skin. This pigment, known as eumelanin, is produced during exposure to sunlight to block the penetration of light into cells.

Patients with EPP have high levels of a substance called protoporphyrin IX in the body. Protoporphyrin IX is phototoxic and, when exposed to light, causes the painful reactions seen with this condition. By stimulating the production of eumelanin in the skin, Scenesse reduces the penetration of light through the skin, thus helping to prevent the painful reactions.

What benefits of Scenesse have been shown in studies?

Scenesse has been shown in a study to lead to an increase in the amount of time patients can spend in sunlight. In the study, involving 93 patients with EPP, patients were treated with either Scenesse or a placebo (a dummy treatment) over a six-month period. Daily records of exposure to sunlight between 10 am and 6 pm showed that patients treated with Scenesse spent on average 116 hours in direct sunlight without experiencing pain during the six-month period compared with 61 hours for patients treated with placebo.

What are the risks associated with Scenesse?

The most common side effects seen in studies with Scenesse were nausea (feeling sick), headache and reactions at the implant site (such as discoloration, pain and redness). These affected around 1 in 5 patients and were generally mild in severity.

Scenesse must not be used in patients with reduced liver or kidney function. For the full list of all side effects and restrictions with Scenesse, see the package leaflet.

Why is Scenesse approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Scenesse's benefits are greater than its risks and recommended that it be given marketing authorisation. The CHMP noted that Scenesse led to an increase in the amount of time patients could spend in direct sunlight without experiencing pain. Although the additional time spent in sunlight was small, the Committee considered the possible improvements in quality of life, the unmet medical need in patients with EPP, and the mild side effects seen during short-term treatment with the medicine in deciding to recommend approval for Scenesse in the EU. The Committee also consulted individual patients and experts on their experience with Scenesse.

Scenesse has been authorised under 'exceptional circumstances'. This is because it has not been possible to obtain complete information about the benefits of Scenesse, in part due to the rarity of the disease. Every year, the European Medicines Agency will review any new information that becomes available and this summary will be updated as necessary.

What information is still awaited for Scenesse?

Since Scenesse has been approved under exceptional circumstances, the company that markets Scenesse will provide longer-tem data on the benefits and safety of the medicine from an EU registry of patients taking the medicine.

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

A risk management plan has been developed to ensure that Scenesse is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Scenesse, including information on the appropriate precautions to be followed by healthcare professionals and patients.

In addition, the company that markets Scenesse will ensure that doctors receive educational material and are trained in how to use the medicine. Doctors will also be given information on the EU registry.

Further information can be found in the summary of the risk management plan.

Other information about Scenesse

The European Commission granted a marketing authorisation valid throughout the European Union for Scenesse on 22 December 2014.

The full EPAR and risk management plan summary for Scenesse 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 Scenesse, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

The summary of the opinion of the Committee for Orphan Medicinal Products for Scenesse can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/Rare disease designation.

This summary was last updated in 12-2014.