

IPAR

Public Assessment Report for a Traditional Herbal Medicinal Product for Human Use

Weleda Calendula Cuts and Grazes Skin Salve Ointment
Calendula tincture

TR0407/003/001
TR holder: Weleda (UK) Ltd

I INTRODUCTION

Specific provisions were introduced for traditional herbal medicinal products (THMPs) in accordance with the Traditional Herbal Medicinal Products Directive (2004/24/EC). The national regulations, the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007) which implement this Directive came into force on 23rd July 2007. Consequently the Health Products Regulatory Authority (HPRA) has established the Traditional Herbal Medicinal Products Registration Scheme.

The Public Assessment Report reflects the scientific conclusion reached by the HPRA at the end of the evaluation process and provides a summary of the grounds for approval of a Certificate of Traditional Use Registration for a specific traditional herbal medicinal product for human use. It is made available by the HPRA for information to the public, after deletion of commercially sensitive information. The legal basis for its creation and availability is contained in Article 21 of EC Directive 2001/83/EC, as amended by Directive 2004/27/EC and Directive 2004/24/EC. It is a concise document which highlights the main parts of the documentation submitted by the applicant and the scientific evaluation carried out by the HPRA leading to the approval of the traditional herbal medicinal product for marketing in Ireland.

Based on the review of the data on quality, safety and traditional use, the HPRA has granted Weleda (UK) Limited a Certificate of Traditional Use Registration for Weleda Calendula Cuts and Grazes Skin Salve Ointment, containing a tincture of Calendula, flower and herb.

This application is for a traditional herbal medicinal product as defined by Article 16a(1) of Directive 2001/83/EC, as amended and was submitted as part of the Traditional Herbal Medicinal Product Registration Scheme.

The Summary of Product Characteristics (SmPC) for this traditional herbal medicinal product is available on the HPRA's website.

II QUALITY ASPECTS

Weleda Calendula Cuts and Grazes Skin Salve Ointment is identical to Calendolon Ointment 20% v/w Calendula officinalis Ointment which has been authorised as a medicinal product since 11th October 1991 (PA 407/5/1) with the same marketing authorisation holder, Weleda (U.K), Ltd. The chemical and pharmaceutical data provided in support of the current application for traditional use registration have not been reassessed at this time.

III NON-CLINICAL ASPECTS

Weleda Calendula Cuts and Grazes Skin Salve Ointment, is identical to Calendolon Ointment 20% v/w Calendula officinalis Ointment which has been authorised as a medicinal product since 11th October 1991 (PA 407/5/1).

No new non-clinical studies have been submitted. Given the type of application and limited data available, it is not possible to assess if the safety package for the phytochemical constituents of Weleda Calendula Cuts and Grazes Skin Salve Ointment, are acceptable to the standards of today's GLP and safety testing requirements.

An environmental risk assessment is not required for herbal medicinal products according to guidance CPMP/SWP/4447/00.

IV CLINICAL ASPECTS

Weleda Calendula Cuts and Grazes Skin Salve Ointment, is a traditional herbal medicinal product used for minor wounds, cuts and grazes. Exclusively based on longstanding use.

IV.1 Clinical Efficacy

Weleda Calendula Cuts and Grazes Skin Salve Ointment, is identical to Calendolon Ointment 20% v/w Calendula officinalis Ointment which has been authorised as a medicinal product since 11th October 1991 (PA 407/5/1). The clinical data provided in support of the current application for traditional use registration have not been reassessed at this time.

The efficacy of this traditional herbal medicinal product is plausible on the basis of long standing use and experience.

The indication proposed for Weleda Calendula Cuts and Grazes Skin Salve ointment is in line with traditional indications recorded and hence, compatible with the requirements of the Traditional Herbal Medicinal Products Directive 2004/24/EC.

IV.2 Clinical Safety

Since no data on the safe use in children are available, the use in children under 6 years of age is not recommended.

If symptoms worsen, persist or do not improve after one week, or if signs of skin infection are observed a qualified health care professional e.g. a doctor or pharmacist should be consulted.

Discontinue use if redness, irritation or dry skin occurs.

Avoid contact with the eyes or mucous membranes.

Contains Wool Fat (Lanolin) which may cause local skin reactions (e.g. contact dermatitis).

Undesirable effects

Skin sensitisation has been reported. The frequency is not known

In conclusion, this product proves not to be harmful in the specified conditions of use.

IV.3 Pharmacovigilance

It should be noted that in accordance with Article 16g of Directive 2001/83/EC, as amended, the pharmacovigilance requirements described in Articles 101- 108 of Directive 2001/83/EC, as amended, also apply in respect of traditional herbal medicinal products.

V OVERALL CONCLUSIONS

Weleda Calendula Cuts and Grazes Skin Salve Ointment is identical to Calendolon Ointment 20% v/w Calendula officinalis Ointment which has been authorised as a medicinal product since 11th October 1991 (PA 407/5/1) with the same marketing authorisation holder, Weleda (U.K), Ltd. The chemical and pharmaceutical data provided in support of the current application for traditional use registration have not been reassessed at this time.

The HPRA, on the basis of the data submitted, considered that Weleda Calendula Cuts and Grazes Skin Salve Ointment demonstrated adequate evidence of traditional use for the approved indication(s) and no new non-clinical or clinical safety concerns have been identified.

A Certificate of Traditional Use Registration for Weleda Calendula Cuts and Grazes Skin Salve Ointment is granted.