

Unofficial translation of the German package leaflet

## Package leaflet: Information for the user

### Soventol® HydroCort 0.5% Spray

5 mg/g solution

Active substance: Hydrocortisone



For use in adults and children over 6 years.

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

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

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

Soventol® HydroCort 0.5% Spray is a glucocorticoid (hormone produced by the adrenal glands) for use on the skin.

#### Intended use

For the relief of uninfected mildly inflamed, allergic or itchy skin conditions that respond to symptomatic treatment with low potency glucocorticoids.

Soventol® HydroCort 0.5% Spray is especially suitable for use on normal or oily skin.

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

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

- if you are allergic to hydrocortisone or any of the other ingredients of Soventol<sup>®</sup> HydroCort 0.5% Spray (listed in section 6),

or for the treatment of:

- specific skin conditions (syphilis, tuberculosis)
- viral infections (e.g., chicken pox, herpes simplex, shingles)
- vaccination reactions
- fungal infections (mycosis)
- bacterial skin infections
- acne vulgaris
- steroid acne
- skin inflammation near the mouth (perioral dermatitis)
- inflammatory redness of the face (rosacea)
- children under 6 years

Do not use Soventol<sup>®</sup> HydroCort 0.5% Spray on open wounds, and do not use for longer than 2 weeks.

### **Warnings and precautions**

Talk to your doctor or pharmacist before using Soventol<sup>®</sup> HydroCort 0.5% Spray.

Particular caution is required when using Soventol<sup>®</sup> HydroCort 0.5% Spray:

- on the face (especially around the eyes), on chafed (intertriginous) areas of skin, around skin ulcers, and in the genital and anal area
- in children and the elderly (ageing skin), due to the weakened barrier function of the outermost layer of the skin (stratum corneum) and due to a larger body surface area in relation to body weight

### **Children**

External treatment with Soventol<sup>®</sup> HydroCort 0.5% Spray should be used with restraint in children over 6 years, and the duration of treatment should not be longer than 2 weeks.

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

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

If you accidentally spray Soventol<sup>®</sup> HydroCort 0.5% into the mouth or onto wounds, you must expect the following interactions:

- cardiac glycosides: the glycoside effect may be increased by potassium deficiency
- diuretics (water pills): there may be increased potassium excretion
- medicines to reduce blood sugar (antidiabetic drugs): the blood sugar lowering effect may be reduced
- medicines to prevent blood clotting (coumarin derivatives): the anticoagulant effect may be reduced
- rifampicin, phenytoin, barbiturates: the corticosteroid effect may be reduced
- non-steroidal anti-inflammatory drugs/painkillers: the risk of gastrointestinal bleeding is increased

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

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.

### Pregnancy

Use of Soventol<sup>®</sup> HydroCort 0.5% Spray should be avoided as far as possible during pregnancy, and if use is absolutely necessary, treatment should be used for the smallest area possible and for the shortest possible time. As growth disorders and damage to the unborn child cannot be ruled out in the event of long-term treatment with glucocorticoids during pregnancy, please tell your doctor if you want to become pregnant, are already pregnant or suspect that you may be pregnant.

### Breast-feeding

Glucocorticoids, including hydrocortisone, pass into breast milk. Harm to the infant has not been reported to date. Nevertheless, if you are breast-feeding, you should only use Soventol<sup>®</sup> HydroCort 0.5% Spray after first consulting your doctor.

If your doctor believes that the use of Soventol<sup>®</sup> HydroCort 0.5% Spray is required during breast-feeding, you should not use the spray in the breast region to avoid unwanted absorption by the infant. If your doctor believes that higher doses are required for health reasons, you should stop breast-feeding.

### **Driving and using machines**

There are no known effects.

### **Soventol<sup>®</sup> HydroCort 0.5% Spray contains propylene glycol.**

Propylene glycol may cause skin irritation.

This medicine is not suitable for people with dry skin or skin diseases that are associated with dry skin.

## **3. How to use Soventol<sup>®</sup> HydroCort 0.5% Spray**

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:

At the start of the treatment, use the spray 2-3 times daily. As the condition improves, a single application per day is generally sufficient (or every 2-3 days).

### Method and duration of administration

Spray for use on the skin.

Use over large areas of skin should be avoided or should only take place following instruction from a doctor.

The spray must not be applied for longer than one week to an area covering more than 1/10 of the body surface.

The duration of treatment must not exceed 2 weeks. If your symptoms worsen or do not improve after 2 weeks, you must consult a doctor.

As this spray contains alcohol, the duration of use may be limited by increasing dryness of the skin. You should consult a doctor in the event of severe signs of skin dehydration (e.g., scaling, tightness, itching), or if the symptoms persist or get worse.

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

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

Reduce the dose or - if possible - stop using the medicine after high-dose and long-term use.

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

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

## **If you stop using Soventol® HydroCort 0.5% Spray**

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:**

Rare: allergic skin reactions

The following side effects are known with long-term use: thinning of the skin (skin atrophy), dilated capillaries visible on the skin (telangiectasia), stretch marks on the skin (striae), steroid acne, skin inflammation around the mouth (perioral dermatitis), abnormal increase in body hair (hypertrichosis), and changes in skin pigmentation.

Prolonged use may cause localised dryness of the skin (e.g., scaling, tightness, itching).

### **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 following bodies:

#### **For Germany**

Bundesinstitut für Arzneimittel und Medizinprodukte  
[Federal Institute for Drugs and Medical Devices]  
Abt. Pharmakovigilanz  
[Department of Pharmacovigilance]  
Kurt-Georg-Kiesinger Allee 3  
D-53175 Bonn  
Website: <http://www.bfarm.de>

#### **For Luxembourg**

Direction de la Santé – Division de la Pharmacie et des Médicaments  
[Health Department - Unit for Pharmacy Services and Medicinal Products]  
Villa Louvigny – Allée Marconi  
L-2120 Luxembourg  
Website: <http://www.ms.public.lu/fr/activites/pharmacie-medicament/index.html>

By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Soventol® HydroCort 0.5% Spray**

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 the label 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% Spray can be stored 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% Spray contains**

- The active substance is hydrocortisone.  
30 ml spray contains 0.15 g hydrocortisone
- The other ingredients are:  
Ethanol 96%, propylene glycol, glycerol 85%, hypromellose, sodium edetate (Ph. Eur.), sodium hydroxide, citric acid monohydrate, purified water

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

Clear colourless solution.

Pack with 30 ml solution.

**Pharmaceutical company and manufacturer**

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