

Unofficial translation of the German package leaflet

Package leaflet: Information for the user

Soventol[®] Hydrocortisone Acetate 0.5%

5 mg/g cream

Active substance: Hydrocortisone acetate (Ph. Eur.)



For use in adults and children over 6 years.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.
- You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet

1. What Soventol[®] Hydrocortisone Acetate 0.5% is and what it is used for
2. What you need to know before you use Soventol[®] Hydrocortisone Acetate 0.5%
3. How to use Soventol[®] Hydrocortisone Acetate 0.5%
4. Possible side effects
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1. What Soventol[®] Hydrocortisone Acetate 0.5% is and what it is used for

Soventol[®] Hydrocortisone Acetate 0.5% is a low potency, low concentration medicine containing a corticosteroid for short-term (maximum of 2 weeks) external use to treat moderately severe inflammatory and allergic skin conditions.

The active ingredient in the gel cream is a 0.5% concentration of the low potency corticosteroid hydrocortisone acetate. It has a mild anti-inflammatory effect.

Soventol[®] Hydrocortisone Acetate 0.5% is used:

- to treat moderately severe reddened inflammatory or allergic skin conditions for which low potency, low concentration corticosteroids are indicated.

2. What you need to know before you use Soventol[®] Hydrocortisone Acetate 0.5%

Do not use Soventol[®] Hydrocortisone Acetate 0.5%:

- if you are allergic to hydrocortisone acetate (Ph. Eur.) or any of the other ingredients of this medicine listed in section 6 (see "Other information")
- without a medical prescription in children under 6 years
- for certain skin conditions (syphilis, tuberculosis of the skin)
- for viral infections, such as chicken pox, herpes or shingles
- for skin reactions after vaccinations
- for acne vulgaris or acne after cortisone treatment (steroid acne)
- for skin inflammation near the mouth (perioral dermatitis)
- for inflammatory redness of the face (rosacea)
- around the eyes
- on open wounds

Warnings and precautions

Talk to your doctor or pharmacist before using Soventol[®] Hydrocortisone Acetate 0.5%.

If you also have a skin infection caused by bacteria or fungi, this infection must also be treated with another medicine.

Ask your doctor for advice if you want to apply the product over a large area or if you want to cover the treated skin with a bandage.

Soventol[®] Hydrocortisone Acetate 0.5% must not be applied for longer than one week to an area covering more than 1/10 of the body surface.

If the condition worsens or the symptoms persist for longer than two weeks, the diagnosis should be checked, and an infection or hypersensitivity to the product should be ruled out.

Children

Clinical studies on efficacy and tolerability are only available for patients over 18 years of age.

Children under 6 years of age must only be treated with Soventol[®] Hydrocortisone Acetate 0.5% on medical prescription. If a doctor has prescribed Soventol[®] Hydrocortisone Acetate 0.5% for your infant or toddler, please make sure that you do not apply the gel under disposable nappies, plasters, or dressings.

Other medicines and Soventol[®] Hydrocortisone Acetate 0.5%:

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

There are no known interactions with other medicines.

Soventol[®] Hydrocortisone Acetate 0.5% with food and drink

No interactions with food and drink are known to date.

Pregnancy and breast-feeding

Pregnancy

There is no data on the use of Soventol[®] Hydrocortisone Acetate 0.5% in pregnant women. No increased risk of malformation or other birth defects have been observed in 363 children of women who were treated with topical glucocorticoids during pregnancy. In consideration of the low exposure following topical application, Soventol[®] Hydrocortisone Acetate 0.5% can be used during pregnancy, however, application over a large area or long-term use should be avoided during pregnancy, as well as occlusive (airtight) dressings.

Breast-feeding

If you are breast-feeding, you must not apply Soventol[®] Hydrocortisone Acetate 0.5% to the breast area to avoid direct contact between the infant and the active ingredient.

Ask your doctor or pharmacist for advice before using any medicine during pregnancy and breast-feeding.

Driving and using machines

No specific precautions are necessary.

3. How to use Soventol[®] Hydrocortisone Acetate 0.5%

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

Children under 6 years

You should only treat your child with Soventol[®] Hydrocortisone Acetate 0.5% if the doctor has prescribed Soventol[®] Hydrocortisone Acetate 0.5% for your child.

