

Ayrton Saunders (Ireland) Ltd.

Sprilon[®]

12.5%w/w / 1.04%w/w

Cutaneous Spray Suspension

Zinc Oxide / Dimeticone

115g

Non-irritant

Protective

Water-repellent

Spray ointment

PA22906/001/001

MA Holder: Ayrton Saunders (Ireland) Limited, 8A Sandyford Business Centre, Blackthorn Avenue, Sandyford, Dublin 18, Ireland.

Manufacturer: MIAS Pharma Limited, Suite 1, Stafford House, Strand Road, Portmarnock, Co. Dublin, Ireland.

Fire hazard. Do not smoke or go near naked flames; clothing & bedding with this product dried on them can catch fire easily.

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1. WHAT SPRILON IS AND WHAT IT IS USED FOR

Sprilon contains Zinc Oxide and Dimeticone. Sprilon is used for the prevention and treatment of pressure sores, and skin damage from contact with body fluids, e. g. around the perineum, fistulae, colostomies, ileostomies, eczematous areas etc. It is also used for the protection and treatment of fissures and leg ulcers, and the protection of skin beneath plaster casts.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE SPRILON

Do not use Sprilon and talk to your doctor if:

- You are allergic to zinc oxide, dimeticone, wool fat or any of the other ingredients.
- You are sensitive to cetostearyl alcohol.

Cetostearyl alcohol and wool fat may cause local skin reactions (e.g. contact dermatitis). Ask your doctor for advice before taking any medicine if you are pregnant or breast-feeding.

Warnings and precautions

Avoid inhalation or contact with the eyes. If condition is aggravated, discontinue use and consult doctor. Do not smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

3. HOW TO USE SPRILON

For external use only.

Shake the can well. Hold the can 20cm (8") away from the skin surface, at a right angle. Gently press the nozzle to apply a thin even layer. Two to three seconds of spraying should be sufficient to cover

an area the size of the buttocks. A mild cooling sensation may be experienced. Re-apply as often as necessary.

Frequent, repeated application to the same area could lead to skin irritation. Other skin preparations may disrupt the Sprilon film if applied to the same area. If you accidentally spray into your eyes, bathe them thoroughly in water and talk to your doctor.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Sprilon can cause side effects, although not everybody gets them.

Stop use and talk to your doctor or pharmacist if:

- You develop an allergic reaction (e.g. a rash)
- You experience local skin irritation.
- The condition becomes worse
- Any side effect becomes more serious
- You notice any side effect not listed

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to:

HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2

Tel: +353 1 6764971, Fax: +353 1 6762517

Website: <http://www.hpra.ie>, e-mail: medsafety@hpra.ie

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

5. HOW TO STORE SPRILON

Keep out of the sight and reach of children.

Do not store above 25°C. Replace the cap after use. Danger: Extremely flammable. Keep away from heat, sunlight, hot surfaces, sparks, open flames and other ignition sources. No smoking. The canister contains a pressurised liquid. Do not expose to temperature higher than 50°C, and do not pierce the canister. Do not use after expiry date shown on the base. 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

The active substances are:

zinc oxide 12.5% w/w and dimeticone 1.04% w/w.

The other ingredients are:

white soft paraffin, wool fat, liquid paraffin, cetostearyl alcohol, wool alcohols, dextran CB and purified water.

The propellant is isobutane.

For information in large print, audio CD or braille please contact the Marketing Authorisation Holder.

This text was revised in December 2022.