

## ACTIV-RUB PAIN RELIEF EMULSION GEL

### Active Ingredients:

Methyl Salicylate ..... 30% w/w  
Menthol ..... 8% w/w

### Presentations:

Aluminium tube with HDPE plastic cap of 30g and 50g.

### Product Descriptions:

White to off-white gel.

### Pharmacology:

#### Pharmacodynamic

Methyl salicylate:

Methyl salicylate is a salicylic acid derivative. Salicylates inhibit cyclooxygenase, thereby reducing the formation of prostaglandins, and cause platelet dysfunction. It 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 muscles or joints.

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 faster onset of action.

#### Pharmacokinetic

Methyl salicylate:

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 increase 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 to 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 glucuronide.

### Indications:

Activ-Rub Pain Relief provides temporary pain relief from minor aches and pains of muscles and joints associated with arthritis, simple backache, strains and sprains.

### Directions of Use:

For topical use only.

Apply a small quantity of gel 3 to 4 times daily. Gently massage onto the painful area until the gel is fully absorbed into the skin.

### Symptoms and Treatments of Overdose:

#### 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 symptoms: severe abdominal pain, nausea, vomiting, vertigo, ataxia, drowsiness, and coma; instant collapse in infants after the local application of menthol to their nostrils.

### 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 convulsion must be controlled first through supportive care including anticonvulsant therapy.

### Contraindications:

Do not use in patients with aspirin or salicylate idiosyncrasy. Patients with known hypersensitivity to any of the ingredients in the product. Do not use during pregnancy or when breastfeeding. This product should not be used in children under 12 years of age.

### Precautions:

This product contains methyl salicylate and when applied or rubbed onto the skin, can be absorbed through the skin into the blood. For patients taking warfarin, excessive application onto the skin for muscle or joint pains may increase the chances of bleeding. If you are taking warfarin, please consult your doctor before using this product.

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.

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. Do not apply over large areas of the body. Do not use bandage or heating pad on the applied area. If symptoms persist, consult your doctor.

### Use in Pregnancy and Lactation:

Do not use during pregnancy or when breastfeeding.

### Undesirable Effects:

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.

### Effects on ability to drive and use machines:

Not known.

### Interactions with Other Medicaments:

For patients taking warfarin, excessive application onto the skin for muscle or joint pains may increase the chances of bleeding.

### Storage:

Store below 30°C. Protect from light. Keep cap tightly closed.

Keep out of reach of children.

Jauhkan daripada capaian kanak-kanak.

### Shelf Life:

2 years from the date of manufacture.

Manufacturer and Product Registration Holder

**WINWA MEDICAL SDN. BHD.**

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**MAL0000000X**

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Size: 75mm x 140mm  
 Dark Blue (Pantone 2767U)