Drugfield PHARMACEUTICALS LIMITED

SUMMARY OF PRODUCT CHARACTERISTIC

(SmPC)

DRULLOMACK® SOLUTION
(Salicylic Acid 2.0g + Lactic Acid 0.5g + Polidocanol 0.2g)

1. NAME OF THE MEDICINALPRODUCT

DRULLOMACK® SOLUTION
(Salicylic Acid 2.0g + Lactic Acid 0.5g + Polidocanol 0.2g)

2. QUALITATIVE AND QUANTITATIVECOMPOSITION

Each ml contains Salicylic Acid 2.0g + Lactic Acid 0.5g + Polidocanol 0.2g

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Liquid (Solution)

4. Clinical particulars

4.1 Therapeutic indications

Salicylic Acid

Salicylic acid has keratolytic properties. Preparations containing up to 60% salicylic acid havebeen used as a caustic for the removal of plantar warts, corns or calluses

Lactic Acid

Lactic Acid is employed topically in the treatment of warts often with salicylic acid. Lactic acid isused in the treatment of mild to severe forms of dry scaly skin. Lactic acid is a humectants.
Exactly how it works is unknown but it increases the amount of water in the skin, making itsofter and more pliable.

Polidocanol

Polidocanol is a sclerosing agent used as a local anaesthetic and antipruritic. It is a nonionicsurface

Drullomack® Solution is used for the removal of corns, warts and callus.

Posology and method of administration

Posology

Important Dosage and Administration Instructions

Drullomack® to be applied twice a day directly on corns. After a few days' application, corns can be removed. When applying between toes, it is advisable to protect the healthy skin with zinc oxide ointment.

Drullomack® to be applied twice a day directly on calluses, after an application of 3-4 days soak foot in hot water and peel off loose parts. If the callus still persists, continue Drullomack® applications until it can be removed completely.

Drullomack® to be applied twice a day directly on warts. Small to medium-size warts disappear after a few days application. Soaking the affected area in hot water has a supporting effect.

Initial Dosage

Apply one drop of the solution in the morning and in the evening. After a few days of treatment, a hot bath is indicated in order to achieve detachment of the corn.

Method of administration

Topical administration

4.2 Contraindications

Drullomack® Solution is contraindicated in patients with a prior hypersensitivity reaction to salicylic acid, lactic acid or any other ingredient of the preparation.

Do not use on open wounds, irritated or reddened skin, or any area that is infected. Do not use on moles, birthmarks, genital warts, warts on the face or mucous membranes, or warts withhair growing from them, red edges, or an unusual colour.

4.3 Special warnings and precautions for use

Drullomack® Solution should not be on the face or anogenital regions. Avoid applying to normal skin. Salicylic acid and lactic acid solution may cause eye irritation. Avoid contact with eyes and other mucous membranes. In case of accidental contact with the eyes or other mucous membranes, flush with water for 15 minutes. Avoid exposure to healthy skin (see Undesirable Effects). Salicylic acid and lactic acid solution may cause skin irritation. If undue skin irritation develops treatment should be discontinued. Consider alternative treatments if warts cover a large area of the body (more than 5 cm2) due to the potential risk of salicylate toxicity.

Interaction with other medicinal products and other forms of interaction

Topical salicylic acid and lactic acid solution may increase the absorption of other topically applied medicines. Therefore, concomitant use of DRULLOMACK SOLUTION and other topical medicines on the treated area should be avoided. As systemic exposure of topically applied salicylic acid and lactic acid solution is low, interaction with systemically administered medicinesis not anticipated.

4.4 Pregnancy and Lactation

Pregnancy

The safety of salicylic acid and lactic acid solution during human pregnancy has not been established. Studies in animals given salicylic acid orally demonstrated embryo-toxicity at highdoses.

Lactation

Drullomack® Solution is not advised to be used during breastfeeding. If used or administereddduring lactation, care should be taken to avoid contact with the breast area in order to avoid accidental ingestion by the infant.

Females and Males of Reproductive Potential

No human studies of the effects of clotrimazole on fertility have been performed; however,animal studies have not demonstrated any effects of the drug on fertility.

4.5 Effects on ability to drive and use machines

No effects are anticipated based on the adverse reaction profile.

