

Package leaflet: Information for the user

Soventol[®] Gel

20 mg/g gel

Active substance: Bamipine lactate



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

1. What Soventol[®] Gel is and what it is used for

Soventol[®] Gel is an antihistamine.

Soventol[®] Gel is used

- to provide relief for itching caused by mild to moderate reactions to insect bites (e.g., mosquito bites)

2. What you need to know before you use Soventol® Gel

Do not use Soventol® Gel:

- if you are allergic to bamipine lactate or any of the other ingredients of this medicine (listed in section 6)
- if you are pregnant or breast-feeding

Warnings and precautions

Talk to your doctor or pharmacist before using Soventol® Gel.

Please consult a doctor as soon as possible in the event of insect bites associated with very painful swelling and redness in the region of the bite.

If you experience generalised symptoms such as shortness of breath, nausea, dizziness or cardiovascular symptoms, immediate medical treatment is required, and an emergency doctor must be called, if applicable.

If applied to acute eczema where the skin is weeping there is a risk that the condition may be aggravated.

Other medicines and Soventol® Gel

No interactions with other medicinal products are currently known.

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

Soventol® Gel with food and drink

No interactions with food and drink are currently known.

Pregnancy and breast-feeding

There is no clinical data available on the use of bamipine lactate in pregnant women, and no animal studies have been conducted in connection with this. Therefore, Soventol® Gel should not be used during pregnancy.

It is not known whether bamipine lactate passes into breast milk; therefore Soventol® Gel should not be used while 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.

Driving and using machines

No specific precautions are necessary.

Soventol® Gel contains propylene glycol.

Propylene glycol may cause skin irritation.

3. How to use Soventol® Gel

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:

A thin layer of Soventol® Gel is to be applied to the affected areas of skin several times a day, if necessary at half-hour intervals. If possible, the product can also be massaged in gently.

Method of administration

To be applied to the skin.

Duration of treatment

The duration of treatment depends on the severity of the symptoms.

Please talk to your doctor or pharmacist if you feel that the effect of Soventol® Gel is too strong or too weak.

If you take more Soventol® Gel than you should

Symptoms of overdose are not to be expected with the application of Soventol® Gel if it is used correctly.

If you forget to use Soventol® Gel

Forgetting a single application will not lead to any negative effects. Reapply Soventol® Gel at the next possible time.

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

If you stop using Soventol® Gel

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

Very rare: hypersensitivity reactions; mild burning sensation after application that usually fades after a few minutes and is replaced by the cooling and soothing effect of the gel.

If Soventol® Gel is applied to large areas of skin, in particular to areas of skin with inflammatory changes, a generalised effect on the body may be observed due to the absorption of large amounts of bupivacaine through the skin.

Very rare: Agitation, confusion and dilation of the pupils in children; in adults, mainly fatigue. Experience has shown that these side effects subside fully after discontinuation of the treatment.

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 relevant body:

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® Gel

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:

Soventol® Gel must not be stored above 25°C for extended periods. Brief storage above this temperature (e.g., if taken to the beach) is possible.

Note about shelf-life after opening

Soventol® Gel 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® Gel contains

- The active substance is:
Bamipine lactate 20 mg/g gel
- The other ingredients are:
Purified water, hypromellose, poly(oxyethylene)-6-glycerol (mono, di) alkanoate (C₈-C₁₀), propylene glycol

What Soventol® Gel looks like and contents of the pack

Clear gel

Soventol® Gel is available in packs with 20 g and 50 g gel.

Pharmaceutical company and manufacturer

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This leaflet was last revised in June 2015.