SILON 12.5% W/W / 1.04% W/W CUTANEOUS SPRAY
PL 16431/0022

UKPAR

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LAY SUMMARY

The MHRA granted Ayrton Saunders Limited a Marketing Authorisation for the medicinal product Silon 12.5% w/w / 1.04% w/w Cutaneous Spray (PL 16431/0022) on 30th November 2007. This is a General Sales List medicine (GSL) and is used for the prevention and treatment of pressure sores, or around fistulae. It can also be used for the protection and treatment of fissures, leg ulcers, moist eczema and to protect the skin beneath plaster casts.

The active ingredients, zinc oxide are used as a soothing and protective ointment and dimethicone is used as a silicone that forms a barrier on the skin.

This application is identical to a previously granted application for Sprilon Spray (PL 16431/0020, granted to the same Marketing Authorisation on 23rd March 2005).

No new or unexpected safety concerns arose from this simple application and it was, therefore, judged that the benefits of taking Silon 12.5% w/w / 1.04% w/w Cutaneous Spray outweigh the risks; hence a Marketing Authorisation has been granted.

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SCIENTIFIC DISCUSSION

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INTRODUCTION

The UK granted a marketing authorisation for the medicinal product Silon 12.5% w/w / 1.04% w/w Cutaneous Spray (PL 16431/0022) to Ayrton Saunders Limited on 30th November 2007. The product is a general sales list (GSL) medicine for sale to the general public.

The application was submitted as a simple abridged application according to Article 10c of Directive 2001/83/EC, as amended, cross-referring to Sprilon Spray authorised to the same Marketing Authorisation Holder (PL 16431/0020), approved on 23rd March 2005.

No new data were submitted nor was it necessary for this simple application, as the data are identical to that of the previously granted cross-reference product. As the cross-reference product was granted prior to the introduction of current legislation, no Public Assessment Report (PAR) has been generated for it.

The product contains the active ingredient zinc oxide and dimeticone which are used in the treatment of pressure sores and skin damage from contact with body fluids, e.g around the perineum, fistulae, colostomies, eczematous area.

PHARMACEUTICAL ASSESSMENT

LICENCE NO: PL 16431/0022
PROPRIETARY NAME: Silon 12.5% w/w / 1.04% w/w Cutaneous Spray
ACTIVE(S): Zinc oxide and Dimeticone
COMPANY NAME: Ayrton Saunders Limited
E.C. ARTICLE: Article 10c (formerly Article 10.1(a)(i)) of Directive 2001/83/EC
LEGAL STATUS: GSL

1. INTRODUCTION

This is a simple, informed consent application for Silon 12.5% w/w / 1.04% w/w Cutaneous Spray submitted under Article 10c (formerly Article 10.1(a)(i)) of Directive 2001/83/EC. The proposed MA holder is Ayrton Saunders Limited, Pennisular Business Park, Reeds Lane, Moreton, Merseyside, CH46 1DW, UK.

The application cross-refers to Sprilon Spray, approved on 23rd March 2005 to the same marketing authorisation holder. The current application is considered valid.

2. MARKETING AUTHORISATION APPLICATION FORM

2.1 Name(s)

The proposed name of the product is Silon 12.5%w/w/1.04%w/w Cutaneous Spray. The product has been named in line with current requirements.

2.2 Strength, pharmaceutical form, route of administration, container and pack sizes

The product contains zinc oxide and dimeticone, equivalent to 12.5%w/w and 1.04%w/w respectively. It is to be stored in an aluminium pressurised container with a plastic cap The proposed shelf-life (36 months) and storage conditions ("Store away from heat") is consistent with the details registered for the cross-reference product.

2.3 Legal status

On approval, the products will be available as prescription-only medicines (GSL).

2.4 Marketing authorisation holder/Contact Persons/Company

Ayrton Saunders Limited, Pennisular Business Park, Reeds Lane, Moreton, Merseyside, CH46 1DW, UK.
The QP responsible for pharmacovigilance is stated and his CV is included.

2.5 Manufacturers

The proposed manufacturing sites are consistent with those registered for the cross-reference product and evidence of GMP compliance has been provided.

2.6 Qualitative and quantitative composition

The proposed composition is consistent with the details registered for the cross-reference product.

2.7 Manufacturing process

The proposed manufacturing process is consistent with the details registered for the cross-reference product and the maximum batch size is stated.

2.8 Finished product/shelf-life specification
The proposed finished product specification is in line with the details registered for the cross-reference product.

2.9 Drug substance specification
The proposed drug substance specification is consistent with the details registered for the cross-reference product.

2.10 TSE Compliance
With the exception of wool fat, no materials of animal or human origin are included in the product. This is consistent with the cross-reference product.

A satisfactory TSE certificate of suitability has been provided for the supplier of wool fat.

3. EXPERT REPORTS
The applicant has included expert reports in Module 2 of the application. Signed declarations and copies of the experts' CVs are enclosed in Module 1.4 for the quality, non-clinical and clinical experts. All are considered to have sufficient experience for their responsibilities.

