Public Assessment Report

Zeroneum

Soya Bean Oil

PL 18962/0004

Zeroderma Ltd

Table of Contents

Lay Summary

The MHRA granted a Marketing Authorisation (licence) to Zeroderma Ltd for the medicinal product Zeroneum on 11/08/2008. The product contains the active ingredient Soya bean oil and is indicated for use to treat dry skin conditions including those associated with dermatitis and eczema. Zeroneum was developed in response to the need for a suitable non-irritant cleansing agent for patients with eczema. The product is available without prescription.

Scientific Discussion

INTRODUCTION

Based on the review of the quality, safety and efficacy, the MHRA granted a marketing authorisation for the medicinal product Zeroneum (PL 18962/0004) on 11/08/2008. The product is available without prescription. The application for a marketing authorisation was submitted under Article 10a off EC Directive 2001/83/EC, a bibliographic application.

The product formulation is based on that of Balneum which is currently marketed in the UK. Zeroneum differs in composition to Balneum, however, the medical assessor is content that there is sufficient similarity between the products for a Licence be granted for Zeroneum for the same indications as Balneum and a bibliographical application is appropriate.

The product contains the active ingredient Soya bean oil and is indicated for use to treat dry skin conditions including those associated with dermatitis and eczema. Zeroneum was developed in response to the need for a suitable non-irritant cleansing agent for patients with eczema. As the skin in this condition requires the application of large amounts of fat, cleansing properties as well as greasing properties were combined. Zeroneum contains a plant oil having a high proportion of unsaturated fatty acid (linoleic acid up to 60%). The emulsifier used is a mixture of fatty acid amides with aliphatic alcohol and readily dispersible macrogol lauryl ester.

PHARMACEUTICAL ASSESSMENT

DRUG SUBSTANCE

An appropriate specification based on the Ph Eur monograph for soya bean oil has been provided.

Analytical methods have been appropriately validated and are satisfactory for ensuring compliance with the relevant specifications.

Soya bean oil is stored in appropriate packaging. The specifications and typical analytical test reports are provided and are satisfactory.

Batch analysis data are provided and comply with the proposed specification. The applicant has confirmed that the soya bean oil will comply with the Ph Eur specification immediately prior to use.

DRUG PRODUCT

Other ingredients

The other ingredients in the drug product are

Macrogol lauryl ether (Laureth-4)
Comperlan (oleic acid diethanolamide)
Butylated hydroxytoluene (E321)
Propylene glycol
Perfume (Balneum A167139).

Manufacture
A description and flow-chart of the manufacturing method has been provided.

In-process controls are appropriate considering the nature of the product and the method of manufacture. Process validation has been carried out on batches of each strength. The results are satisfactory.

Finished product specification
The finished product specification is satisfactory. Acceptance limits have been justified with respect to conventional pharmaceutical requirements and, where appropriate, safety. Test methods have been described and have been adequately validated, as appropriate. Batch data have been provided and comply with the release specification.

Container
The product is contained in a HDPE bottle with pack sizes of 250ml and 500ml. Specifications and Certificates of Analysis for all packaging types used have been provided. These are satisfactory.

Stability
Finished product stability studies have been conducted in accordance with current guidelines. Based on the results, a shelf-life of 2 years has been set, which is satisfactory. Storage conditions are “Do not store above 25 degrees”.

ASSESSOR’S OVERALL CONCLUSIONS ON QUALITY AND ADVICE
A Marketing Authorisation was granted.

PRE-CLINICAL ASSESSMENT

No new pre-clinical data were submitted and none were required for this application.

