



THREE LEGS ROLL ON LINIMENT (ORANGE)

Active ingredients: Menthol 8%w/v, Camphor 10%w/v, Methyl Salicylate 50%w/v

Product Description: Clear liniment with orange smell.

Indication: For symptomatic relief of muscular pain, joint pain, rheumatic pain and sprain.

Direction of Use: Apply onto affected area 2 to 3 times a day.

Route of Administration: Topical

Pharmacodynamics

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 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 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 the pain in rheumatic conditions and painful muscle or joints.

Pharmacokinetics

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. Camphor crosses the placenta.

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.

Contraindications:

Do not use in patients with aspirin or salicylate idiosyncrasy. Patient with known hypersensitivity to any of the ingredients in the product.

Warnings and Precautions:

This product is contraindicated in children below 2 years of age. Caution must be exercised when older children are treated. It is dangerous to place any camphor containing product into the nostril of children. A small amount applied this way may cause immediate collapse.

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.

Initially apply a small amount to a limited skin area and observe whether there is discomfort or itch before applying to larger skin area. Discontinues use if irritation develops. 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.

For external use only. Keep out of reach of children.

Effects on Ability to Drive and Use Machines: Not 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.

Symptoms and Treatment 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 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 or 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, hypokalemia and dehydration if present.

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

Storage Conditions: Store below 30°C. Protect from direct sunlight.

Shelf Life: Please refer to the packaging. Do not use beyond the expiry date.

Dosage Form: Liniment

Packing: 10ml

Manufactured by Product Registration Holder:

Syarikat Wen Ken Drug Sdn. Bhd.

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81200 Johor Bahru, Johor, Malaysia.

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