

MENTHOL AND WINTERGREEN CREAM

Methyl Salicylate 5.00% w/w, Levomenthol 2.00% w/w, Oleoresin Capsicum 0.20% w/w, Turpentine Oil 13.18% w/w

PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without a prescription. Nevertheless you will still need to use Menthol and Wintergreen Cream carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not included in this leaflet. See section 4.
- You must see a doctor if your symptoms do not improve after using Menthol and Wintergreen Cream.

In this leaflet:

1. What Menthol and Wintergreen Cream is and what it is used for
2. Before you use Menthol and Wintergreen Cream
3. How to use Menthol and Wintergreen Cream
4. Possible side effects
5. How to store Menthol and Wintergreen Cream
6. Further information

1. WHAT MENTHOL AND WINTERGREEN CREAM IS AND WHAT IT IS USED FOR

The name of your treatment is Menthol and Wintergreen Cream. It is a pale peach-coloured topical cream. Menthol and Wintergreen Cream contains Methyl salicylate 5.00% w/w, Levomenthol 2.00% w/w, Oleoresin capsicum 0.20% w/w and Turpentine oil 13.18% w/w as the active ingredients. Menthol and Wintergreen Cream is used to relieve the symptoms of muscular pains, rheumatic pain, fibrositis, strains and lumbago.

2. BEFORE YOU USE MENTHOL AND WINTERGREEN CREAM

Do not use Menthol and Wintergreen Cream

- On mucous membranes (e.g. nostrils, mouth, lips, ears, eyelids and genital area) or broken skin,
- On children under 16 years of age due to the presence of salicylates
- If you are allergic to methyl salicylate, levomenthol, oleoresin capsicum, turpentine oil or any of the other ingredients of this medicine which are liquid paraffin, cetostearyl alcohol, sodium laurilsulfate, sunset yellow (E110) and purified water.

Warnings and Precautions

- For external use only.
- Wash hands thoroughly after applying.
- Avoid contact with eyes, broken skin, mucous membranes.
- If the condition gets worse or does not improve, consult your doctor.
- Do not smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings, etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

Other Medicines and Menthol and Wintergreen Cream

- Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Pregnancy, breast-feeding and fertility

- Ask your doctor or pharmacist for advice before taking any medicine.

Menthol and Wintergreen Cream contains: liquid paraffin, cetostearyl alcohol, sodium laurilsulfate, sunset yellow (E110) and purified water. Sunset yellow (E110) may cause allergic reactions. Cetostearyl Alcohol may cause local skin reactions (e.g. contact dermatitis). This medicine contains 0.47ml Sodium laurilsulfate in each 100 ml volume. Sodium laurilsulfate may cause local skin reactions (such as stinging or burning sensation) or increase skin reactions caused by other products when applied on the same area.

3. HOW TO USE MENTHOL AND WINTERGREEN CREAM

Apply directly to the affected area. Massage into affected part until absorbed. Repeat several times for continued relief.

If you use more Menthol and Wintergreen Cream than you should

No special procedures or antidote are likely to be necessary.

If you forget to use Menthol and Wintergreen Cream

Apply Menthol and Wintergreen Cream as soon as you remember it.

4. POSSIBLE SIDE EFFECTS

Menthol may cause a hypersensitivity reaction including contact dermatitis, itching or a rash. In the event of an allergic reaction, the product should be washed off the skin with soap and water.

The assessment of the side effects is based on the following frequencies:

Common: less than 1 in 10, but more than 1 in 100 patients

Uncommon: less than 1 in 100, but more than 1 in 1,000 patients

Rare: less than 1 in 1000, but more than 1 in 10,000

Very rare: less than 1 in 10,000

Not known: the frequency cannot be estimated from the available information

- Burns at application site

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRAs Pharmacovigilance. Website: www.hpra.ie;

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE MENTHOL AND WINTERGREEN CREAM

Keep this medicine in a safe place out of reach and sight of children. Do not store above 25°C. Do not freeze. Do not use this medicine after the expiry date which is stated on the back label and outer carton after EXP. The expiry date refers to the last day of that month. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment. Store in the original carton in order to protect from light. Keep the cap tightly closed when not in use.

6. FURTHER INFORMATION

What Menthol and Wintergreen Cream contains

The active substances are methyl salicylate, levomenthol, oleoresin capsicum and turpentine oil.

The other ingredients are liquid paraffin, cetostearyl alcohol, sodium laurilsulfate, sunset yellow (E110) and purified water.

What Menthol and Wintergreen Cream looks like and contents of the pack

Menthol and Wintergreen Cream is a pale peach-coloured cream for topical application to the skin. It is available in 125ml size.

MARKETING AUTHORISATION HOLDER AND MANUFACTURER

The Marketing Authorisation holder and manufacturer is Ovelle Ltd., Coe's Road, Dundalk, Co Louth, Ireland Tel: +353 (0) 42 93 32304

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