

Summary of Product Characteristics

1. Name of the medicinal product

WHITFIELD'S OINTMENT BP

2. Qualitative and quantitative composition

Benzoic Acid BP.....6 % W/W

Salicylic Acid3 % W/W

Paraffin Base..... Q.S.

For the full list of excipients see section 6.1

3. Pharmaceutical form

Ointment

4. Clinical particulars

4.1 Therapeutic indications

Whitfield's Ointment BP contains Benzoic Acid & Salicylic Acid. It is indicated for the topical treatment of localised fungal infections of the skin. Benzoic acid helps prevent infection caused by bacteria. Salicylic acid helps the body shed rough or dead skin cells. Benzoic acid and salicylic acid topical (for the skin) is a combination medicine used to treat skin irritation and inflammation caused by burns, insect bites, fungal infections, or eczema.

4.2 Posology and method of administration

Topical administration Adults (including the elderly) and Children Apply to the affected area 1 to 3 times a day as necessary or as advised by a doctor.

4.3 Contraindications

Hypersensitivity to any of the ingredients of the Whitfield's Ointment BP.

4.4 Special warnings and precautions for use

Should not be applied over mucous membranes, large areas of skin or denuded skin surfaces. If symptoms persist beyond 10 days, the advice of a doctor should be sought. Prolonged and excessive use may result in absorption of sufficient salicylic acid to interact with other drugs such as anticoagulants.

4.5 Interaction with other medicinal products and other forms of interaction

None stated.

4.6 Fertility, pregnancy and lactation

Safety of use during pregnancy or lactation has not been established and the use requires careful consideration of benefits versus potential and unknown risks.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

Side effects With Whitfield's Ointment BP are very rare.

Benzoic Acid: Allergic reactions to Benzoic Acid have been reported. It can be irritant to the eyes, skin and mucous membranes.

Salicylic Acid: Salicylic Acid is a mild irritant, and application of preparations containing salicylic acid to the skin may cause dermatitis.

Symptoms of acute salicylate poisoning have been reported after prolonged application of salicylic acid ointments to large areas of the body.

Reporting of suspected adverse reactions: Healthcare professionals are asked to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS)

<https://pv.pharmacyboardkenya.org>

4.9 Overdose

Overdose is unlikely, but in the event of accidental swallowing gastric irritation, nausea and vomiting may occur. Treatment is symptomatic and supportive.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Whitfield's Ointment BP contains Benzoic Acid & Salicylic Acid. Benzoic Acid act as antibacterial and antifungal agent. Salicylic Acid is bacteriostatic and fungicidal. It also possesses keratolytic properties.

5.2 Pharmacokinetic properties

The active ingredients slowly destroy the cells of any fungi or bacteria present. The epithelium is also slowly and painlessly destroyed. If systemic absorption occurs, benzoic acid is conjugated with glycine in the liver to form hippuric acid which is rapidly excreted in the urine. It may also be excreted as benzoglucuronic acid. Salicylic Acid is rapidly distributed to all the body tissues if absorbed, and the rate of excretion in the urine is dependent on the pH.

5.3 Preclinical safety data

None stated.

6. Pharmaceutical particulars

6.1 List of excipients

Cetomacrogol 1000 INH

Cetostearyl Alcohol BP

Hard Paraffin BP

Micro Crystalline Wax BP

White Soft Paraffin BP

6.2 Incompatibilities

None known.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store at temperature not exceeding 30°C.

6.5 Nature and contents of container

20 gm lami tube packed in inner carton along with the leaflet.

6.6 Special precautions for disposal and other handling

Not applicable.

7. Marketing Authorization holder

KREMOINT PHARMA PVT. LTD.

Plant: B-8, Additional Ambernath,

M.I.D.C., Ambernath (East),

Dist. Thane – 421 506.

8. Marketing Authorization Number(s)

H2022/CTD8589/17640

9. Date of first Authorization/renewal of the Authorization

17/09/2019

10. Date of revision of the text

18TH August 2026