

# PACKAGE INSERT TEMPLATE FOR MENTHOL & METHYL SALICYLATE & CAMPHOR

## Brand or Product Name

*[Product name]* Ointment

*[Product name]* Liniment

*[Product name]* Cream

## Name and Strength of Active Substance(s)

Methyl salicylate ....% v/w or % w/w

Menthol ....% v/w or % w/w

Camphor ....% v/w or % w/w

## Product Description

*[Visual description of the appearance of the product (eg colour, texture, odour,etc) ]*

*eg Off-white cream with a tinge of blue and characteristic smell*

## Pharmacodynamics

*Camphor*

Camphor is a stimulant, rubefacient, antipruritic and feebly antiseptic. When in combination with other ingredient like menthol, methyl salicylate, it becomes ideal for neuralgia and other painful areas.

*Menthol*

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.

*Methyl salicylate*

Methyl salicylate is a salicylic acid derivative.

Salicylates inhibit 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.

## Pharmacokinetics

*Camphor*

- Camphor is readily absorbed from all administration sites. Camphor is well absorbed after dermal exposure.
- It is hydroxylated in the liver to yield hydroxycamphor metabolites which are then conjugated with glucuronic acid and excreted in the urine.

*Updated August 2011*

- Camphor crosses the placenta

#### *Menthol*

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

#### *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 metabolised 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

### **Indication**

#### *Topical*

Provide symptomatic relief for mild to moderate muscular and joint aches and pains, muscle cramps, shoulder aches and stiff neck

For the temporary relief of pain associated with rheumatism, arthritis, neuralgia, sprains and strains of joints and muscles, lumbago and fibrositis

### **Recommended Dosage**

#### *Cream/Ointment/Liniment*

Adults & children above 2 years old

Apply to the affected area not more than 3 to 4 times daily.

Rub/ Massage gently.

For external application only

### **Mode of Administration**

Topical

*Updated August 2011*

## **Contraindications**

- Do not use in patients with aspirin or salicylate idiosyncrasy.
- Hypersensitivity to any of the ingredients in the product.
- 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

## **Warnings and Precautions**

[Specific package insert requirement for camphor]

### **WARNING:**

This product is contraindicated in infants below 2 years of age. Caution must be exercised when older children are treated.

### **PRECAUTION:**

It is dangerous to place any camphor containing product into the nostril of children. A small amount applied this way may cause immediate collapse.

[Specific package insert requirement for methyl salicylate]

The following statements shall be included in the package insert and product literature of topical preparations containing methyl salicylate  $\geq 5\%$

### **Under Caution:**

This product contains methyl salicylate and when applied or rub 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 joint pains may increase the chances of bleeding.

### **Warning:**

- 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 a 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.

*Updated August 2011*

- If symptoms persist, consult your doctor.

#### *Effects on Ability to Drive and Use Machines*

None known

#### **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.

#### **Statement on Usage During Pregnancy and 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.

#### **Adverse Effects / Undesirable 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

#### **Overdose and Treatment**

##### *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.

*Updated August 2011*

### *Symptoms of camphor/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/camphor to their nostrils.

Seizures may be the first clinical sign of severe toxicity of camphor; however, seizures are usually self-limited. Severe toxicity of camphor 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

### **Storage Conditions**

*[ eg Store below ... °C ]*

### **Dosage Forms and Packaging Available**

*[Packaging type & pack size]*

### **Name and Address of Manufacturer**

*[Name & full address of manufacturer]*

### **Name and Address of Marketing Authorization Holder**

*[Name & full address of marketing authorization holder]*

### **Date of Revision of Package Insert**

*[day/month/year]*

*Updated August 2011*