

Package leaflet: Information for the user

Bascellex 50 mg/g cream

imiquimod

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, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Bascellex is and what it is used for
2. What you need to know before you use Bascellex
3. How to use Bascellex
4. Possible side effects
5. How to store Bascellex
6. Contents of the pack and other information

1. What Bascellex is and what it is used for

Your doctor may prescribe Bascellex for the treatment of

- actinic keratosis.

Actinic keratoses are rough areas of skin found in people who have been exposed to a lot of sunshine over the course of their lifetime. Some are skin coloured, others are greyish, pink, red or brown. They can be flat and scaly, or raised, rough, hard and warty. Bascellex should only be used for flat actinic keratoses on the face and scalp in patients with a healthy immune system where your doctor has decided that Bascellex is the most appropriate treatment for you.

Bascellex helps your body's own immune system to produce natural substances which help fight your actinic keratosis.

2. What you need to know before you use Bascellex

Do not use Bascellex

- if you are allergic to imiquimod or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before using Bascellex:

- if you have previously used Bascellex or other similar preparations
- if you have problems with your immune system
- if you have an abnormal blood count
- Do not use Bascellex until the area to be treated has healed after previous drug or surgical treatment
- Avoid contact with the eyes, lips and nostrils. In the event of accidental contact, remove cream by rinsing with water
- Do not apply the cream internally
- Do not use more cream than your doctor has advised
- Do not cover the treated area with bandages or other dressings after you have applied Bascellex
- If the treated site becomes too uncomfortable, wash the cream off with mild soap and water. As soon as the problem has stopped you may restart to apply the cream

- Do not use sunlamps or tanning beds, and avoid sunlight as much as possible during treatment with Bascellex. Wear protective clothing and wide brimmed hats when outdoors.

Do not smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

Because of the way Bascellex works, there is a possibility that the cream may worsen existing inflammation in the treatment area.

Whilst using Bascellex and until healed, the treatment area is likely to appear noticeably different from normal skin.

Children and adolescents

Use in children and adolescents is not recommended.

Other medicines and Bascellex

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. There are no medicines known to be incompatible with Bascellex.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

You must tell your doctor if you are pregnant or intend to become pregnant. Your doctor will discuss the risks and benefits of using Bascellex during pregnancy.

Do not breast-feed your infant during treatment with Bascellex, as it is not known whether imiquimod is secreted in human milk.

Driving and using machines

This medicine has no or negligible influence on the ability to drive and use machines.

Bascellex contains methyl parahydroxybenzoate, propyl parahydroxybenzoate, cetyl alcohol, stearyl alcohol and benzyl alcohol

Methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) may cause allergic reactions (possibly delayed). Cetyl alcohol and stearyl alcohol may cause local skin reactions (e.g. contact dermatitis). Benzyl alcohol may cause mild local irritation.

Bascellex contains white soft paraffin

Healthcare professionals should be aware that if this product comes into contact with dressings, clothing and bedding, the fabric can be easily ignited with a naked flame. Patients should be warned of this risk and advised to keep away from fire when using this product.

3. How to use Bascellex

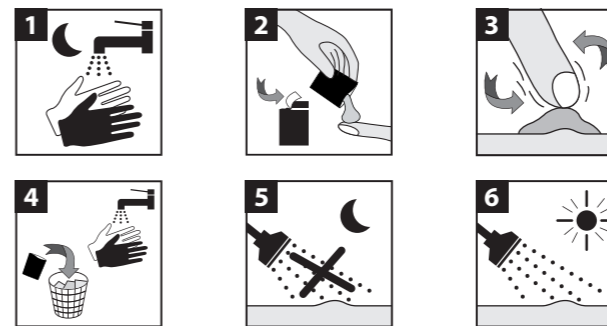
Children and adolescents

Use in children and adolescents is not recommended.

Adults

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Wash hands carefully before and after applying the cream. Do not cover the treated area with bandages or other dressings after you have applied Bascellex. Open a new sachet each time you use the cream. Dispose of any cream left in the sachet after use. Do not save the opened sachet for use at a later date.

Bascellex Cream Application Instructions



Application Instructions

1. Before going to bed, wash your hands and the treatment area with mild soap and water. Dry thoroughly.
2. Open a new sachet and squeeze some cream onto your fingertip.
3. Apply the cream to the affected area. Rub gently into the area until the cream vanishes.
4. After application of the cream, throw away the opened sachet and wash hands with soap and water.
5. Leave Bascellex on the skin for about 8 hours. Do not shower or bathe during this time.
6. After about 8 hours, wash the area where Bascellex was applied with mild soap and water.

