

DERMASAFE DEEP RUB OINTMENT

Methyl Salicylate / Menthol (25% w/w / 5% w/w)

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What Dermasafe Deep Rub Ointment is used for

It is used for relief of minor aches and pains associated with:

- Muscular pain and stiffness in simple backache
- Lower back pain
- Joint pain
- Rheumatic conditions such as pain, swelling, stiffness and limited movement in joints, muscles and ligaments and other related condition.

How Dermasafe Deep Rub Ointment works

This ointment contains 2 active ingredients which are Methyl Salicylate and Menthol. They work together to soothe and relieve minor pains.

Before you use Dermasafe Deep Rub Ointment

- When you must not use it

If you are allergy (hypersensitive) to any of ingredients in Dermasafe Deep Rub Ointment.

- Before you start use it

Do not use Dermasafe Deep Rub Ointment on:

- Infants below 2 years of age.
- Avoid direct application into nostrils. There have been reports of cessation of breathing especially during sleep and instant collapse in infants following the

local application of menthol to their nostril.

- Individuals with aspirin or salicylate habit.
- Individuals taking warfarin, excessive application onto the skin for muscle or joint pains may increase the chances of bleeding.
- Children suffering from flu, chickenpox, or fever should avoid using this product because salicylates may induce Reyes Syndrome.
- 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.

Dermasafe Deep Rub Ointment is only for use on the skin.

Pregnancy and breastfeeding

Safety for use in pregnancy has not been established; therefore, the potential benefit of the product should weigh against the possible risks to the mother.

However, you must tell your doctor if you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby.

Your doctor or pharmacist will advise you if you can use Dermasafe Deep Rub Ointment during pregnancy or while you are breast-feeding.

- Taking other medicines

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.

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

How to use Dermasafe Deep Rub Ointment

- How much to use

- Initially apply small amount to a limited skin area and observe whether there is discomfort or itch before applying to a larger skin area. Discontinue use if irritation develops.
- Gently massage a thin layer of Dermasafe Deep Rub Ointment to the affected area until the ointment is rubbed in.
- Use 3 to 4 times daily depending on the severity of pain.
- Always wash your hand immediately after use so that you do not transfer to sensitive areas such as your lips or eyes. If this occurs, wash away with plenty of clean water.

- When to use it

Follow the instructions on the label carefully and as instructed by your doctor or pharmacist.

- How long to use it

Continue taking Dermasafe Deep Rub Ointment for as long as your doctor recommends.

If your symptoms do not improve, see your doctor.

- If you forget to use it

If you forget to apply the medicine, use it as soon as you remember. If it is almost time for your next application, wait until then to use the ointment and skip the missed dose.

Do not apply extra to make up for the missed application.

- If you use too much (overdose)

Ingestion of menthol is reported to cause severe abdominal pain, nausea, vomiting, vertigo, ataxia, drowsiness and coma.

If you accidentally squeeze out too much ointment, use a tissue to wipe off any excess. Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have accidentally

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swallow this ointment. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using Dermasafe Deep Rub Ointment

- Things you must do

- For external use only; not to be taken.
- Take your medicine exactly as your doctor or pharmacist has told you to.

- Things you must not do

- Do not apply on broken skin or inflamed skin or near to the sensitive area (e.g eyes or mouth).
- Do not use your medicine to treat any other complaints unless your doctor or pharmacist tells you to.

- Things to be careful of

Topical analgesic preparations containing methyl salicylate should be used with caution in individuals at increased risk of developing salicylate adverse effects.

Children suffering from flu, chickenpox, or fever should avoid using this product because salicylate may induce Reyes Syndrome.

Side Effect

Like all medicines, can cause side effects, although not everybody gets them. If you get any of these, stop using the ointment immediately and tell your doctor or pharmacist.

- Allergic reaction. This may be mild with just itching or redness of the skin but sometimes severe allergic reactions can occur. Symptoms could include dizziness, or fainting, faster heart rate, swelling of the face, tongue and throat.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the

website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Dermasafe Deep Rub Ointment

- Storage

Keep out of the reach and sight of children. Store below 30°C, away from direct light.

Do not use Dermasafe Deep Rub Ointment after the expiry date stated on the packaging. The expiry date refers to the last day of that month.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose the medicines if no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

A white to pale yellow coloured ointment with a pleasant odour.

- Ingredients

- Active ingredients:

- Methyl Salicylate 25% w/w
- Menthol 5% w/w

- Inactive ingredients:

- Cetostearyl Alcohol
- Hard Paraffin Wax
- White Soft Paraffin
- Emulsifying Wax

-MAL number:

MAL20013174X

Product Registration Holder & Manufacturer

InspiraPharma Sdn. Bhd.

(200401023395)

Lot 24 & 25, Jalan 8,

Kawasan Perusahaan Bakar Arang,

08000 Sungai Petani,

Kedah Darul Aman, Malaysia.

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