SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

2. Qualitative and quantitative composition

3. Pharmaceutical form

4. Clinical particulars

4.1 Therapeutic indications

4.2 Posology and method of administration

4.3 Contraindications

4.4 Special warnings and precautions for use

4.5 Interaction with other medicinal products and other forms of interaction

4.6 Fertility, pregnancy and lactation

4.7 Effects on ability to drive and use machines

4.8 Undesirable effects

4.9 Overdose

5. Pharmacological properties

5.1 Pharmacodynamic properties

5.2 Pharmacokinetic properties

5.3 Preclinical safety data

6. Pharmaceutical particulars

6.1 List of excipients

6.2 Incompatibilities

6.3 Shelf life

6.4 Special precautions for storage

6.5 Nature and contents of container

6.6 Special precautions for disposal and other handling

7. Marketing authorisation holder

8. Marketing authorisation number(s)

9. Date of first authorisation/renewal of the authorisation

10. Date of revision of the text

1. Name of the medicinal product

PODOSAL OINTMENT

2. Qualitative and quantitative composition

Each gm contains Podophyllum resin 20% w/w, Salicylic acid 25% w/w

3. Pharmaceutical form

Topical Ointment.

4. Clinical particulars

4.1 Therapeutic indications

For the topical treatment of warts

4.2 Posology and method of administration

For adults, children and the elderly: Podosal Ointment should be applied once daily. The Ointment should be applied once every night. Treatment can take several weeks for resistant lesions to disappear and it is necessary to persevere with the treatment.

1. Every night, soak the affected site in warm water for 2 to 3 minutes.

2. Dry thoroughly with the patient's own towel.

3. Carefully apply one or two drops of the Ointment to the lesion and allow to dry over its surface. Take care to avoid surrounding normal skin. No adhesive plaster is necessary.

4. The following evening, carefully remove and discard the elastic film formed from the previous application, and re-apply the Ointment. Occasionally, if removal of the elastic film proves difficult, carefully re-apply the Ointment over it and allow to dry. This should help thicken the film to assist removal. If necessary, such re-application may be made on two or three successive days.

5. Once a week, gently rub away the treated surface using an emery board, as provided, or pumice stone used only for this purpose, before re-applying the Ointment.

6. The wart, verruca, corn or callus may take several weeks to disappear and it is important to persevere with the treatment.

7. At the end of treatment, if the elastic film is difficult to remove, it may be allowed to remain on the skin until it sheds.

4.3 Contraindications

Not to be used on or near the face, neck, intertriginous or anogenital regions, or by diabetics or individuals with impaired peripheral blood circulation.

Not to be used on moles, birthmarks, hairy warts or on any other skin lesions for which the Ointment is not indicated.

Not to be used in cases of sensitivity to any of the ingredients.

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

Concomitant use with other Podophyllotoxin containing preparations.

4.4 Special warnings and precautions for use

Where the area of treatment is greater than 4 cm2, it is recommended that treatment takes place under the direct supervision of a healthcare professional.

Avoid applying the cream to warts occurring on mucous membranes of the genital area (including the urethra, rectum and vagina).

Avoid applying the cream to surrounding healthy tissue.

Avoid contact with eyes. Should the cream accidentally come into the eye, the eye should be thoroughly rinsed with water and medical advice sought.

Occlusive dressings should not be used on areas treated with the cream.

Local irritation may occur on the second or third day of application associated with the start of wart necrosis. In most cases, the reactions are mild. If severe local skin reactions occur (bleeding, swelling, excessive pain, burning, itching) the cream should be washed immediately from the treatment area with mild soap and water, treatment discontinued and the patient advised to seek medical advice.

Keep away from the eyes, mucous membranes and from cuts and grazes.

The Ointment should be applied carefully to the wart, verruca, corn or callus only, to avoid possible irritation of surrounding normal skin.

Do not use excessively.

Some mild, transient irritation may be expected, but in cases of more severe or persistent pain/irritation, the treatment should be suspended and/or discontinued. See also section “Undesirable Effects”.

Avoid inhaling vapour, and keep cap firmly closed when not in use.

Contact with clothing, fabrics, plastics and other materials may cause damage, and should be avoided.

For external use only.

Keep all medicines out of reach and sight of children.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

No special precautions necessary.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Podosal Ointment may be irritant in certain patients, which in rare instances may appear as a temporary blemish on the skin. See also section “Special Warnings and Precautions for Use”.

