

## **PACKAGE INSERT**

### **Product name**

NW Methyl Salicylate 50% w/w Ointment

### **Name and Strength of Active Ingredient (s)**

Methyl Salicylate.....50% w/w

### **Product Description**

Yellowish green translucent ointment

### **Pharmacodynamics**

Methyl salicylate is a salicylic acid derivative.

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**

Not available

### **Indication**

Use to relief minor aches and pains of the muscles or joints (e.g: arthritis, backache, sprains).

### **Recommended Dosage**

Adults and children above 12 years: No special dosage recommendation. Apply a thin layer to the affected area and rub gently until completely absorbed. NW Methyl Salicylate 50% w/w Ointment can be used up to three to four times daily.

Infants and children below 12 years: Not recommended

### **Contraindication**

Contraindicated in patients with allergic to the ingredients.

### **Warning and Precautions**

- For external used only. Do not get it in your eyes, ears, lips, mouth, or genital area. If you get it in any of these areas, rinse away with cool water.
- NW Methyl Salicylate 50% w/w Ointment may cause harm if it is swallowed. If you may have taken it by mouth, contact your poison centre or emergency room right away.
- 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.

### **Interaction with Other Medicaments**

Although certain medicines should not be used together at all, in other cases two different medicines may be used together even if an interaction might occur. 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. Tell your healthcare professional if you taking any medication.

### **Pregnancy and Lactation**

*Pregnancy* – It is not known whether methyl salicylate will harm an unborn baby. Ask your doctor if you are pregnant or plan to become pregnant while using this medication

*Breast-feeding* - It is not known whether methyl salicylate topical passes into breast milk or if it could harm a nursing baby. Do not apply topically methyl salicylate to your breast area if you are breastfeeding a baby.

### **Adverse effect/undesirable effect**

NW Methyl Salicylate 50% w/w Ointment may cause hives, difficulty breathing, swelling of your face, lips, tongue, or throat. Get emergency medical help if you have any of these signs of a severe allergic reaction.

### **Overdose and treatment**

When used externally as directed, overdose is unlikely. However, symptoms of systemic salicylate poisoning have been reported after the application of salicylates to large areas of skin or for prolonged periods. Salicylism may also occur in the unlikely event of large quantities being ingested.

### **Salicylate poisoning**

Common features include vomiting, dehydration, tinnitus, vertigo, deafness, sweating, warm extremities with bounding pulses, increased respiratory rate and hyperventilation. Some degree of acid-base disturbance is present in most cases.

A mixed respiratory alkalosis and metabolic acidosis with normal or high arterial pH (normal or reduced hydrogen ion concentration) is usual in adults and children over the age of four years. In children aged four years or less, a dominant metabolic acidosis with low arterial pH (raised hydrogen ion concentration) is common. Acidosis may increase salicylate transfer across the blood brain barrier.

Uncommon features include haematemesis, hyperpyrexia, hypoglycaemia, hypokalaemia, thrombocytopenia, increased INR/PTR, intravascular coagulation, renal failure and non-cardiac pulmonary oedema.

Central nervous system features including confusion, disorientation, coma and convulsions are less common in adults than in children.

If someone has overdosed and has serious symptoms such as passing out or trouble breathing, contact your doctor/pharmacist.

### **Treatment/Management**

Activated charcoal may be administered if significant quantities have been ingested within an hour of presentation. The plasma salicylate concentration should be measured, although the severity of poisoning cannot be determined from this alone and the clinical and biochemical features must be taken into account. Elimination is increased by urinary alkalinisation, which is achieved by the administration of 1.26% sodium bicarbonate. The urine pH should be monitored. Correct metabolic acidosis with intravenous 8.4% sodium bicarbonate (first check serum potassium). Forced diuresis should not be used since it does not enhance salicylate excretion and may cause pulmonary oedema.

Haemodialysis is the treatment of choice for severe poisoning and should be considered in patients with plasma salicylate concentrations >700mg/L (5.1mmol/L), or lower concentrations associated with severe clinical or metabolic features. Patients under ten years or over 70 have increased risk of salicylate toxicity and may require dialysis at an earlier stage.

### **Incompatibilities**

Not applicable

### **Instructions for use and handling, and disposal**

Store on the original packaging

Any unused product or waste material should be discarded in accordance with the local requirements. No additional environment precautions for disposal are necessary.

### **Storage Condition** Store

below 30°C.

Store away from heat, moisture, and light.

Keep out of reach of children.

Do not use after expiry date.

### **Shelf Life**

2 Years

### **Dosage forms and all packaging available**

30g and 60g in HDPE white bottle

**Name and Address of Manufacturer/ of Marketing Authorization**

**Holder** Natural Wellness Industries Sdn. Bhd. No: 78, Jalan Kilang Midah,  
Taman Midah, 56000, Cheras, Kuala Lumpur.

**Date of Revision of Package Insert**

29/01/2018