IRISH MEDICINES BOARD ACT 1995, as amended

Medicinal Products (Control of Placing on the Market) Regulations, 2007, as amended

PA0102/017/001
Case No: 2043376

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Norgine Limited

Chaplin House, **Widewater Place, Moorhall Road**, **Harefield**, **Uxbridge**, **Middlesex UB9 6NS**, **United Kingdom**

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Posalfilin Ointment

the particulars of which are set out in the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **01/04/2008**.

Signed on behalf of the Irish Medicines Board this

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A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Posalfilin Ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 10 g tube of POSALFILIN Ointment contains 20% w/w Podophyllum Resin and 25% w/w Salicylic Acid.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Dark brown opaque ointment with a characteristic odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the treatment of plantar warts.

4.2 Posology and method of administration

Adults (including the elderly) and Children: A corn ring should be placed around the wart, cutting the ring to fit if necessary. A minimal amount of ointment should be applied to the exposed wart, taking care to avoid normal skin. The wart and corn ring should be covered with a plaster and the treatment repeated daily. When the wart appears soft and spongy, it should be left exposed and allowed to drop off. If the wart remains, the procedure should be repeated.

4.3 Contraindications

Use in pregnancy, breastfeeding mothers, bleeding or friable warts. Patients with peripheral neuropathy, diabetes mellitus or peripheral vascual insufficiency. Should not be used on the skin of the face, arm pits or ano-genital region.

4.4 Special warnings and precautions for use

Misapplication of POSALFILIN Ointment to healthy skin may cause inflammation, desquamation or necrosis. Treatment should be suspended if such inflammation occurs.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

Contraindicated in pregnancy and breastfeeding mothers.

4.7 Effects on ability to drive and use machines

There is no effect on the ability to drive and use machines

4.8 Undesirable effects

POSALFILIN Ointment does not normally cause side effects when used as directed.

4.9 Overdose

Over-application can cause cutaneous necrosis and should be treated as a caustic burn.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

The salicylic acid macerates the horny layer covering the wart and allows the podophyllum to penetrate the wart where it has a specific cytotoxic effect on the nuclei of the hyperplastic cells.

5.2 Pharmacokinetic properties

Not applicable, as POSALFILIN Ointment applied topically directly to the wart.

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 of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Yellow Soft Paraffin.
Liquid Paraffin.

6.2 Incompatibilities

None known.

6.3 Shelf Life

The shelf life is 4 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Aluminium tube containing 10g of ointment.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

None.

7 MARKETING AUTHORISATION HOLDER

Norgine Limited,
Chaplin House,
Widewater Place,
Moorhall Road,
Harefield,
UXBRIDGE,
Middlesex,
UB9 6NS,
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA 102/17/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st April 1983

Date of last renewal: 1st April 2008

10 DATE OF REVISION OF THE TEXT

June 2010