

Unofficial translation of the German package leaflet

**Package leaflet: Information for the user**

**Soventol® HydroCort 0.5%**

5 mg/g cream

Active substance: Hydrocortisone



For adults and children over 6 years.

For short-term (max. 2 weeks) external use.

Not for use in children under 6 years without medical prescription.

**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® HydroCort 0.5% is and what it is used for
2. What you need to know before you use Soventol® HydroCort 0.5%
3. How to use Soventol® HydroCort 0.5%
4. Possible side effects
5. How to store Soventol® HydroCort 0.5%
6. Contents of the pack and other information

**1. What Soventol® HydroCort 0.5% is and what it is used for**

Soventol® HydroCort 0.5% 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<sup>®</sup> HydroCort 0.5% is used**

- for the treatment of all skin conditions that respond to treatment with corticosteroids, for example, inflammatory, allergic or itchy skin conditions (skin inflammation, eczema).

## **2. What you need to know before you use Soventol<sup>®</sup> HydroCort 0.5%**

### **Do not use Soventol<sup>®</sup> HydroCort 0.5%:**

- if you are allergic to hydrocortisone or any of the other ingredients of this medicine (listed in section 6)
- in children under 6 years of age (children under 6 years must only be treated with Soventol<sup>®</sup> HydroCort 0.5% on medical prescription. When used on infants and young children, make sure that conditions are not airtight [for example, under nappies].)
- for skin conditions caused by syphilis or tuberculosis
- for chicken pox and vaccination reactions

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<sup>®</sup> HydroCort 0.5%.

Use of the product over a large area or under a dressing (occlusive application) should only take place under medical supervision.

Soventol<sup>®</sup> HydroCort 0.5% must not be applied for longer than one week to an area covering more than 1/10 of the body surface. Do not use in the eyes or on open wounds.

### **Other medicines and Soventol<sup>®</sup> HydroCort 0.5%:**

There are to date no known interactions with other medicines when taken at the same time or applied externally.

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

### **Soventol<sup>®</sup> HydroCort 0.5% with food and drink**

No interactions with food and drink are currently known.

### **Pregnancy and breast-feeding**

During pregnancy, Soventol<sup>®</sup> HydroCort 0.5% should only be used in urgent cases, and such treatment should not be administered on a long-term basis or to large areas of skin (more than 30% of the body surface area). Breast-feeding mothers must not apply Soventol<sup>®</sup> HydroCort 0.5% to the breast area to avoid direct contact between the infant and the active ingredient.

### **Driving and using machines**

No specific precautions are necessary.

### **Soventol<sup>®</sup> HydroCort 0.5% contains sorbic acid, potassium sorbate and cetostearyl alcohol.**

These may cause localised skin reactions (e.g., contact dermatitis).

## **3. How to use Soventol<sup>®</sup> HydroCort 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 of age must only be treated with Soventol<sup>®</sup> HydroCort 0.5% on medical prescription.

The recommended dose is:

Apply a thin layer of Soventol<sup>®</sup> HydroCort 0.5% 2-3 times daily to the affected areas of skin and massage in gently. Once the condition has improved, once daily application is often sufficient.

### Method of administration

To be applied to the skin.

Before first use, the thin aluminium foil seal must be pierced using the spike on the lid.

### Duration of treatment

The duration of use depends on the success of treatment and should not be longer than 2 weeks without consulting a doctor.

Please talk to your doctor or pharmacist if you feel that the effect of Soventol<sup>®</sup> HydroCort 0.5% is too strong or too weak.

### **If you use more Soventol<sup>®</sup> HydroCort 0.5% than you should**

Hydrocortisone is a low potency corticosteroid that is present in Soventol<sup>®</sup> HydroCort 0.5% at a relatively low dose. Therefore no symptoms of poisoning are expected after an overdose. Please inform your doctor of the administration error at your next visit.

### **If you forget to use Soventol<sup>®</sup> HydroCort 0.5%**

Forgetting a single application will not lead to any negative effects. Re-apply the normal amount of Soventol<sup>®</sup> HydroCort 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<sup>®</sup> HydroCort 0.5%**

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

### **Important side effects or signs that you should look out for**

Soventol<sup>®</sup> HydroCort 0.5% is generally very well tolerated by the skin. In very rare cases, particularly sensitive patients may experience allergic skin reactions (hypersensitivity symptoms).

### **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 using the notification form for adverse drug reactions (ADRs) (<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<sup>®</sup> HydroCort 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.

### **Storage conditions**

Do not store above 25°C.

### **Note about shelf-life after opening:**

Soventol<sup>®</sup> HydroCort 0.5% 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<sup>®</sup> HydroCort 0.5% contains**

- The active substance is:  
Hydrocortisone 5 mg/g cream
- The other ingredients are:  
Liquid paraffin; cetostearyl alcohol (Ph. Eur.); white petroleum jelly; cetomacrogol 1000; emulsifying wax; propylene glycol; phenoxyethanol (Ph. Eur.), potassium sorbate (Ph. Eur.), sorbic acid (Ph. Eur.), sodium edetate (Ph. Eur.), purified water

### **What Soventol<sup>®</sup> HydroCort 0.5% looks like and contents of the pack**

White cream

Soventol<sup>®</sup> HydroCort 0.5% is available in original packs with 15 g and 30 g cream.

### **Pharmaceutical company and manufacturer**

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