MEDICAL ASSESSMENT

Introduction

Skin conditions such as eczema and dermatitis constitute a large burden on the NHS. The overall cumulative prevalence of atopic dermatitis alone is between 5-15% by 7 years of age and 2-10% in adults and dermatological conditions account for approximately 8% of GP consultations (of which about 25% are for dermatitis of some form). Thus effective self-management using emollients has a major role in containing such conditions. In addition, significant psychological morbidity is associated with unsightly skin conditions. Emollients trap water on the surface of the skin, causing swelling of the stratum corneum and closure of the cracks which are associated with dry (ichthyotic) skin conditions. They thus restore the epidermal barrier. They are used to soothe, smooth and hydrate the skin and are indicated for all dry or scaling skin disorders, including eczema. A wide range of emollients is available ranging from aqueous cream to greasier preparations including soft white paraffin and emulsifying ointments/liquids. In addition cleaning agents, for use instead of soap which may exacerbate some skin conditions, are available. The effects of emollients are short-lived and they must be applied frequently, even after improvement occurs.

Zeroneum is a liquid preparation with skin cleansing and emollient properties which is intended for external administration by addition to bath water. The active ingredient, soya bean oil, is a purified mixture of glycerides present as linoleic, linolenic, oleic, palmitic and stearic acids with other acids present in trace quantities. The main excipients are laureth-4 (Simulsol P4), a non-ionic surfactant with skin-cleansing activity and which may improve the penetration of the soya oil into the skin layer and oleic acid diethanolamide, a thickener which may have some emollient activity of its own.

Overall Conclusion and Risk/Benefit Analysis

Quality

The quality aspects of the product were confirmed to be identical to the reference product.

Pre-Clinical

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

Clinical

No new clinical data were submitted and none are required for applications of this type.

Risk/Benefit Analysis

The product was demonstrated to be sufficiently similar to the reference product, which has already been found to have a positive risk/benefit ratio.

Steps Taken During Assessment

1	The MHRA received the application on 04/04/2002.
2	Following standard checks and communication with the applicant the MHRA considered the application valid on 24/06/2002.
3	Following assessment of the application the MHRA requested further information from the applicant regarding the quality assessment on 19/07/2002 and on the medical assessment on 12/07/2002
4	The applicant provided further information in regard to the quality assessment on 14/07/2003 and 0/03/2008 and on the medical assessment on 14/07/2003
5	The application was determined on 11/08/2008.

Steps Taken after Assessment

No non-confidential changes have been made to the market authorisation.

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Zeroneum.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Soya bean oil, refined 83.35% w/w.

3 PHARMACEUTICAL FORM

Cutaneous Solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Dry skin conditions including those associated with dermatitis and eczema.

4.2 Posology and method of administration

For cutaneous use.

The liquid should be added to the bath water.

For full bath (approx. 100 litres) - 20ml (1 measure).

For child's bath (approx. 25 litres) - 5ml (1/4 measure).

For partial bath (approx. 5 litres) - 2.5ml (1/8 measure).

In particularly dry skin, 2-3 times the above quantities can be used.

Generally, 2-3 baths should be taken weekly. For babies and infants a daily bath is recommended.

4.3 Contraindications

Known hypersensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

This product contains soya oil and should not be used by patients who are allergic to peanut or soya.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

Not known.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

None.

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Zeroneum was developed in response to the need for a suitable non-irritant cleansing agent for patients with eczema. As the skin in this condition requires the application of large amounts of fat, cleansing properties as well as greasing properties were combined. Zeroneum contains a plant oil having a high proportion of unsaturated fatty acid (linoleic acid up to 60%). The emulsifier used is a mixture of fatty acid amides with aliphatic alcohol and readily dispersible macrogol lauryl ester. Butylated hydroxytoluene is added as an antioxidant.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Macrogol lauryl ether (Laureth-4)
Comperlan (oleic acid diethanolamide)
Butylated hydroxytoluene (E321)
Propylene glycol
Perfume (Balneum A167139).

6.2 Incompatibilities

None known.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Container: HDPE bottle with polyethylene or polypropylene cap containing 250ml or 500ml of solution.

6.6 Special precautions for disposal

None.

7 MARKETING AUTHORISATION HOLDER

Zeroderma Ltd
Manor House
Victors Barn
Northampton Road
Brixworth
Northamptonshire NN6 9DQ

8 MARKETING AUTHORISATION NUMBER(S)

PL 18962/0004.

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

11/08/2008

10 DATE OF REVISION OF THE TEXT

11/08/2008

Labels and Leaflets