

PACKAGE INSERT

1. Name of product :

MASABALM

2. Name and strength of the medicine :

Each 100 g contains : -

Methyl salicylate	10.2000	g
Menthol	5.4400	g
Eugenol	1.3600	g

3. Product description :

White cream

The composition are following

Methyl salicylate	10.2000	g
Menthol	5.4400	g
Eugenol	1.3600	g
Sodium lauryl sulfate	1.0000	g
Carbopol 934	0.8000	g
Simethicone emulsion 30%	0.0056	g
Glyceryl monostearate	4.0000	g
Neowax SE-20	10.0000	g
Sodium hydroxide	0.2444	g
Purified water	65.5560	g
Purified water q.s.to	100.0000	g

4. Pharmacodynamic / Pharmacokinetic

4.1 Pharmacodynamic

Methyl salicylate

The haemolytic effect of methyl salicylate (MS) on human and sheep erythrocytes is reported for the first time to our knowledge. Human erythrocytes are more sensitive to this effect. Haemolysis is proportional to the concentration of methyl salicylate and the duration of incubation. Lowering of surface tension and the ensuing membrane damage appear to be the mechanism by which the haemolytic effect is produced.

Menthol

Menthol's ability to chemically trigger the cold-sensitive TRPM8 receptors in the skin is responsible for the well known cooling sensation that it provokes when inhaled, eaten, or applied to the skin. Menthol has analgesic properties that are mediated through a selective activation of k-opioid receptors.

Eugenol

Eugenol, the principal chemical component of clove oil from *Eugenia aromatica* has been long known for its analgesic, local anesthetic, anti-inflammatory, and antibacterial effects.

4.2 Pharmacokinetic

Methyl salicylate and Menthol occur in numerous over-the-counter products. Although extensively used, there have been no estimates of human exposure following administration via dermal application. Furthermore, there is little information about the pharmacokinetics of those compound. The authors report the plasma concentrations of the intact compounds as a function of dose following dermal patch application. Three groups of 8 subjects (4 male, 4 female) applied a different number of commercial patches (2, 4 or 8) to the skin for 8 hours. Plasma samples were assayed using sensitive and selective gas-chromatographic methods. For the 8 patch group, the average maximum plasma concentrations ($C_{max} \pm SD$) were 29.5 ± 10.5 ng/mL and 31.9 ± 8.8 ng/mL for methyl salicylate and menthol, respectively. The corresponding values for the 4-patch group were 16.8 ± 6.8 ng/mL and 19.0 ± 5.4 ng/mL. The harmonic mean terminal half-lives were 3.0 ± 1.2 hours and 4.7 ± 1.6 hours for methyl salicylate and menthol, respectively. The 2-patch group had measurable but low plasma concentrations of each compound. Low-dose dermal application for an extended time results in low plasma concentration of compounds. Four and 8 patches, when applied for 8 hours, gave measurable and nearly proportional plasma concentrations. Although unable to determine the absolute dermal bioavailability of these compound, there appears to be relatively low systemic exposure to these potentially toxic compounds, even when an unrealistically large number of patches are applied for an unusually long time.

5. Indication :

MASABALM cream is applied for relief of muscular aches, joint pain, strains and sprains.

6. Recommended dose :

Apply to the affected area three or four times daily.

7. Mode of administration :

Wash your hands apply a thin layer of medication to the affected area no more than 3 to 4 times a day. Rub in gently and thoroughly. After applying the medication, wash your hands unless you are using this medication to treat the hands. If treating the hands, wait at least 30 minutes after applying the medication to wash your hands. Do not apply this medication to skin that is injured or irritated.

8. Contraindications :

Do not use MASABALM if you are allergic to any ingredient.



9. Warnings and precautions :

Before using this product, tell your doctor or pharmacist if you have any other allergies. If you have any of the following health problems, consult your doctor or pharmacist before using this product : asthma, injured/ irritated skin in the affected area, growths in the nose (nasalpolyps). Some products should not be used on children younger than 12 years without a doctor's advice. Check the label carefully before using on children between 2 and 12 years old.

Caution

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.

10. Interaction with other medicaments :

If you are using this product under your doctor's direction, your doctor or pharmacist may already be aware of possible drug interactions and may be monitoring you for them. Do not start, stop, or change the dosage of any medicine before checking with your doctor or pharmacist first. Before using this product, tell your doctor or pharmacist if you use any of the following products: "blood thinners" (e.g., warfarin). This document does not contain all possible interactions. Therefore, before using this product, tell your doctor or pharmacist of all the products you use. Keep a list of all your medications with you, and share the list with your doctor and pharmacist.

When applied to the skin, eugenol, a component of clove, may reduce the ability to feel and react to painful stimulation. Therefore, use of clove products on the skin with other numbing or pain-reducing products such as lidocaine/prilocaine cream (Emla®) theoretically may increase effects.

11. Pregnancy and lactation :

This product should be used only when clearly needed. Discuss the risks and benefits with your doctor. It is not known whether this product passes into breast milk. Consult your doctor before lactation.

12. Undesirable effects :

Methyl salicylate and Menthol

Redness, warmth, stinging, or burning on the application site may occur. If any of these effects persist or worsen, contact your doctor or pharmacist promptly. If your doctor has directed you to use this medication, remember that he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects. Stop using

this medication and tell your doctor immediately if any of these unlikely but serious side effects occur: blistering/ swelling/ severe redness at the application site, nausea/vomiting, ringing in the ears. A very serious allergic reaction to this drug is rare. However, seek immediate medical attention if you notice any symptoms of a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing. This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist.

Eugenol

When applied to the skin or inside of the mouth, eugenol can cause burning, loss of sensation or painful sensation, local tissue damage, dental pulp damage, higher risk of cavities, or sore lips. Undiluted clove oil has a high risk of causing contact dermatitis (rash) and even burns if applied to the skin at full strength.

13. Overdose and treatment :

This medication may be harmful if swallowed. If swallowing or overdose is suspected, contact your local poison control center or emergency room immediately.

14. Storage condition :

Keep in tight container, store below 30°C and shelf-life is 3 years after the date of manufacture.

15. Dosage forms and packaging available :

Aluminium tube of 30 g in to a paper box.

16. Name and address of manufacturer / Marketing authorization holder :

Manufacturer :



UMEDA CO., LTD.

26/18-21 Soi yuyen, Ram-Indra Road, Moo 9,
Taraeng, Bang Khen, Bangkok 10230, Thailand
Tel. (662) 943-6366 Fax (662) 943-6989

Marketing Authorization Holder :

HEALTH PHARM MARKETING SDN BHD
30-4, Jalan 3/146, Bandar Tasik Selatan,
57000 Kuala Lumpur

17. Date of revision of package insert :

20 July 2017

