



DERMASAFE DEEP RUB OINTMENT

PRODUCT DESCRIPTION

A white to pale yellow coloured ointment with a pleasant odour.

Each gram contains:
Methyl Salicylate 25% w/w
Menthol 5% w/w

ROUTE OF ADMINISTRATION

Topical

PHARMACODYNAMICS

Methyl salicylate is a salicylic derivative. It inhibits cyclooxygenase, thereby reducing the formation of prostaglandins, and cause platelet dysfunction. Methyl salicylate is used topically as a counter-irritant. Upon application, it is absorbed through the skin and is applied for the relief of pain in rheumatic conditions and painful muscle or joints.

When applied to the skin menthol dilates the blood vessels causing a sensation of coldness followed by an analgesic effect. Menthol also acts as a penetration enhancer, increasing the penetration of drugs when applied on the skin, to give a faster onset of action.

PHARMACOKINETICS

Methyl salicylate

- May be absorbed through intact skin.
- The absorption of topical salicylates is proportional to the surface area involved, duration of exposure, concentration and skin integrity.
- Absorption characteristics of salicylates vary with the dose, formulation and route of administration.
- Percutaneous absorption is enhanced by exercise, heat, occlusion, or disruption of the integrity of the skin or application to large areas of skin.
- Both the rate and extent of absorption increases after repeated application; increasing the bioavailability.
- Methyl salicylate is extensively metabolized to salicylic acid in the dermal and subcutaneous tissues after topical application.
- At therapeutic levels, the half-life of salicylates is 2-4 hours. As salicylate level increase into the toxic range, the half-life can be greater than 18 hours.

Menthol

- After absorption, menthol is excreted in the urine and bile as a glucuronide.

INDICATION

For the relief of minor aches and pains of muscles and joints associated with simple backache, arthritis and rheumatic conditions.

RECOMMENDED DOSAGE

Adults & children above 2 years old:

Apply to the affected area not more than 3 to 4 times daily. Rub or massage gently. For external application only.

CONTRAINDICATIONS

- Product can cause convulsions. Contraindicated in infants below 2 years of age. Caution must be exercised when older children are treated. Avoid direct application into nostrils.
- Hypersensitivity to any of the ingredients in the product.
- Do not use in patients with aspirin or salicylate idiosyncrasy.

WARNINGS AND PRECAUTIONS

Warnings:-

This product contains Methyl Salicylate and when applied or rub onto the skin can be absorbed through the skin into the blood. For the patients taking warfarin, excessive application onto the skin for muscle or joint pains may increase the chances of bleeding.

- Can cause convulsions.
- Topical analgesic preparations containing methyl salicylate should be used with caution in patients at increased risk of developing salicylate adverse effects.
- Children suffering from flu, chickenpox, or fever should avoid using this product because salicylates may induce Reyes Syndrome.

Precautions:-

- Initially apply small amount to a limited skin area and observe whether there is discomfort or itch before applying to a larger skin area. Discontinue use if irritation develops.
- For external use only; not to be taken. Avoid contact with the eyes and mucous membranes.
- Do not apply to open wounds or damaged skin.
- Avoid excessive use during pregnancy and lactation.
- Do not apply over large areas of the body or bandage or use with heating pads.

If symptoms persist, consult your doctor.

INTERACTIONS WITH OTHER MEDICAMENTS

This product contains methyl salicylate and when applied or rubbed on to the skin, can be absorbed through the skin into the blood. For patients taking warfarin, excessive application on to the skin for muscle or joints pains may increase the chances of bleeding.

PREGNANCY & LACTATION

Safety for use in pregnancy has not been established; therefore, the potential benefit of the product should be weighed against the possible risks to the mother and child.

SIDE/ADVERSE EFFECTS

This product can cause convulsions.

Headache, dizziness, nausea and vomiting, skin irritation, contact dermatitis, rash, itching, redness or swelling, burning or stinging sensation may occur.

May cause hypersensitivity/allergic reactions in some individuals with sensitive skin.

SYMPTOMS AND TREATMENT FOR OVERDOSAGE

Symptoms of methyl salicylate overdose:-

Salicylate intoxication can occur after ingestion or topical application of methyl salicylate. Mild chronic salicylate intoxication, or salicylism, usually occurs only after repeated use of large doses. Salicylism can also occur following excessive topical application of salicylates.

Symptoms include dizziness, tinnitus, deafness, sweating, nausea and vomiting, headache, and confusion, and may be controlled by reducing the dosage.

Symptoms of more severe intoxication or of acute poisoning following overdose include hyperventilation, fever, restlessness, ketosis, and respiratory alkalosis and metabolic acidosis.

Depression of the CNS may lead to coma; cardiovascular collapse and respiratory failure may also occur.

Symptoms of menthol overdose:-

Ingestion of significant quantities is reported to cause symptom: severe abdominal pain, nausea, vomiting, vertigo, ataxia, drowsiness, and coma; instant collapse in infants after the local application of menthol to their nostrils. Seizures may be the first clinical sign of severe toxicity of menthol; however, seizures are usually self-limited. Severe toxicity of menthol can result in delirium, visual hallucinations, cerebral edema, and status epilepticus. Systemic toxicity may include hypotension, tachycardia, respiratory failure, and death.

Treatment:-

The stomach should be emptied by gastric lavage or administration of oral activated charcoal. Fluid and electrolyte management is the mainstay of treatment with the immediate aim of correction of acidosis, hyperpyrexia, hypokalaemia and dehydration if present. Any convulsions must be controlled first through supportive care including anticonvulsant therapy.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

None known.

STORAGE CONDITION

Store below 30°C, away from direct light.

SHELF LIFE

Product should not be used beyond the expiry date imprinted on the product packaging.

PACK SIZES

- i) Tube of 30GM.
- ii) Plastic Container of 500GM

REGISTRATION NUMBER

MAL20013174X

FOR EXTERNAL USE ONLY

**KEEP MEDICINES OUT OF REACH OF CHILDREN
JAUHI UBAT-UBATAN DARI KANAK-KANAK**

For further information, please consult your doctor or your pharmacist.

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Lt-185.05_Product Registration Holder and Manufacturer

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