

Unofficial translation of the German package leaflet

Package leaflet: Information for the user

Soventol[®] Hydrocortisone Acetate 0.25%

2.5 mg/g cream

Active substance: Hydrocortisone 21-acetate



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 0.25% is and what it is used for
2. What you need to know before you use Soventol[®] Hydrocortisone Acetate 0.25%
3. How to use Soventol[®] Hydrocortisone Acetate 0.25%
4. Possible side effects
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1. What Soventol[®] Hydrocortisone Acetate 0.25% is and what it is used for

Soventol[®] Hydrocortisone Acetate 0.25% is a low potency corticosteroid (group I) for the treatment of skin conditions.

Hydrocortisone is physiologically the most important corticosteroid from the group of glucocorticoids. When used externally, hydrocortisone blocks inflammatory processes (anti-inflammatory effect) regardless of their cause; it also regulates the formation of connective tissue cells (fibroblasts) and collagen synthesis (anti-proliferative effect).

Soventol[®] Hydrocortisone Acetate 0.25% is used:

- for the treatment of inflammatory and allergic skin conditions (skin inflammation and eczema) of mild to moderate severity which respond to external treatment with low potency corticosteroids.

2. What you need to know before you use Soventol[®] Hydrocortisone Acetate 0.25%

Do not use Soventol[®] Hydrocortisone Acetate 0.25%:

- if you are allergic to hydrocortisone 21-acetate or any of the other ingredients of Soventol[®] Hydrocortisone Acetate 0.25% (listed in section 6).
- for skin conditions caused by syphilis or tuberculosis
- for chicken pox and vaccination reactions

When used on infants and young children, make sure that conditions are not airtight (for example, under nappies).

In the event of simultaneous skin infection with bacteria or fungi, these must be treated separately.

Warnings and precautions

Talk to your doctor or pharmacist before using Soventol[®] Hydrocortisone Acetate 0.25%.

Do not use Soventol[®] Hydrocortisone Acetate 0.25% in or around the eyes.

Other medicines and Soventol[®] Hydrocortisone Acetate 0.25%

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

No interactions with other medicinal products are currently known.

Soventol[®] Hydrocortisone Acetate 0.25% with food and drink

No interactions with food and drink are currently known.

Pregnancy and breast-feeding

Soventol[®] Hydrocortisone Acetate 0.25% should not be used over large areas during pregnancy, in particular during the first 3 months. Breast-feeding mothers should not apply Soventol[®] Hydrocortisone Acetate 0.25% to the breast region.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

No specific precautions are necessary.

3. How to use Soventol[®] Hydrocortisone Acetate 0.25%

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.

The recommended dose is:

Apply a thin layer of Soventol[®] Hydrocortisone Acetate 0.25% to the affected areas of skin 2-3 times daily. If possible, the product can also be massaged in gently. A mild burning sensation may be experienced immediately after the application of Soventol[®] Hydrocortisone Acetate 0.25%, but this quickly disappears.

Method of administration

To be applied to the skin.

Duration of treatment

The duration of use depends on the success of treatment and should not be longer than 4 weeks without consulting a doctor.

Please talk to your doctor or pharmacist if you feel that the effect of Soventol[®] Hydrocortisone Acetate 0.25% is too strong or too weak.

If you use more Soventol[®] Hydrocortisone Acetate 0.25% than you should

Symptoms of overdose are not expected for 0.25% strength formulations of hydrocortisone when used according to the instructions.

If you forget to use Soventol[®] Hydrocortisone Acetate 0.25%

Forgetting a single application will not lead to any negative effects. Reapply Soventol[®] Hydrocortisone Acetate 0.25% at the next possible time.

Do not use a double quantity to make up for a forgotten application.

If you stop using Soventol[®] Hydrocortisone Acetate 0.25%

There are no known negative effects.

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:

If you experience one of the following side effects, do not continue to use Soventol[®] Hydrocortisone Acetate 0.25%, and see your doctor as soon as possible.

Soventol[®] Hydrocortisone Acetate 0.25% is generally very well tolerated by the skin. In very rare cases, particularly sensitive patients may experience allergic skin reactions (symptoms of hypersensitivity).

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 0.25%

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.

Storage conditions

Do not freeze. Do not store above 25°C.

Note about shelf-life after opening:

Soventol[®] Hydrocortisone Acetate 0.25% can be kept for 12 months after 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 Soventol[®] Hydrocortisone Acetate 0.25% contains

- The active substance is:
Hydrocortisone 21-acetate 2.5 mg/g cream
- The other ingredients are:
Ammonia; Carbopol 1382 polymer; sodium edetate (Ph. Eur.); decyl oleate; purified water; isopropyl myristate (Ph. Eur.); macrogol 400; soft paraffin; perfume oil; isopropyl alcohol

What Soventol[®] Hydrocortisone Acetate 0.25% looks like and contents of the pack

White gel cream.

Soventol[®] Hydrocortisone Acetate 0.25% is available in packs with 20 g and 50 g cream.

Pharmaceutical company and manufacturer

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