4. PRODUCT NAME & APPEARANCE
See 2.1 for details of the proposed product name. The appearance of the product is identical to the cross-reference product.

5. SUMMARY OF PRODUCT CHARACTERISTICS
The proposed summary is consistent with the details registered for the cross-reference product.

6. PATIENT INFORMATION LEAFLET/CARTON
PIL
The patient information leaflet has been prepared in-line with the details registered for the cross-reference product. The marketing authorisation holder has provided a commitment to update the marketing authorisation with a package leaflet in compliance with Article 59 of Council Directive 2001/83/EC and that the leaflet shall reflect the results of consultation with target patient groups, no later than 1st July 2008.

Carton
The proposed artwork is comparable to the artwork registered for the cross-reference product and complies with statutory requirements. In line with current legislation the applicant has also included the name of the product in Braille on the outer packaging and has included sufficient space for a standard UK pharmacy dispensing label.

7. CONCLUSIONS
The data submitted with the application are acceptable. A Marketing Authorisation should be granted.

PRECLINICAL ASSESSMENT

No new preclinical data have been supplied with this application and none are required for an application of this type.

CLINICAL ASSESSMENT

No new clinical data have been supplied with this application and none are required for an application of this type.

OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY

The data for this application is consistent with that previously assessed for the cross-reference product and as such has been judged to be satisfactory.

PRECLINICAL

No new preclinical data were submitted and none are required for an application of this type.

EFFICACY

Zinc oxide and dimeticone are well known drugs and have been used together as a medicine that soothes and protects the skin for many years. This application is identical to previously granted application for Sprilon Spray (PL 16431/0020).
No new or unexpected safety concerns arise from this application.

The SPC, PIL and labelling are satisfactory and consistent with that for the cross-reference product.

RISK BENEFIT ASSESSMENT

The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. The applicant's product is identical to the cross-reference product. Extensive clinical experience with zinc oxide and dimeticone is considered to have demonstrated the therapeutic value of the compounds. The risk benefit is therefore considered to be positive.

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STEPS TAKEN FOR ASSESMENT

1	The MHRA received the marketing authorisation application on 17th May 2005.
2	Following standard checks and communication with the applicant the MHRA considered the application valid on 15th June 2005.
3	Following assessment of the application the MHRA requested further information relating to the quality dossier on 18th July 2005, 12th April 2006 and 22nd May 2007.
4	The applicant responded to the MHRA's requests, providing further information on 29th November 2005, 27th August 2006, and 19th September 2007.
5	The application was determined on 30th November 2007

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STEPS TAKEN AFTER ASSESSMENT

Date submitted	Application type	Scope	Outcome

SILON 12.5% W/W / 1.04% W/W CUTANEOUS SPRAY
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SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Silon 12.5% w/w / 1.04% w/w Cutaneous Spray

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Zinc Oxide	12.5% w/w
Dimeticone	1.04% w/w
White Petrolatum	12.5% w/w
Wool fat	5.19% w/w
Liquid Paraffin	5.19% w/w
Cetostearyl Alcohol	0.519% w/w
Wool Alcohols	0.519% w/w
Dextran CB	0.363% w/w
Purified Water	14.2% w/w
Propellant: Butane (E943a) / Propane (E944) Mix	47.98% w/w

3 PHARMACEUTICAL FORM

Cutaneous Spray

An aerosol spray, delivering an ointment and a water repellent barrier to the skin.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

For the prevention and treatment of pressure sores, skin maceration due to faeces or urine, or around fistulae and ileostomies. Protection and treatment of fissures, leg ulcers, moist eczema. Protection of skin beneath plaster casts.

4.2 POSOLOGY AND METHOD OF ADMINISTRATION

Route of administration: Shake can well. Spray on to the skin at right angles from distance of 20cm (8”). Two to three seconds should be sufficient for the area the size of the buttocks.

4.3 CONTRAINDICATIONS

Do not use on patients with known sensitivity to wool fats. May cause local skin reactions (e.g. contact dermatitis) due to the presence of wool fat and Cetostearyl alcohol.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Protect the eyes. Keep out of the reach of children. DO NOT puncture, incinerate or heat can above 50ºC even when empty. Highly flammable.

4.5 INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

Other topical preparations may disrupt the Silon film.

4.6 PREGNANCY AND LACTATION

Can be used in pregnant and lactating women.

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. Undesirable effects are very rare (less than 1 in 10,000).

4.9 OVERDOSE

Excess application may be easily removed with ether.

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Silon consists of dimeticone, which has a liquid repellent effect. The zinc oxide ointment base helps to moisturise skin. The spray rapidly forms a white, durable, flexible film which, while protecting the skin and assisting healing, allows normal transepidermal water loss. The pharmacotherapeutic group of Silon is 'Emollients and Protectives', and the ATC Code is D02AX.

5.2 PHARMACOKINETIC PROPERTIES

Not applicable.

5.3 PRECLINICAL SAFETY DATA

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

White Petrolatum
Wool fat
Liquid Paraffin
Cetostearyl Alcohol
Wool Alcohols
Dextran CB
Purified Water
Propellant: Butane (E943a) / Propane (E944) Mix

6.2 INCOMPATIBILITIES

None presently known.

