Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Sprilon 12.5 % Zinc Oxide and 1.04 % Dimeticone Cutaneous Spray, Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Zinc Oxide 12.5 % w/w
Dimeticone 350 1.04 % w/w

Excipients with known effect
Wool Fat 5.19 % w/w
Cetostearyl Alcohol 0.519 % w/w

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous Spray, Suspension.
White, water-repellant, viscous ointment suspended in a propellant.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

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.

Protection and treatment of fissures and leg ulcers.

Protection of skin beneath plaster casts.

4.2 Posology and method of administration

Shake can well. Spray surfaces at right angles from a distance of 20 cm (8”). Two to three seconds should be sufficient for the area the size of the buttocks. Sprilon can be re-applied as often as necessary.

4.3 Contraindications

Do not use on patients with known sensitivity to wool fats.

4.4 Special warnings and precautions for use

Avoid inhalation or contact with the eyes. Keep out of the reach and sight of children.
If condition is aggravated, discontinue use and consult the doctor.
Instruct patients not to 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.
This product contains wool fat and cetostearyl alcohol which may cause local skin reactions (eg. contact dermatitis).

4.5 Interaction with other medicinal products and other forms of interactions

Other topical preparations may disrupt the Sprilon film.

4.6 Fertility, pregnancy and lactation

The safety of Sprilon during pregnancy and lactation has not been established, but use of the product is not considered to be contraindicated during these periods.

4.7 Effects on ability to drive and use machines

Unlikely to produce any effect.

4.8 Undesirable effects

Skin irritation has been observed on rare occasions.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to:

HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie.

4.9 Overdose

It is very unlikely that overdose would occur with Sprilon. Theoretically, frequently repeated topical application on the same site could lead to skin irritation.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: emollient and protective, ATC code: D02AA00.

Sprilon consists of dimeticone, which has a liquid repellent effect. The zinc oxide ointment base helps moisturise skin. The spray rapidly forms a white, durable, flexible film which, while protecting the skin and assisting healing, allows normal transepidermal water loss.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

White soft paraffin
Wool fat (anhydrous lanolin)
Liquid paraffin
Cetostearyl alcohol
Wool alcohols (wool wax alcohols)

Dextran CB
Purified water
Propellant: isobutane

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25°C. Extremely flammable.
The canister contains a pressurised liquid. Do not expose to temperatures higher than 50°C. Do not pierce the canister.

6.5 Nature and contents of container

Aluminium pressurised can with plastic cap containing 115 g Sprilon cutaneous spray, suspension.

6.6 Special precautions for disposal and other handling

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Ayrton Saunders (Ireland) Limited
8a Sandyford Business Centre
Blackthorn Avenue
Sandyford
Dublin 18
Ireland

8 MARKETING AUTHORISATION NUMBER

PA22906/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21st May 1996

Date of last renewal: 21st May 2006

10 DATE OF REVISION OF THE TEXT

July 2021