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| Salicylic Acid 60 mg + Benzoic Acid 120 mg |
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**United Home Whitfield's Ointment
Topical Antifungal / Keratolytic**

FORMULATION

Each gram ointment contains:

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| Salicylic Acid | 60 mg |
| Benzoic Acid | 120 mg |

PRODUCT DESCRIPTION

- Salicylic Acid + Benzoic Acid (United Home Whitfield's) is an off-white to light yellow, smooth, non-gritty, homogeneous ointment which spreads uniformly and has a characteristic odor.

WHAT IS IN THE MEDICINE?

- This medicine combines two topical agents, Salicylic Acid and Benzoic Acid, which together inhibit fungal growth. Both agents also possess mild antibacterial activity. The combination of these two topical agents is more effective than when used singly since Salicylic Acid, a keratolytic agent, softens and loosens crusts and scales on the skin and promotes shedding of the outermost skin layer which increases penetration of Benzoic Acid in the skin to control infections. Together, these agents provide better protection against superficial fungal infections.

WHAT IS THIS MEDICINE USED FOR?

- This medicine is used for the treatment of mild superficial fungal skin infections such as athlete's foot (*alipunga*), ringworm (*buni*) and tinea versicolor (*an-an*).

HOW MUCH AND HOW OFTEN SHOULD YOU USE THIS MEDICINE?

Directions for Use

- Wash hands before and after each application.
- Clean the affected and surrounding areas of the skin with mild soap.
- Rinse thoroughly with water and pat dry.

- Apply a sufficient amount of Salicylic Acid + Benzoic Acid (United Home Whitfield's) ointment and rub gently on the affected areas of the skin 2 or 3 times daily. Or, as directed by a doctor.
- For patients with athlete's foot between the toes: apply the medicine to affected skin between and around the toes. Avoid wearing tight footwear. Change socks at least once daily.

WHEN SHOULD YOU NOT USE THIS MEDICINE?

- If you are allergic to any component of the product.
- In infants and children younger than 2 years old.
- In pregnant and breastfeeding women.
- In patients with diabetes and those with impaired or poor circulation.

UNDESIRABLE EFFECTS

Topical Salicylic Acid + Benzoic Acid is generally well tolerated when used as directed. Undesirable effects are most likely to occur when the medicine is used in younger children, in patients with impaired liver or kidneys, on broken or inflamed skin, in high concentrations, over large skin areas, prolonged use, and/or presence of occlusion (i.e., application on skin folds, use of plastic bandages or dressings that prevent air from circulating to the area being treated).

The following undesirable effects have been observed after topical application:

Salicylic Acid

Local irritation, skin inflammation, signs of salicylate toxicity (e.g., thirst, tinnitus or ringing in the ears, loss of hearing, headache, dizziness, vomiting, diarrhea, depression and disorientation) and allergic reactions including itchy rash, anaphylaxis and erythema multiforme (skin reaction characterized by small, red skin elevations or blisters arranged around a common center).

Benzoic Acid

Irritation, itchy rash and allergic reactions.

WHAT OTHER MEDICINE OR FOOD SHOULD BE AVOIDED WHILE USING THIS MEDICINE?

This medicine contains Salicylic Acid which may be absorbed and cause interactions with a number of other medicines. Tell your doctor if you are using the following medicines:

- Topical and oral salicylates (e.g., methyl salicylate-containing products, aspirin)
 - May lead to salicylate toxicity.

- Other topical medicines (e.g., corticosteroids)
 - Salicylic Acid promotes shedding of the outermost skin layer which may increase the clinical effect of certain topical medicines by increasing drug penetration into the skin.
- Acetazolamide, anticoagulants, dipyridamole, heparin, methotrexate, moxalactam, and hypoglycemics (e.g., chlorpropamide, glibenclamide, glimepiride)
 - Toxicity of these drugs may be increased.
- Bumetanide, captopril, probenecid
 - Efficacy of these drugs may be decreased.

WHAT SHOULD YOU DO IF YOU MISS A DOSE?

Just apply the missed dose if still needed for the particular condition being treated and then continue with your regular dosing schedule. Do not double the dose.

HOW SHOULD YOU KEEP THIS MEDICINE?

- Keep container tightly closed.
- Keep the product out of sight and reach of children.
- Store at temperatures not exceeding 30°C.
- Do not freeze.

SIGNS AND SYMPTOMS OF OVERDOSAGE

The use of large doses of topical Salicylic Acid may lead to salicylate intoxication and even death, particularly in children. (See Undesirable Effects)

However, when used as recommended, an overdose of topical Salicylic Acid + Benzoic Acid ointment is unlikely to occur.

WHAT TO DO WHEN YOU HAVE USED MORE THAN THE RECOMMENDED DOSAGE?

If you have used more than the recommended dosage, or in case of accidental swallowing, seek medical help.

CARE THAT SHOULD BE TAKEN WHEN USING THIS MEDICINE

- For external use on the skin only.
- Avoid contact with the eyes, eyelids and mucous membranes. If the ointment comes in contact with these areas, rinse out promptly and thoroughly with water.

- This medicine should not be used for prolonged periods, in high concentrations, on large areas of the body, or on broken or inflamed skin.
- Do not use after the expiry date on the label.

WHEN SHOULD YOU CONSULT YOUR DOCTOR?

- If you are using other medicines on your skin.
- If symptoms persist or condition worsens.
- If undesirable effects are experienced, stop use and consult a doctor.

DATE OF REVISION OF PATIENT INFORMATION LEAFLET (PIL)

Note to ULCH: PIL revision date should be the date when the PIL is approved by the Bureau of Food and Drugs (BFAD)