Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Whitfield's Antifungal 3% w/w & 6% w/w Ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Benzoic Acid 6% w/w and Salicylic Acid 3% w/w.

Excipient: Emulsifying Wax contains 21.84 w/w Cetostearyl alcohol and 5.46 % w/w Sodium laurilsulfate

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Ointment.
Smooth, white opaque ointment with a faint characteristic odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Whitfield's Antifungal 3% w/w & 6% w/w Ointment is recommended for the topical treatment of fungal infections of the skin.

4.2 Posology and method of administration

Whitfield's Antifungal 3% w/w & 6% w/w Ointment is applied topically and is for external use only.
Wash the skin with water and soap. Apply the ointment twice daily in a thin layer to the affected parts of the skin only. Treatment may take several weeks.

Adults: Apply topically to the affected to the affected area twice daily. No more than 3 fingertip units should be applied at any one time unless directed to do so by a doctor. One fingertip unit should be enough to cover twice the area of an adult hand.
Children under 16 years of age: Do not use on children under 16 years of age unless directed to do so by your doctor.
Children between 16 and 18 years of age: Apply no more than two fingertip unit to the affected area twice a day. Do not exceed this dose unless directed to do so by your doctor**.**

4.3 Contraindications

Whitfield's Antifungal 3% w/w & 6% w/w Ointment is contraindicated in patients with a known sensitivity to Benzoic Acid or Salicylic Acid.

4.4 Special warnings and precautions for use

Whitfield's Antifungal 3% w/w & 6% w/w Ointment should not be used on skin affected by psoriasis or eczema. Cetostearyl alcohol may cause local skin reactions (e.g. contact dermatitis).

The thickness of the skin varies considerably according to the body site and with age and can be an important factor in the sensitivity to sodium laurilsulfate (SLS). Sensitivity to SLS will also vary according the type of formulation (and effects of other excipients), the concentration of SLS, contact time and patient population (children, hydration level, skin color and disease). Patient populations with decreased skin barrier functions such as in atopic dermatitis are more sensitive to the irritant properties of SLS.

Whitfield's Antifungal 3% w/w & 6% w/w Ointment may cause allergic reactions in some patients.
Do not smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings, etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it. This preparation may make skin and surfaces slippery.

Contact with the eyes, mouth and other mucous membranes should be avoided.

4.5 Interaction with other medicinal products and other forms of interaction

There are no known interactions with Whitfield's Antifungal 3% w/w & 6% w/w Ointment. However, topical salicylic acid may increase the absorption of other topically applied medicines. Concomitant use of Whitfield's Antifungal 3% w/w & 6% w/w Ointment and other topical medicines on the same area of skin should therefore be avoided.

4.6 Fertility, pregnancy and lactation

Whitfield's Antifungal 3% w/w & 6% w/w Ointment should not be used in pregnancy without medical supervision.

4.7 Effects on ability to drive and use machines

No adverse effects reported.

4.8 Undesirable effects

Common side effects may include warmth or a burning sensation (may last up to 5 minutes after applying).
Benzoic Acid(E 210): 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
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie e-mail: medsafety@hpra.ie.

4.9 Overdose

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 Whitfield's Antifungal 3% w/w & 6% w/w Ointment is used as indicated.

Salicylate poisoning is usually associated with plasma concentrations >350mg/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.
Uncommon features include haematemesis, hyperpyrexia, hypoglycaemia, hypokalaemia, thrombocytopaenia, increased INR/PTR, intravascular coagulation, renal failure and non-cardiac pulmonary oedema.
Central nervous system features including confusion, disorientation, coma and convulsions are less common in adults than in children.
Management
Give activated charcoal if an adult presents within one hour of ingestion of more than 250 mg/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 mg/L (5.1 mmol/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

5.1 Pharmacodynamic properties

ATC Code D01AE12 Other antifungals for topical use.

Benzoic Acid has antibacterial and antifungal properties.

Salicylic Acid is bacteriostatic and fungicidal. It also possesses keratolytic properties.

5.2 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 benzolglucuronic 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

No further information available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

White Soft Paraffin
Liquid Paraffin
*Emulsifying Wax (Type B)
* containing: cetostearyl alcohol, sodium laurilsulfate and purified water.

6.2 Incompatibilities

Benzoic Acid activity may be reduced in the presence of non-ionic surfactants.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.
Keep container tightly closed.

6.5 Nature and contents of container

Whitfield's Ointment is available in pack sizes of 500g and 800g and is packaged in white polypropylene tamper screw cap containers.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Ovelle Limited
Industrial Estate
Coe's Road
Dundalk
Co. Louth
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0206/024/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10th June 1991

Date of last renewal: 10th June 2006

10 DATE OF REVISION OF THE TEXT

February 2022