Apply Bascellex 3 times per week, e.g. on Monday, Wednesday and Friday. One sachet contains enough cream to cover an area of 25 cm² (approx. 4 square inches). Continue treatment for 4 weeks. Four weeks after finishing this first treatment, your doctor will assess your skin. If the lesions have not all disappeared, a further 4 weeks of treatment may be necessary.

If you use more Bascellex than you should

Wash the extra cream away with mild soap and water. When any skin reaction has gone you may then continue with your treatment.

If you accidentally swallow Bascellex please contact your doctor.

If you forget to use Bascellex

If you miss a dose, apply cream as soon as you remember and then continue in your regular schedule. Do not apply the cream more than once per day.

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.

- Serious skin reactions have been reported rarely.

Stop using Bascellex and tell your doctor immediately if you experience skin lesions or spots on your skin that start out as small red areas and progress to look like mini targets, possibly with symptoms such as itching, fever, overall ill feeling, achy joints, vision problems, burning, painful or itchy eyes and mouth sores, stop using Bascellex and tell your doctor immediately.

Tell your doctor or pharmacist as soon as possible

- if you do not feel well while you are using Bascellex
- if your skin reacts badly when using Bascellex. Stop applying the cream and wash the area with mild soap and water.

- if you are more susceptible to infections, you bruise more easily or you feel fatigued. These may be symptoms of a lowering of blood cell counts noted in some individuals.

Some patients have experienced changes in skin colour in the area where Bascellex was applied. While these changes have tended to improve with time, in some patients they may be permanent.

A small number of patients have experienced hair loss at the treatment site or surrounding area.

Other side effects

Many of the undesirable effects of Bascellex are due to its local action on your skin. Local skin reactions can be a sign that the drug is working as intended.

Very common (may affect more than 1 in 10 patients)

- skin may be slightly itchy.

Common (may affect up to 1 in 10 patients)

- pain
- burning
- irritation
- redness
- headache
- anorexia
- nausea
- muscle pain
- joint pain
- tiredness.

If a skin reaction becomes too uncomfortable during treatment, speak to your doctor. He/she may advise you to stop applying Bascellex for a few days (i.e. to have a short rest from treatment). If there is pus (matter) or other suggestion of infection, discuss this with your doctor.

Uncommon (may affect up to 1 in 100 patients)

- changes at the application site (bleeding, inflammation, discharge, sensitivity, swelling, small swollen areas in the skin, pins and needles, scabbing, scarring, ulceration or a feeling of warmth or discomfort)
- inflammation of the lining of the nose
- stuffy nose
- flu or flu-like symptoms
- depression
- eye irritation
- swelling of the eyelid
- throat pain
- diarrhea
- actinic keratosis
- swelling of the face
- ulcers
- pain in extremity
- fever
- weakness
- shivering.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.



BASCELLEX
50 mg/g
CREAM
(Imiquimod)

5. How to store Bascellex

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

Do not use this medicine after the expiry date which is stated on the carton and sachet.

Do not store above 25°C.

Sachets should not be re-used once opened.

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 to protect the environment.

6. Contents of the pack and other information

What Bascellex contains

- The active substance is imiquimod. Each sachet contains 12.5 mg of imiquimod in 250 mg cream (1 g of cream contains 50 mg of imiquimod).
- The other ingredients are isostearic acid, benzyl alcohol, cetyl alcohol, stearyl alcohol, paraffin white soft, polysorbate 60, sorbitan monostearate, glycerol, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), xanthan gum, water, purified.

What Bascellex looks like and contents of the pack

Bascellex cream is a white to slightly yellow cream.

The cream is available in packs containing 12 or 24 single-use aluminium foil sachets (250 mg of cream/sachet).

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Sun Pharmaceutical Industries Europe B.V.
Polarisavenue 87
2132 JH Hoofddorp
The Netherlands

This medicinal product is authorised in the Member states of the EEA under the following names:

Belgium:	Bascellex
Germany:	Aksunim
France:	Bascellex
Netherlands:	Bascellex
Norway:	Bascellex
Sweden:	Bascellex
United Kingdom:	Bascellex

This leaflet was last revised in 04/2019