

SM PHARMACEUTICALS SDN. BHD.

BENZYL BENZOATE APPLICATION BP

DESCRIPTION:

A white coloured viscous emulsion.

COMPOSITION:

Each 100 ml contains: Benzyl Benzoate BP 25% w/v

ACTIONS AND MODE OR MECHANISMS OF ACTION:

Benzyl Benzoate is an acaricide used in the treatment of scabies. It is customary to apply benzyl benzoate as a 25% application to the whole body from the neck down immediately after a bath. In concentrations of 10-20% v/v benzyl benzoate is toxic to *Sarcoptes scabiei* as well as pediculosis. In vitro, the sarcoptes mite is killed in 5 minutes in benzyl benzoate. Its mechanism of action is unclear but in view of its effects on vertebrates, it is thought that it may act on the nervous system of the parasite.

PHARMACOLOGY (SUMMARY OF PHARMACODYNAMICS AND PHARMACOKINETICS):

Absorption:

There is no information available about percutaneous absorption of benzyl benzoate. Older reports suggested some absorption of the drug but this was not quantified.

Metabolism:

If any of the applied benzyl benzoate is absorbed it is rapidly hydrolysed to benzoic acid and benzyl alcohol, the latter being further oxidized to benzoic acid. The benzoic acid is conjugated with glycine to form hippuric acid which is the major excretory product in the urine.

INDICATIONS:

Benzyl benzoate is an acaricide used in the treatment of scabies where it is more efficient, cleaner and easier to use than sulphur preparations. But it may not be effective in some cases of Norwegian scabies.

CONTRAINDICATIONS:

Benzyl benzoate should not be used on the face due to its irritant effect on the skin, and should not be used on broken, irritated or inflamed skin.

SIDE EFFECTS / ADVERSE REACTIONS:

Benzyl benzoate may cause irritation of the skin, eyes and mucous membranes. If incorrectly used for long periods of time it will induce both irritant and allergic dermatitis reactions.

PRECAUTIONS / WARNINGS:

Avoid contact with eyes and mucous membranes; do not use on broken or secondarily infected skin; pregnancy and breast-feeding.

Neonates

The preparation should not be used, as in neonates, face and scalp may be affected in scabies.

Children

The preparation should be diluted with one part water. However, not recommended for children – dilution to reduce irritant effect also reduces efficacy.

The elderly

In the elderly, the xerosis of the skin make the skin more susceptible to the drying effects of benzyl benzoate and irritation may be worse in this group of patients. Alternative treatment in the elderly should be used.

DRUG INTERACTIONS:

No interactions have been reported.

RECOMMENDED DOSAGE, DOSAGE SCHEDULE AND ROUTE OF ADMINISTRATION:

The patient should apply the emulsion to the entire skin surface, excluding the face and neck, but with special attention to hands, breasts and genitalia. The nails should be carefully treated using a nailbrush. The emulsion should be allowed to dry and reapplied after 24 hours. If hands are washed during the treatment time, the emulsion should be reapplied to these sites after a further 24 hours, all bedding and clothing coming into intimate contact with the body should be changed and laundered. The patient should take a bath. A second application may be made within 5 days. Alternatively three applications may be made at 12- hourly intervals.

All members of the family, sexual partners and friends who have come into intimate physical contact with the patient should be treated at the same time.

Infection from fomites only occurs in the Norwegian form of scabies, and it is probably unnecessary to worry about treatment of clothing and bedding.

Itching may persist for up to 2 weeks after successful treatment due to circulating antigens. Further treatment with benzyl benzoate should be avoided and a topical corticosteroid should be used.

Other acarides are preferred for infants and children, but if benzyl benzoate is used, then the application should be diluted to minimise the risk of irritation.

SYMPTOMS AND TREATMENT FOR OVERDOSE AND ANTIDOTE(S):

Overdosage

When ingested in large amounts, benzyl benzoate may cause convulsions. Poisoning should be treated by inducing emesis or gastric lavage. Convulsions can be controlled with anticonvulsants.

PACKING / PACK SIZES:

Plastic bottles of 100 ml, 120 ml and 200 ml;
Plastic containers of 1.0 L and 3.6 L.

STORAGE CONDITIONS, USER INSTRUCTIONS AND PHARMACEUTICAL PRECAUTIONS:

Store below 30°C in a well-filled airtight containers. Protect from light.

SHAKE WELL BEFORE USE.

SHELF LIFE: 3 years

NAME AND ADDRESS OF MANUFACTURER AND DISTRIBUTOR IN MALAYSIA:

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