Package leaflet: Information for the patient

SCENESSE 16 mg implant
afamelanotide

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What SCENESSE is and what it is used for
2. What you need to know before you receive SCENESSE
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1. What SCENESSE is and what it is used for

SCENESSE contains the active substance afamelanotide (as acetate). Afamelanotide is a synthetic form of a body hormone called alpha-melanocyte stimulating hormone (α-MSH). Afamelanotide works in a way similar to the natural hormone, by making skin cells produce eumelanin which is a brown-black type of melanin pigment in the body.

Afamelanotide is used to increase the tolerance to sunlight in adults with a confirmed diagnosis of erythropoietic protoporphyria (EPP). EPP is a condition in which patients have an increased sensitivity to sunlight, which can cause toxic effects such as pain and burning. By increasing the amount of eumelanin, SCENESSE can help to delay the onset of pain due to skin photosensitivity (sensitive to sunlight).

2. What you need to know before you receive SCENESSE

Do not use SCENESSE

- if you are allergic to afamelanotide or any of the other ingredients of this medicine (listed in section 6).
- if you have any severe condition of the liver.
- if you have liver problems.
- if you have kidney problems.

Warnings and precautions

Talk to your doctor before receiving SCENESSE if you have or have ever had:
- heart problems or severe breathing problems;
- gastrointestinal problems;
- diabetes;

- Cushing's disease (a hormone disorder where the body produces too much of the hormone cortisol);
- Addison's disease (a disorder of the adrenal glands causing a lack of some hormones);
- Peutz-Jeghers syndrome (a disorder that causes blockage of the bowel and where your hands, soles of your feet and surface of your lips may have brown freckles);
- epilepsy (or have been told that you are at risk of having fits);
- anaemia (low counts of red blood cells in your blood);
- melanoma (an aggressive type of skin cancer), including in-situ melanoma, e.g. lentigo maligna; or if you have certain inherited conditions that increase the risk of developing a melanoma;
- skin cancer of the types, basal cell carcinoma or squamous cell carcinoma (inclusive of carcinoma *in situ*, e.g. Bowen's disease), Merkel cell carcinoma or other malignant or premalignant skin problems.

Talk to your doctor before receiving SCENESSE if you are over 70 years of age.

If you have ever had any of these conditions your doctor may have to monitor you more closely during your treatment.

Sun protection

Do not change the sun protection measures you normally follow to manage your EPP and according to your skin phototype (UV sensitivity). Keep in mind that increased exposure to UV light will contribute to skin cancer development.

Skin monitoring

Because this medicine increases eumelanin, in most treated patients the skin will darken. This is an expected response to this medicine, and the darkening will slowly fade unless another implant is used.

Your doctor will need to regularly check your skin (full body) to monitor changes in moles (e.g. darkening) or other skin abnormalities. This is recommended to be performed every 6 months.

Please inform your doctor about new or changing skin abnormalities. Arrange for an early appointment with your porphyria specialist if pigmented lesions like moles grow or if other growing, non-healing, weeping, plaque-like, wart-like, or ulcerated lesions appear. A referral to a dermatology specialist might be necessary.

Children and adolescents

This medicine should not be given to children and adolescents under 18 years of age because it has not been tested in this age group.

Other medicines and SCENESSE

Tell your doctor if you are taking, have recently taken or might take any other medicines.

Tell your doctor if you are taking anticoagulant medicines used to prevent blood clots. These may include-warfarin, acetylsalicylic acid (a substance present in many medicines used to relieve pain and lower fever or to prevent blood clotting) and a group of medicines called non-steroidal anti-inflammatory drug (NSAIDs), used to treat common ailments, such as arthritis, headaches, mild fever, rheumatism and sore throats. This is because patients taking such medicines may experience increased bruising or bleeding at the site of the implant.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, you should not receive SCENESSE, since it is not known how it will affect your unborn baby or the breastfed infant.

Women who could become pregnant should use adequate contraception such as oral contraceptives, diaphragm plus spermicide, intrauterine device (also known as a coil) during treatment and for three months after the last SCENESSE implantation.

Driving and using machines

There is a risk of feeling drowsy and tired when using this medicine, especially within 72 hours of administration. If you are affected, do not drive or use any tools or machines. If you suffer from continued drowsiness, then you should speak to your doctor.

3. How to use SCENESSE

The implant will be inserted by a doctor who has been trained in the administration procedure. The doctor will decide with you the most suitable time and the site for inserting the implant.

One implant is injected every 2 months prior to expected and during increased sunlight exposure. The number of implants per year and the overall duration of treatment is decided by your specialist physician.

The implant is given as injection under your skin using a catheter tube and needle (subcutaneous use). Before inserting this medicine, your doctor may decide to give you a local anaesthetic to numb the area where the implant is to be inserted. The implant is inserted directly under the skin folds on your waist or abdomen in an area known as the supra-iliac crest.

At the end of the insertion procedure, you may be able to feel the implant under your skin. Over time the implant will be absorbed by the body, this will happen within 50 to 60 days after implantation.

If you experience discomfort and are concerned, speak to your doctor. The implant may be removed by a simple surgical procedure if needed.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects are considered to be:

Very common (may affect more than 1 in 10 people):
- nausea (feeling sick),
- headache.

Common (may affect up to 1 in 10 people):
- flu, upper respiratory tract infection (colds),
- general changes to the skin including darkening of freckles and moles,
- rash with small blisters, itch, rash, red rash, itchy rash,
- dizziness, drowsiness and migraine (severe headache),
- hot flushes, flushing, feeling hot and redness of the skin,
- abdominal (tummy) pain, toothache, diarrhoea and vomiting,
- pain in arms and legs, pain or weakness in muscles and bones, back pain,

- fatigue, pain, fever, reactions at the implant site including pain, bruising, swelling, bleeding, itching and changes to the colour of overlying skin, flu-like illness, cough, blocked nose, inflamed nose and throat.