6.3 SHELF LIFE

Three years.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Highly flammable. Packaging carries appropriate warning.

Store away from heat.

6.5 NATURE AND CONTENTS OF CONTAINER

Aluminium pressurised container with plastic cap containing 115g

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

Spray skin from distance of 20cm.

Do not puncture, incinerate or expose to temperatures over 50ºC (122ºF) even when empty.

7 MARKETING AUTHORISATION HOLDER

Ayrton Saunders Ltd.
Peninsular Business Park
Reeds Lane, Moreton,
Wirral, Merseyside
CH46 1DW

United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL16431/0022

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30/11/2007

10 DATE OF REVISION OF THE TEXT

30/11/2007

SILON 12.5% W/W / 1.04% W/W CUTANEOUS SPRAY
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PATIENT INFORMATION LEAFLET

SILON* 12.5% w/w / 1.04% w/w CUTANEOUS SPRAY
Zinc Oxide/Dimeticone
PL16431/0022

Please read this information carefully before you apply this spray. This leaflet does not contain the complete information about this medicine. If you have any questions or are not sure about anything ask your doctor, nurse or pharmacist.

WHAT IS YOUR MEDICINE?
The name of this spray ointment is Silon.
The spray contains the active ingredients Zinc Oxide 12.5% w/w, a soothing and protective ointment, and Dimeticone 1.04% w/w, a silicone that forms a barrier on the skin.
The spray belongs to a group of medicines that soothe and protect the skin. Each can contains 115g of spray ointment.

WHAT IS YOUR MEDICINE FOR?
Silon is used for the prevention and treatment of pressure sores, skin maceration due to faeces or urine, or around fistulae and ileostomies. It is also used for the protection and treatment of fissures, leg ulcers, moist eczema and the protection of skin beneath plaster casts.

IMPORTANT INFORMATION BEFORE TAKING YOUR MEDICINE
Make sure it is safe for you to apply this medicine.
- Are you allergic to wool fat (lanolin)?
- Are you sensitive to Cetostearyl alcohol?
- Have you ever used this medicine before and suffered a reaction to it?

If the answer is **YES** to any of these questions, do not use Silon and tell your doctor, nurse or pharmacist. If you are unsure apply some of the spray to a small area and leave it for about 30 minutes to see if a reaction develops.

HOW TO APPLY YOUR MEDICINE
It is important to apply the spray as directed by the doctor or nurse who prescribed or recommended it to you.

- This spray is for external use only.
- SHAKE THE CAN WELL BEFORE USE.
- Remove the white plastic cap.
- Hold the can eight inches away from the skin surface and protect the eyes if necessary, especially in young children.
- Press the nozzle gently to apply the spray at right angles to the skin surface, in a thin, even layer.
- Two to three seconds should be sufficient for an area the size of the buttocks.
- Avoid inhaling the spray. A mild cooling sensation may be experienced on application.
- The spray can be re-applied as often as necessary and for as long as the skin requires protection.

IMPORTANT INFORMATION AFTER TAKING YOUR MEDICINE
This medicine may cause side effects in some people, including local skin reactions (eg. contact dermatitis) due to the presence of Wool fat and Cetostearyl alcohol.
If you develop an allergic reaction after using this medicine or if the skin condition is made worse, discontinue use and consult your doctor.
If you accidentally spray this medicine into your eyes, bathe them thoroughly in water and consult your doctor.
When used with other skin applications, the film created by this medicine may be disturbed.

STORING YOUR MEDICINE
Store away from heat and replace the plastic cap after use. The can is a pressurised aerosol container. Do not puncture, incinerate or expose to temperatures over 50°C (122°F), even when it is empty. It is highly flammable.
Keep this medicine out of reach and sight of children.
If you have any medicine left after finishing your treatment, you may return it to your pharmacist or nurse.
Do not use this medicine after the date printed on the base of the can.

MORE INFORMATION ABOUT YOUR MEDICINE
The spray contains the active ingredients Zinc Oxide 12.5% w/w and Dimeticone 1.04% w/w.
The spray also contains White Petrolatum, Wool fat, Liquid Paraffin, Cetostearyl alcohol, Wool alcohols, Dextran CB, Purified water and propellant Butane (E943a) / Propane (E944) mix.

One of the active ingredients in this medicine is Dimeticone. This is the new name for Dimethicone. The ingredient itself has not changed.

REMEMBER: This spray is for YOU. It has been prescribed or recommended for you. Never give it to anyone else. It may be unsuitable for them even if their symptoms are the same as yours.

The Manufacturing Authorisation Holder is: Ayrton Saunders Ltd., Peninsular Business Park, Reeds Lane. Morton, Wirral, Merseyside, CH46 1DW, United Kingdom.

The manufacturer is: Pharmasol Limited, North Way, Walworth Industrial Estate, Andover, Hants. SP10 5AZ, United Kingdom.

The information in this leaflet only applies to Silon.
*Trade mark of Ayrton Saunders Ltd.

Date of preparation: June 2007

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LABELLING