Package leaflet: Information for the patient

Epsolay 50 mg/g crème
benzoyl peroxide, hydrous

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 or 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 Epsolay is and what it is used for
2. What you need to know before you use Epsolay
3. How to use Epsolay
4. Possible side effects
5. How to store Epsolay
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1. What Epsolay is and what it is used for

Epsolay contains the active substance benzoyl peroxide. The cream is used on the skin to treat pimples and spots found with rosacea in adults 18 years of age and older.

2. What you need to know before you use Epsolay

Do not use Epsolay
- if you are allergic to benzoyl peroxide or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or pharmacist before using Epsolay.
- Before using Epsolay, tell your doctor or pharmacist about all your medical conditions, including if you have other **skin problems** such as dry skin, eczema, cuts, or sunburn.
- Avoid using Epsolay on skin areas with cuts, abrasions, eczema, or on sunburned skin.
- Limit your time in sunlight. **Avoid sunlight** or artificial sunlight such as sunlamps or tanning beds. Epsolay may make your skin more sensitive to the sun and the light from sunlamps and tanning beds. **Use sun protection** measures such as sunscreen and wear loose-fitting clothes that cover your skin while out in sunlight. Stop using Epsolay if you get sunburn.
- Epsolay **must not get into the eyes**, since this may cause reddening and burning. If Epsolay accidentally comes into contact with the eyes, rinse them thoroughly with water.
- Avoid getting Epsolay in your hair or on coloured fabric. Epsolay may **bleach hair or coloured fabric.**
- Epsolay may cause **skin irritation** such as redness, scaling, dryness, itching, stinging, or burning. These adverse reactions are more common at the beginning of treatment and usually decrease over time. You may use a moisturiser if you develop skin irritation. Tell your doctor if your symptoms do not improve, as you may need to stop treatment with Epsolay.
- Stop using Epsolay, if you develop **severe itching, swelling or blistering of the skin**, and ask your doctor for advice.

- If you notice any of the signs of an **allergic reaction**, as described in section 4, stop using Epsolay immediately and seek medical help right away.

Children and adolescents
The safety and efficacy of Epsolay in children and adolescents under the age of 18 is unknown.

Other medicines and Epsolay
Tell your doctor or pharmacist if you are using, have recently used, or might use any other medicines.

- Do not apply Epsolay at the same time as retinoid treatments (tretinoin, isotretinoin, adapalene). If using both, apply them at different times (e.g., morning and evening).

- Use caution with products that can dry or irritate the skin (including facial scrubs, and products with alcohol or salicylic acid) as these may increase skin irritation when combined with Epsolay.

Pregnancy and breastfeeding
If you are pregnant or breastfeeding, think you may be pregnant, or are planning to have a baby, ask your doctor for advice before using this medicine.

You can use Epsolay during pregnancy and breastfeeding, because very little of the medicine enters your bloodstream. If you are breastfeeding, do not apply Epsolay to your breast area. This prevents your child from accidentally swallowing or touching the medicine.

Driving and using machines
Epsolay has no or negligible influence on the ability to drive and use machines.

Epsolay contains cetyl alcohol
May cause local skin reactions (e.g. contact dermatitis).

Epsolay contains benzoic acid (as degradation product of benzoyl peroxide)
May cause local irritation.

3. How to use Epsolay

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- Apply Epsolay to your face 1 time each day on clean and dry skin.
- Before you use Epsolay for the first time, prime the pump by pressing down until the first drop of cream is released.
- Apply a pea-size amount of Epsolay for each area of the face (forehead, chin, nose, each cheek) on clean and dry skin. Spread as a thin layer, covering the entire face. Avoid the eyes, lips and mouth.
- Continue using Epsolay daily until your skin appears clear or nearly free of rosacea symptoms. Your doctor will advise you when you can stop the treatment.
- Wash your hands immediately after applying Epsolay.

Tell your doctor **if your rosacea symptoms come back** later after having improved. You might need to start using the treatment once a day again.

If you use more Epsolay than you should
Do not use more of Epsolay or apply it more often than recommended. It will not help faster or better, and skin irritation, as described in section 4, might be increased. If too much of Epsolay has been applied to the skin, wipe off the excess with a paper towel or wash it off with water.
If swallowed by accident, Epsolay may cause chest pain, stomach pain, feeling sick, or throwing up. Please contact a doctor immediately.

If you forget to use Epsolay
Do not use a double dose to make up for a forgotten dose.
Apply the next dose at the usual time.

If you stop using Epsolay
Do not stop Epsolay without advice.

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.

Epsolay may cause serious side effects:

- **Allergic reactions** (anaphylaxis, angioedema, urticaria; frequency not known), see "Warnings and precautions".
  Stop using Epsolay and seek medical help straight away if you have any of the following signs during treatment with Epsolay:
  - hives, rash, or severe itching
  - swelling of your face, eyes, lips, tongue, or throat
  - trouble breathing or throat tightness
  - feeling faint, dizzy, or lightheaded

Other side effects:

Common: may affect up to 1 in 10 people
- Pain, redness, itching, and swelling at the application site (see "Warnings and precautions")

Not known: frequency cannot be estimated from the available data
- Severe itching, swelling or blistering of the skin (contact dermatitis, see "Warnings and precautions")
- Skin flaking at the administration site
- Burning or stinging feeling on skin
- Dry skin

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 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 to store Epsolay

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 after "Exp:". The expiry date refers to the last day of that month.
Do not store above 25ºC.
Do not freeze.
Discard unused Epsolay 60 days after first opening.
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 Epsolay contains
- The active substance is benzoyl peroxide, hydrous.
- The other excipients are citric acid (E 330), cetrimonium chloride, cetyl alcohol, cyclomethicone, disodium edetate (E 385), glycerol (E 422), hydrochloric acid (E 507), lactic acid (E 270), macrogol stearate (Type I) (E 431), glycerol monostearate 40-55 (Type II), phenoxyethanol, polyquaternium-7, silica colloidal hydrated, sodium hydroxide (E 524), and purified water.

What Epsolay looks like and contents of the pack
Epsolay is a white to off-white cream packed in an airless pump containing 30-mL (30 g fill) of cream.

Houder van de vergunning voor het in de handel brengen en fabrikant
Vergunninghouder:
INFECTOPHARM Arzneimittel und Consilium GmbH
Von-Humboldt-Strasse 1
64646 Heppenheim
Duitsland

Fabrikant:
INFECTOPHARM Arzneimittel und Consilium GmbH
Von-Humboldt-Strasse 1
64646 Heppenheim
Duitsland

In het register ingeschreven onder:
RVG 135063

Dit medicijn is geregistreerd in lidstaten van de Europese Economische Ruimte onder de volgende namen:
<{Name of the Member State}> <{Name of the medicine}>

Deze bijsluiter is voor het laatst goedgekeurd in oktober 2026.