

SUMMARY OF PRODUCT CHARACTERISTICS

1. COMPOSITION

Each 50g Balm contains:

Methyl Salicylate, BP12.17%w/w

2. DESCRIPTION

Methyl salicylate

Methyl salicylate (oil of wintergreen) is a natural product of many species of plants. Methyl salicylate can be produced by esterifying salicylic acid with methanol. It is used as a rubefacient in deep heating liniments, and in small amounts as a flavoring agent at no more than 0.04%. It is absorbed through the skin and is applied for the relief of pain in lumbago, sciatica, and rheumatic conditions. Creams which contain salicylates offer pain relief and reduced joint inflammation.

Excipients

Capsicum: Capsaicin has been found useful to decrease pain from shingles, arthritis, neuropathy and fibromyalgia with repetition and topical daily application. There are multiple mechanisms of action for the pain-relieving function of capsaicin. When applied to the skin, the capsaicin from the cayenne pepper is thought to block pain by decreasing Substance P, a chemical that transmits pain signals between nerves. Capsaicin cream quickly dilates small capillaries and increases circulation to the skin in the area where the capsaicin has been applied. Capsaicin can quickly stimulate blood flow to an injured area while acting as a nerve block and reducing pain. Cayenne(Capsicum Family), a natural pain-relieving compound is known to cause vasodilation.

Eucalyptol: Used as a counter irritant and cutaneous stimulant in the treatment of chronic inflammatory conditions and to relieve neuralgia and rheumatic pains.

Methyl salicylate: Methyl salicylate (oil of wintergreen) is used as a rubefacient in deep heating liniments, and in small amounts as a flavoring agent. Applied for the relief of pain in lumbago, sciatica and rheumatic conditions.

Thymol: Thymol is used for topical analgesia. In addition, thymol may partially block voltage-gated sodium channels, which could be a potential molecular mechanism for its pain-relieving properties.

Menthol: Menthol has local anesthetic and counterirritant qualities, and it is widely used to relieve minor throat irritation. It dilates the vessels, causing a sensation of coldness followed by an analgesic effect, Menthol is included in many products for a variety of reasons such as:

- In non-prescription products for short-term relief of minor sore throat **e.g.** lip balms and cough medicines.
- As an antipruritic to reduce itching , topical analgesic to relieve minor aches and pains such as muscle cramps, sprains, headaches and similar conditions, alone or combined with chemicals like camphor, eucalyptus oil or capsaicin
- In decongestants for chest and sinuses **e.g.** Vicks VapoRub, Mentholatum.
- In certain medications used to treat sunburns, as it provides a cooling sensation.
- Commonly used in oral hygiene products and bad-breath remedies like mouthwash, toothpaste, mouth and tongue-spray, and more generally as a food flavor agent; **e.g.** in chewing-gum, candy.

Glycerinum Amyli: Starch soaks up secretions and helps to render injured parts, also may be employed as an emollient for the skin. As a protective application in skin diseases and for chilblains it may be used in the form of Glycerinum Amyli.

3. THERAPEUTIC INDICATIONS

This is used to relieve pain of muscle aches and sprains, arthritis and similar conditions like.

- Rheumatism
- Gout
- Sore throat
- Headache
- Lumbago
- Sciatica
- Chests Colds
- Neuralgia

4. DOSAGE AND ADMINISTRATION

It should be gently rubbed over the painful area two three times daily or as prescribed by the physician

How to use:

This medication is for use on the skin only. Do not use on scraped, irritated or broken skin. To use, apply a thin layer to the affected area and rub in gently. Do not cover with a tight bandage or use with a heating pad as this may cause skin damage. Avoid use near the eyes and mucous membranes. Wash hands thoroughly after applying.

5. CONTRAINDICATIONS

- Hypersensitivity to any of the ingredients or the excipients.
- Do not apply to skin abrasions.
- Do not apply to irritated skin.

6. WARNINGS AND PRECAUTIONS

Wintogeno is for external use only. It should not use on wounds or damaged skin, with a heating pad, or on a child under 12 years of age.

If you have redness over the affected area, consult your doctor before using the product. When using this product avoid contact with eyes or mucous membranes. Also do not apply bandages tightly over the area being treated.

Stop use and ask a doctor if your condition worsens or symptoms persist for more than 3 days, symptoms clear up and occur again within a few days, or excessive skin irritation develops.

7. ADVERSE REACTIONS

Redness or irritation may occur, especially in persons with sensitive skin. If this continues or skin becomes itchy, swollen or you develop a rash, notify your doctor. If applied to large areas or broken skin, the medication may be absorbed. Notify your doctor if you experience: ringing in the ears, nausea or vomiting. If you notice other effects not listed above, contact your doctor or pharmacist immediately.

8. DRUG INTERACTIONS

Tell your doctor of any over-the-counter or prescription medication you may take including: blood thinners. Do not start or stop any medicine without doctor or pharmacist approval.

9. PREGNANCY AND LACTATION

N/A

10. SPECIAL POPULATION

10.1 Pediatric Use

N/A

10.2 Geriatric Use

N/A

11. CLINICAL PHARMACOLOGY

11.1 Pharmacodynamics

N/A

11.3 Pharmacokinetics

After absorption, menthol is excreted in the urine and bile as a glucuronide. Methyl salicylate is absorbed through the skin.

12. OVERDOSAGE

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 hematemesis, hyperpyrexia, hypoglycemia, hypokalemia, 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.

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 alkalinization, 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.

Hemodialysis is the treatment of choice for severe poisoning and should be considered in patients with plasma salicylate concentrations $>700\text{mg/L}$ (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.

13. HOW SUPPLIED

13.1 Presentation

Wintogeno Balm: Available in 50 gm in a pack.

13.2 Shelf life

36 months (03 years)

13.3 Storage

- Store below $30\text{ }^{\circ}\text{C}$.
- Protect from light and heat.
- Keep all the medications out of the reach of Children.

13.4 Manufactured by:

MARTIN DOW MARKER LTD

7, Jail Road, Quetta,

Pakistan