

1. NAME OF THE MEDICINAL PRODUCT

Whitfield's Ointment

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Salicylic Acid 3% Benzoic Acid 6%

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Ointment (Semi-solid)

4. Clinical particulars

Therapeutic indications

Whitfield's Ointment is used for the treatment of ringworm, and other fungal skin infections.

- (a) Salicylic acid has keratolytic properties and is applied topically in the treatment of hyperkeratotic and scaling skin conditions such as dandruff and seborrhoeic dermatitis, ichthyosis, psoriasis and acne; Whitfield's is used for mild dermatophytes infections particularly tinea pedis and tinea corporis.
- (b) Benzoic acid helps prevent infection caused by bacteria. Salicylic acid helps the body shed rough or dead skin cells.
- (c) 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.
- (d) Benzoic acid and salicylic acid may also be used for other purposes not listed in this medication guide.

Posology and method of administration

Posology

Important Dosage and Administration Instructions

This medicine is usually applied 2 times per day. Follow all directions on your prescription label. Do not use this medicine in larger or smaller amounts or for longer than recommended.

Do not take by mouth. Benzoic acid and salicylic acid is for use only on the skin. Do not use this medicine on open wounds or on sunburned, windburned, dry, chapped, or irritated skin. **If this medicine gets in your eyes, nose, mouth, rectum, or vagina, rinse with water.**

Wash your hands before and after applying benzoic acid and salicylic acid.

Gently rinse the affected skin with saline or water before treating it with this medicine. Pat the skin dry with a clean towel or cotton gauze.

Apply a generous amount of the medicine and spread it evenly to form a 1/8-inch thick layer over the treated area.

It is best to apply this medicine to your skin with a clean cotton swab. Throw the swab away after one use. You may also apply the medicine to a cotton gauze pad and then place the gauze over your skin.

Keep the treated skin area clean and expose it to air whenever possible.

Do not cover the treated skin area with an adhesive bandage unless your doctor tells you to.

Initial Dosage

Apply locally on the affected area 2-3 times per day.

Method of administration

Topical administration

Contraindications

The following conditions are contraindicated with this drug. Check with your physician if you have any of the following:

Conditions:

- peripheral vascular disease
- anemia from pyruvate kinase and G6PD deficiencies
- aspirin exacerbated respiratory disease

Allergies:

- Salicylates
- NSAIDS (Non-Steroidal Anti-Inflammatory Drug)
- Benzoic Acid
- Benzoate Analogues

Special warnings and precautions for use

Avoid using wet packs or wet-to-dry packs on the treated skin areas. They can make this medicine less effective.

Avoid getting the medicine in your eyes, mouth, or nose. If it does get into any of these areas, rinse with water.

Avoid using other medications on the areas you treat with benzoic acid and salicylic acid unless your doctor tells you to.

Interaction with other medicinal products and other forms of interaction

Avoid using other medications on the areas you treat with benzoic acid and salicylic acid unless your doctor tells you to.

It is not likely that other drugs you take orally or inject will have an effect on topically applied benzoic acid and salicylic acid. But many drugs can interact with each other. Tell each of your health care providers about all medicines you use, including prescription and over-the-counter medicines, vitamins, and herbal products.

Pregnancy and Lactation

Pregnancy

Risk Summary

It is not known whether benzoic acid and salicylic acid will harm an unborn baby. Tell your doctor if you are pregnant or plan to become pregnant while using this medicine.

Clinical Considerations

Tell your doctor if you are pregnant or plan to become pregnant while using this medicine.

Lactation

Risk Summary

It is not known whether benzoic acid and salicylic acid passes into breast milk or if it could harm a nursing baby.

Clinical Considerations

Tell your doctor if you are breast feeding a baby.

Females and Males of Reproductive Potential

Infertility

No sufficient studies in humans.

Effects on ability to drive and use machines

It is not likely for Whitfield's ointment to have effect on ability to drive and use machines.

Undesirable effects

Get emergency medical help if you have any of these **signs of an allergic reaction**: hives; difficult breathing; swelling of your face, lips, tongue, or throat.

Call your doctor at once if you have:

- severe burning or skin irritation; or
- burning sensation for longer than 10 days.

Common side effects may include:

- warmth or a burning sensation (may last up to 5 minutes after applying).

Overdose

Clinical Presentation

Symptoms of systemic salicylate poisoning (tinnitus, dizziness and deafness) have been reported after the application of salicylic acid to large areas of skin and for prolonged periods. Salicylism may also occur in the unlikely event of large quantities being ingested. Salicylism is unlikely to occur if Salicylic Acid Ointment BP is used as indicated.

Salicylate poisoning is usually associated with plasma concentrations $>350\text{mg/L}$ (2.5mmol/L). Most adult deaths occur in patients whose concentrations exceed 700mg/L (5.1mmol/L). Single doses less than 100mg/kg are unlikely to cause serious poisoning.

Symptoms

Common features include vomiting, dehydration, tinnitus, vertigo, deafness, sweating, warm extremities with bounding pulses, increased respiratory rate and hyperventilation. Some degree of acid-base disturbance is present in most cases.

A mixed respiratory alkalosis and metabolic acidosis with normal or high arterial pH (normal or reduced hydrogen ion concentration) is usual in adults and children over the age of four years. In children aged four years or less, a dominant metabolic acidosis with low arterial pH (raised hydrogen ion concentration) is common. Acidosis may increase salicylate transfer across the blood brain barrier.

Treatment of Overdose

Give activated charcoal if an adult presents within one hour of ingestion of more than 250mg/kg . The plasma salicylate concentration should be measured, although the severity of poisoning cannot be determined from this alone and the clinical and biochemical features must be taken into account. Elimination is increased by urinary alkalinisation, which is achieved by the administration of 1.26% sodium bicarbonate. The urine pH should be monitored. Correct metabolic acidosis with intravenous 8.4% sodium bicarbonate (first check serum potassium). Forced diuresis should not be used since it does not enhance salicylate excretion and may cause pulmonary oedema.

Haemodialysis is the treatment of choice for severe poisoning and should be considered in patients with plasma salicylate concentrations $>700\text{mg/L}$ (5.1mmol/L), or lower concentrations associated with severe clinical or metabolic features. Patients under ten years or over 70 have increased risk of salicylate toxicity and may require dialysis at an earlier stage.

5. PHARMACOLOGICAL PROPERTIES

Pharmacodynamics propertie

Pharmacotherapeutic group: Benzomorphan derivatives}, ATC code: NO2ADO1

Mechanism of Action

Benzoic acid helps prevent infection caused by bacteria. Salicylic acid helps the body shed rough or dead skin cells.

Pharmacodynamics

Benzoic Acid has antibacterial and antifungal properties. Salicylic Acid is bacteriostatic and fungicidal. It also possesses keratolytic properties.

Pharmacokinetic properties

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.

Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections.

6. PHARMACEUTICAL PARTICULARS

List of excipients

White soft paraffin

Liquid paraffin

Incompatibilities

None have been reported or are known

Shelf life

36 Months

Special precautions for storage

Store below 30°C in tight container protected from light and moisture.

Nature and contents of container and special equipment for use, administration or implantation

Whitfield's Ointment is presented in a printed aluminum 20g tube with aluminum seal covered with a white screw cap, packed in hard board packaging.

Special precautions for disposal and other handling

No special requirements.

7. APPLICANT/MANUFACTURER

Nino Pharm & Chem Co. Ltd
1, Nino Crescent Era Town,
Off Badagry Expressway,
Ojo LGA Lagos.