4.6 Undesirable effects

The following convention is used for the classification of the frequency of an adverse reactionand is based on the CIOMS guidelines:

Very common:≥1/10
Common:≥1/100 to <1/10
Uncommon:≥1/1000 to <1/100
Rare:≥1/10000 to <1/1000 Very
rare:<1/10000
Not known:(Cannot be estimated from the available data)

Clinical Trial Date
Immune system disorders
Common: Rash Skin and subcutaneous tissue disorders
Very common: Application site reaction, pruritus, burning sensation, erythema, scaling, drynessCommon: Skin hypertrophy

4.7 Overdose

Symptoms and Signs

In the event of accidental oral ingestion symptoms of salicylate toxicity may occur.The risk of developing symptoms of salicylate poisoning or salicylism is increased if topical salicylic acid andlactic acid solution is used excessively or if it is used for prolonged periods of time. Therefore, duration of use and recommended frequency compliance is very important.

Treatment

Management should be as clinically indicated or as recommended by the national poisons centre, where available. There is no specific treatment for accidental oral ingestion of salicylicacid and lactic acid solution. If accidental oral ingestion occurs, the patient should be treatedaccording to local guidelines with appropriate monitoring as necessary.

5. PHARMACOLOGICALPROPERTIES

5.1 Pharmacodynamics properties

Pharmacotherapeutic group: Antifungals for topical use – imidazole and triazole derivatives ATC Code: D01A C01

Mechanism of Action And Pharmacodynamics

Topically applied salicylic acid is keratolytic. The keratolytic activity produces desquamation bysolubilising the intercellular cement in the stratum corneum resulting in the shedding of skin scales.
Lactic acid affects the keratinisation process, reducing the hyperkeratosis which is characteristic of warts, corns and calluses. At high concentrations it can cause epidermolysis, leading to the destruction of the keratotic tissue, and in the case of warts, of the causative virus. It also has antiseptic properties. Flexible collodion provides a viscous vehicle that allows accurate application of the active ingredients to the wart, corn or callus. It also forms a film thathelps to hydrate and promote the destruction of hyperkeratotic tissue.

5.2 Pharmacokinetic properties

Absorption
Salicylic acid is absorbed through the skin; where detectable, maximum plasma levels are found 6 to 12 hours after application. Systemic absorption of salicylic acid has been reported to range from 9% to 25% after topical application of other salicylic acid-containing preparations. The extent of absorption is variable depending on the duration of contact and the vehicle. Despite percutaneous absorption, the systemic exposure is low given the low dosetopically administered to small, localised areas of hyperkeratotic tissue. Human abdominal skin in a flow-through diffusion system was used to assess the in vitropercutaneous absorption of lactic acid. At a pH of 3, the amount of radioactivity detected in the receptor fluid, stratum corneum, epidermis, and dermis was 3.6, 6.3, 6.6, and 13.9%, respectively.
Distribution
Following percutaneous absorption, salicylic acid is distributed in the extracellular space; approximately half of which is protein bound to albumin.
Metabolism
Salicylates are metabolised in the liver by microsomal enzymes to salicyluric acid and phenolicglucuronides of salicylic acid. That which is not metabolised is excreted in the urine as unchanged salicylic acid.
Elimination
Within 24 hours of salicylic acid being absorbed and distributed in the intercellular space, approximately 95% of the absorbed dose can be recovered in the urine.

5.3 Preclinical safety data

Preclinical safety data on salicylic acid and lactic acid obtained from the literature and in-househave not revealed findings which are of relevance to the recommended dosage and use of theproduct

6.0 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Dibutylphthalate

Resorcinol

Ethyl Cellulose

Acetone

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 Months

6.4 Special precautions for storage

Store below 30^{o}C in tight container protected from light and moisture.

6.5 Nature and contents of container and special equipment for use, administration orimplantation

Drullomack® is a colourless solution in amber bottle with a total content of 10ml covered witha white plastic cap packed in hardboard carton with leaflet enclosed.

6.6 Special precautions for disposal and other handling

No special requirements.

7.0 Applicant/Manufacturer

Drugfield Pharmaceuticals Limited

Lynson Chemical Avenue Km38,

Lagos-Abeokuta Expressway Sango-Otta, Ogun State,

Nigeria Tel: +2348033513989

Email:Info@drugfieldpharma.com