4.9 Overdose

Any excessive use of Podosal Ointment could cause irritation of the skin. If this occurs, Podosal Ointment should be used more sparingly or applied less frequently.

While serious systemic effects have not been reported with the recommended dosage of topical Podophyllotoxin, topical overdosage would be expected to increase systemic absorption of the drug and increase the potential for systemic effects, e.g. altered mental state and bone marrow suppression. Following oral ingestion, Podophyllotoxin may also cause severe gastroenteritis.
Treatment
If topical overdosage occurs, Podophyllotoxin should be washed immediately from the treatment area and symptomatic and supportive therapy initiated.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Podophyllotoxin is a metaphase inhibitor in dividing cells binding to at least one binding site on tubulin. Binding prevents tubulin polymerization required for microtubule assembly. At higher concentrations, podophyllotoxin also inhibits nucleoside transport through the cell membrane.

The chemotherapeutic action of podophyllotoxin is assumed to be due to inhibition of growth and the ability to invade the tissue of the viral infected cells.

The active ingredient, salicylic acid, is a well-established pharmacopoeial substance, which has been used extensively in dermatological therapy for its keratolytic properties.

When applied topically, and in high enough concentrations, salicylic acid acts by achieving a slow, painless destruction of the thickened stratum corneum. It softens and destroys the thickened stratum corneum of the affected tissue by reducing the adhesiveness of the corneocytes while causing the cornified epithelium to swell, soften, macerate and finally desquamate. In the treatment of warts and verrucas, a mild inflammatory reaction, which may render the virus more prone to immunologic attack, may assist resolution of the condition.

The use of topical salicylic acid formulated in simple dosage forms at high concentrations and in evaporative vehicles designed to concentrate in use, thereby localising the keratolytic precisely over circumscribed small areas of skin, is commonplace. It has become exceedingly popular with doctors and patients alike, where its safety and efficacy have been very well established through widespread use over many decades.

5.2 Pharmacokinetic properties

Podophyllotoxin is a metaphase inhibitor in dividing cells binding to at least one binding site on tubulin. Binding prevents tubulin polymerization required for microtubule assembly. At higher concentrations, Podophyllotoxin also inhibits nucleoside transport through the cell membrane.

The chemotherapeutic action of Podophyllotoxin is assumed to be due to inhibition of growth and the ability to invade the tissue of the viral infected cells.

Podosal Ointment presents 25% salicylic acid in an evaporative collodion-like Ointment application which dries to form a cohesive and adhesive film on the skin.

The formulation offers the highest concentration of salicylic acid commensurate with presenting it in a convenient collapsible Aluminium tube fitted with a special applicator nozzle, allowing it to be dispensed precisely to the affected area(s). This minimizes the spread of the preparation onto the surrounding healthy skin, which could otherwise lead to inflammation, irritation and poor patient compliance.

The film-forming characteristics of the collodion-like Ointment vehicle also offer distinct advantages in clinical usage. The Ointment quickly forms a surface film, well before it dries completely, thereby prolonging the period during which the keratolytic solution can properly infiltrate and achieve intimate contact with the surface layers of the thickened stratum corneum.

Furthermore, even when the film appears to dry completely, a proportion of the salicylic acid remains in solution within the vehicle, thus permitting continued release of the keratolytic, which may otherwise be entrapped within the dried collodion-like film. The Ointment yields a robust flexible film which is firmly anchored to the skin, and can therefore be used, even on the sole of the foot, without the added protection of a plaster.

The availability of salicylic acid has been demonstrated by applying the Ointment to the normal skin of human volunteers, whereupon the salicylic acid produced a marked irritant effect similar to that of existing preparations. In clinical use, its application will, of course, be restricted to the hyperkeratotic lesions.

5.3 Preclinical safety data

No special information.

6. Pharmaceutical particulars

6.1 List of excipients

Liquid Paraffin; White soft paraffin

6.2 Incompatibilities

None known.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

Collapsible tube containing 10g,

6.6 Special precautions for disposal and other handling

Not applicable.

7. Marketing authorization holder

Biodeal Laboratories Ltd
Plot No.123, Lunga Lunga P.O Box 32040-00600, Nairobi, Kenya
Telephone: +254 720 333829
E-mail: regulatoryaffairs@biodealkenya.com

8. Marketing authorization number(s)

H2009/20690/316

9. Date of first authorization/renewal of the authorization

19 July 2009.

10. Date of revision of the text

July 2022.