

Benzoic acid salicylic 3% w/w & 6% w/w Ointment

Indications

Benzoic acid salicylic 3% w/w & 6% w/w Ointment is recommended for the topical treatment of fungal infections of the skin.

Posology and method of administration

Benzoic acid salicylic 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 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.

Contraindications

Benzoic acid salicylic 3% w/w & 6% w/w Ointment is contraindicated in patients with a known sensitivity to Benzoic Acid or Salicylic Acid.

Special warnings and precautions for use

Benzoic acid salicylic 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 to 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.

Benzoic acid salicylic 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.

Interaction with other medicinal products and other forms of interactions

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

Fertility, pregnancy and lactation

Benzoic acid salicylic 3% w/w & 6% w/w Ointment should not be used in pregnancy without medical supervision.

Effects on ability to drive and use machines

No adverse effects reported.

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.

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 Benzoic acid salicylic 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, thrombocytopenia, 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.

Special precautions for storage

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