The recommended dose is:

Adults and children over 6 years

Apply a thin layer of Soventol[®] Hydrocortisone Acetate 0.5% to the affected areas of skin up to 3 times daily, and lightly massage the gel in. A mild burning sensation may be felt immediately after applying the gel, but this usually disappears rapidly. Once the condition has improved, once daily application is often sufficient.

Method of administration

Soventol[®] Hydrocortisone Acetate 0.5% is applied to the skin in a thin layer and rubbed in gently.

The tube is sealed with a thin aluminium film. Use the spike in the top of the cap to pierce this seal when you first use it.

Duration of treatment

The length of use depends on how well you respond to the treatment. However, Soventol[®] Hydrocortisone Acetate 0.5% should not be used for more than 2 weeks without consulting your doctor.

Please talk to your doctor or pharmacist if you feel that the effect of Soventol[®] Hydrocortisone Acetate 0.5% is too strong or too weak.

If you use more Soventol[®] Hydrocortisone Acetate 0.5% than you should

The active ingredient hydrocortisone acetate (Ph. Eur.) is a low-potency corticosteroid that is only present at a relatively low dose in Soventol[®] Hydrocortisone Acetate 0.5%. Therefore, no increased side effects are expected even after an overdose.

If you forget to use Soventol[®] Hydrocortisone Acetate 0.5%

Do not worry if you miss a single application. Just re-apply the normal amount of Soventol[®] Hydrocortisone Acetate 0.5% at the time of the next application. Do not use a double quantity to make up for a forgotten application.

If you stop using Soventol[®] Hydrocortisone Acetate 0.5%

You should not expect any negative effects if you stop using Soventol[®] Hydrocortisone Acetate 0.5%.

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 frequency data for side effects is based on the following categories:

- Very common: more than 1 in 10 patients treated
- Common: between 1 and 10 patients treated per 100
- Uncommon: between 1 and 10 patients treated per 1,000
- Rare: between 1 and 10 patients treated per 10,000
- Very rare: fewer than 1 in 10,000 patients treated
- Unknown: frequency cannot be estimated from the available data

Possible side effects

A mild burning sensation can often occur immediately after the application of Soventol[®] Hydrocortisone Acetate 0.5%, but this usually quickly disappears. Soventol[®] Hydrocortisone Acetate 0.5% is generally well tolerated by the skin. In very rare cases, particularly sensitive patients may experience allergic skin reactions (symptoms of hypersensitivity).

If you notice symptoms of hypersensitivity, stop using Soventol[®] Hydrocortisone Acetate 0.5%. Please also consult your doctor, so that they can advise you further.

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 to the Bundesinstitut für Arzneimittel und Medizinprodukte [German Federal Office for Drugs and Medical Devices (BfArM)], Abt. Pharmakovigilanz [Pharmacovigilance Department], Kurt-Georg-Kiesinger Allee 3, 53175 Bonn, website: <http://www.bfarm.de>. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Soventol[®] Hydrocortisone Acetate 0.5%

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 tube after "Expiry date". The expiry date refers to the last day of that month.

Do not freeze the medicine, and do not store above 25°C.

Once the tube has been opened, Soventol[®] Hydrocortisone Acetate 0.5% can be stored for 3 months.

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 Soventol[®] Hydrocortisone Acetate 0.5% contains

- The active substance is:
Hydrocortisone acetate (Ph. Eur.)
- The other ingredients are:
Purified water, isopropyl alcohol, decyl oleate, macrogol 400, isopropyl myristate (Ph. Eur.), soft paraffin, Carbopol 1382 carbomer, perfume oil, ammonia, sodium edetate (Ph. Eur.)

What Soventol[®] Hydrocortisone Acetate 0.5% looks like and contents of the pack

Soventol[®] Hydrocortisone Acetate 0.5% is a slightly translucent, milky white gel cream.

Soventol[®] Hydrocortisone Acetate 0.5% is available in packs of 15 g, 20 g, and 30 g cream.

Pharmaceutical company and manufacturer

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