

## **Summary of Product Characteristics for Pharmaceutical Products**

### **1. Name of the medicinal product**

Wintogeno Balm

### **2. Qualitative and quantitative composition**

Each 50g Balm contains:

Methyl Salicylate, BP .....12.17%w/w

For a full list of excipients, see section 6.1.

### **3. Pharmaceutical form**

Balm

A Creamy white, Homogenous emulsion

### **4. Clinical particulars**

#### **4.1 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

#### **4.2 Posology and method of administration**

##### **Posology**

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

##### **Method of administration**

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.

#### **4.3 Contraindications**

Not to be used on children under 6 years old.

Do not apply to skin abrasions.

Do not apply to irritated skin.

Contraindicated in patients who are hypersensitive to salicylates or to any other ingredient in the preparation. If irritation develops, use of the product should be discontinued.

#### **4.4 Special warnings and precautions for use**

Wintogeno is for external use only. It should not use on wounds or damaged skin, with a heating pad, or on a child under 6 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.

#### **4.5 Interaction with other medicinal products and other forms of interaction**

There have been reports that topical salicylates may potentiate the anticoagulant effects of warfarin. Menthol has also been reported to interact with warfarin (when taken orally), decreasing its effectiveness.

#### **4.6 Fertility, pregnancy, and lactation**

There is no, or inadequate evidence of safety in human pregnancy or lactation. As a precautionary measure, Wintogeno should only be used during pregnancy or lactation when there is no safer alternative.

#### **4.7 Effects on ability to drive and use machines.**

Not applicable

#### **4.8 Undesirable effects**

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.

**Reporting of suspected adverse reactions:** Healthcare professionals are asked to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) <https://pv.pharmacyboardkenya.org>

#### **4.9 Overdose**

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 >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.

### **Ingestion of menthol**

Ingestion of significant quantities of menthol is reported to cause severe abdominal pain, nausea, vomiting, vertigo, ataxia, drowsiness, and coma. Gastric lavage may be considered if the patient presents within 1 hour of ingestion; any convulsions must be controlled first. Activated charcoal may be given orally.

**Reporting of suspected adverse reactions:** Healthcare professionals are asked to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) <https://pv.pharmacyboardkenya.org>

## **5. Pharmacological properties**

### **5.1 Pharmacodynamic properties**

**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. It has the actions of the salicylates. It is readily absorbed through the skin and has counter-irritant properties

**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:

1. In non-prescription products for short-term relief of minor sore throat e.g. lip balms and cough medicines.
2. 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
3. In decongestants for chest and sinuses e.g. Vicks VapoRub, Mentholatum.
4. In certain medications used to treat sunburns, as it provides a cooling sensation.
5. 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

## 5.2 Pharmacokinetic properties

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

## 5.3 Preclinical safety data

Not applicable

## 6. Pharmaceutical particulars

### 6.1 List of excipients

Glycerin  
Gum Tragacanth  
Maize Starch  
Menthol Crystals  
Oleoresin capsicum  
Oil Of Eucalyptus  
Sodium Alginate  
Sodium Lauryl Sulphate  
Thymol

**6.2 Incompatibilities**

Not applicable

**6.3 Shelf life**

36 months

**6.4 Special precautions for storage:**

Store below 30°C

Protect from light and heat

**6.5 Nature and contents of container**

Wintogeno Balm: Available in 50 gm in a pack.

**6.6 Special precautions for disposal and other handling:**

No special Precautions necessary.

**7. Marketing authorization holder and manufacturing site addresses**

**Marketing authorization holder:**

Company Name: Martin Dow Marker Limited  
Address: 7-Jail, Road Quetta,  
Country: Pakistan  
Telephone: +92-81-111523523  
E-Mail: info@martindowmarker.com

**Manufacturing site address:**

Company Name: Martin Dow Marker Limited  
Address: 7-Jail, Road Quetta,  
Country: Pakistan  
Telephone: +92-81-111523523  
E-Mail: info@martindowmarker.com

**8. Marketing authorization number**

CTD9802

**9. Date of first registration**

20/06/2023

**10. Date of revision of the text:**

14/09/2023

**11. Dosimetry:**

Not Applicable

**12. Instructions for Preparation of Radiopharmaceuticals:**

Not Applicable