Uncommon (may affect up to 1 in 100 people):
- urinary tract infection, infected hair follicle, infection in stomach and intestines,
- hypersensitivity and severe allergic reaction including anaphylaxis (signs may include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue)
- decreased or increased appetite,
- depressed mood including depression, inability to sleep, poor quality sleep,
- fainting, fainting sensation, weakness, inability to get legs comfortable, disturbance of balance,
- dry eye, eye pain, red eyes, difficulty focusing on objects, sensitivity in eyes to light, ringing in ears,
- palpitations, bruising, bleeding, hight blood pressure,
- blocked sinuses,
- inflamed stomach and intestines, heartburn, irritable bowel syndrome, wind, lip swelling, reduce sense of touch in the mouth, gum pain,
- acne, eczema, red swelling on skin, dry skin, hair colour changes, excessive sweating, pigmentation in nails, colouration on lip, skin peeling, skin burning sensation, changes to the colour of the skin including loss of colour, oily skin, hives,
- joint stiffness, stiffness of muscle and bones, sudden muscle contraction, sore muscle,
- breast tenderness, irregular period, painful period,
- chills, feeling hot, hangover, malaise, swelling in legs or hands,
- abnormal liver function tests, decreased iron binding, increased sugar level, decreased blood iron level, blood in urine,
- fall and wound,
- device expulsion.

Rare (may affect up to 1 in 1000 people):
- fungal infection,
- decrease white blood cells,
- increased cholesterol,
- confusion, headache following injury, abnormal taste sensation,
- swollen eye lids,
- fast heart rate,
- irregular bowel movements, inflamed lips, discoloured gums, lips and tongue,
- red or brownish nodules on the skin (called “Lichen planus”), vitiligo,
- heavy prolonged period, discharge from vagina, decreased sex drive,
- increase in body weight,
- wound complication, nausea following implant insertion.

Reporting of side effects
If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How SCENESSE is stored

Keep this medicine out of the sight and reach of children.

This medicine must not be used after the expiry date which is stated on the vial and the outer carton. Your doctor will check the expiry date before an implant is used.

Store in a refrigerator (2ºC - 8ºC).

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What SCENESSE contains

- The active substance is afamelanotide. One implant contains 16 mg of afamelanotide (as acetate).
- The other ingredient is poly (D,L-lactide-co-glycolide).

What SCENESSE looks like and contents of the pack

The implant is a solid white to off-white rod approximately 1.7 cm in length and 1.5 mm in diameter in an amber glass vial sealed with a PTFE coated rubber stopper.
Pack size of one vial containing one implant.

Marketing Authorisation Holder

CLINUVEL EUROPE LIMITED
10 Earlsfort Terrace
Dublin 2
D02 T380
Ireland
Tel: +353 1513 4932
mail@clinuvel.com

Manufacturer

CLINUVEL EUROPE LIMITED
Alexandra House
The Sweepstakes
Ballsbridge
Dublin 4
D04 C7H2
Ireland

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This medicine has been authorised under ‘exceptional circumstances’. This means that because of the rarity of this disease, for scientific reasons, and for ethical reasons it has been impossible to get complete information on this medicine.
The European Medicines Agency will review any new information on this medicine every year and this leaflet will be updated as necessary.

Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu. There are also links to other websites about rare diseases and treatments.

The following information is intended for healthcare professionals only:

Method of administration

SCENESSE is administered subcutaneously under aseptic conditions as described below. Administration should be performed by a physician trained and accredited by the marketing authorisation holder to administer the implant.

Instruction for use

- Take the packed implant out of the refrigerator and allow the medicinal product to warm up to ambient temperature.
- Have the patient sit in a comfortable position or lie on his/her back with the upper part of the body slightly raised.
- Disinfect the skin above the supra-iliac crest.
- Anaesthetize the insertion area if deemed necessary and in consultation with the patient.
- Select a 14 gauge (1.6 mm inner diameter) catheter with needle.
- Mark 1.5 to 2 cm on the catheter shaft using surgical ink.
- Hold the catheter at its base using a sterile technique, pinch and hold the skinfold cranial to, or overlying the patient's supra-iliac crest with two fingers.
- With the bevel of the needle facing upwards, insert the catheter laterally 1.5 to 2 cm into the subcutaneous layer at a 30 to 45 degree angle to the skin surface in one continuous flowing movement.
- With the catheter in place, aseptically remove the implant from the vial.
- Remove the needle from within the catheter using a sterile technique.
- Transfer the implant to the outlet of the catheter.
- Using a suitable device (such as a stylet) gently push the implant down the full length of the catheter lumen.
- Apply some pressure to the insertion area with your finger while removing the stylet and the catheter.
- Confirm insertion of the implant by palpating the skin with subcutis cranial to/overlying the suprailiac crest until the implant is located. Always verify the presence of the implant, if in doubt of its presence, check whether the implant has remained in the catheter. If the implant has not been administered during the procedural steps described above, discard the implant and administer a new implant. Do not administer a new implant unless it has been unequivocally confirmed that the first one had not been inserted.
- Apply a small pressure dressing to the injection site.
- Observe the patient for 30 minutes to ensure that you will notice if the patient develops an allergic or hypersensitivity reaction (immediate type).

The implant can be surgically removed if needed.