PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S0

MENTHOLATUM DEEP HEAT SPRAY

The active substances per 100 g are 1,59 g methyl nicotinate, 4,59 g 2-hydroxyethyl salicylate, 4,59 g ethyl salicylate and 0,99 g methyl salicylate.

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

MENTHOLATUM DEEP HEAT SPRAY is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use MENTHOLATUM DEEP HEAT SPRAY carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share MENTHOLATUM DEEP HEAT SPRAY with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 10 days.

What is in this leaflet

1. What MENTHOLATUM DEEP HEAT SPRAY is and what it is used for
2. What you need to know before you use MENTHOLATUM DEEP HEAT SPRAY
3. How to use MENTHOLATUM DEEP HEAT SPRAY
4. Possible side effects
5. How to store MENTHOLATUM DEEP HEAT SPRAY
6. Contents of the pack and other information

1 What MENTHOLATUM DEEP HEAT SPRAY is and what it is used for

MENTHOLATUM DEEP HEAT SPRAY is used for pain relief and provides temporary relief from the minor pain and stiffness of rheumatism and muscle soreness.

2 What you need to know before you use MENTHOLATUM DEEP HEAT SPRAY

MENTHOLATUM DEEP HEAT SPRAY is for external use only.

Use only as directed.

Do not use MENTHOLATUM DEEP HEAT SPRAY

- if you are hypersensitive (allergic) to methyl nicotinate, 2-hydroxyethyl salicylate, ethyl salicylate or methyl salicylate or any of the other ingredients of MENTHOLATUM DEEP HEAT SPRAY (listed in section 6).
- if you are hypersensitive to aspirin or non-steroidal anti-inflammatory medicines (including when taken by mouth), especially where associated with a history of asthma.
- on children under 5 years of age.

Warnings and precautions

Take special care with MENTHOLATUM DEEP HEAT SPRAY.

- Do not apply on broken skin or raw areas.
- Protect the face when spraying around the neck and shoulders.
- Avoid contact with the eyes and inhalation.
- Always try on a small area first.
- Always use sparingly, as over-use may cause discomfort, particularly in persons with sensitive skins, or if used in hot weather or after a bath.
- Consult your doctor if symptoms persist.
- Exercise special care with sensitive skin.

Discontinue use of MENTHOLATUM DEEP HEAT SPRAY

- if irritation or other unwanted effects occur.

Other medicines and MENTHOLATUM DEEP HEAT SPRAY

Always tell your health care provider if you are taking any other medicines. (This includes complementary or traditional medicines.)

Tell your doctor or pharmacist if you are taking warfarin or antiplatelet medicines including aspirin, before you use MENTHOLATUM DEEP HEAT SPRAY.

Pregnancy and breastfeeding

The safety of MENTHOLATUM DEEP HEAT SPRAY in pregnancy and breastfeeding has not been established.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using MENTHOLATUM DEEP HEAT SPRAY.

Driving and using machines

It is unlikely that treatment with MENTHOLATUM DEEP HEAT SPRAY will have any effect on the ability to drive or use machines, but patients should ensure that they do not engage in the above activities until they are aware of the measure to which MENTHOLATUM DEEP HEAT SPRAY affects them.

3 How to use MENTHOLATUM DEEP HEAT SPRAY

Do not share medicines prescribed for you with any other person.

Always use MENTHOLATUM DEEP HEAT SPRAY exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

FOR EXTERNAL USE ONLY

SHAKE THE CAN BEFORE USE

The usual dose for adults and children over 5 years of age:

- Spray onto the affected parts when necessary, up to three times a day, before or after exercise.
- Point the aperture towards the area of pain.
- Hold the can more or less 15 cm from the skin.
- Press the button and spray 2 to 3 short bursts.
- Massage is not required.

If you use more MENTHOLATUM DEEP HEAT SPRAY than you should

In the event of an overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

4 Possible side effects

MENTHOLATUM DEEP HEAT SPRAY can have side effects.

Not all side effects reported for MENTHOLATUM DEEP HEAT SPRAY are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using MENTHOLATUM DEEP HEAT SPRAY, please consult your health care provider for advice.

Your skin may be sensitive to the product.

Should this occur, discontinue the use immediately.

Symptoms of urticaria (itchy rash), flushing and headache may occur.

You may experience the following side effects:

- skin burns
- blisters
- allergic reactions and
- temporary skin reactions such as redness, burning sensation and rashes may occur.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of MENTHOLATUM DEEP HEAT SPRAY. You may also report side effects directly to https://www.mentholatum.co.za.

5 How to store MENTHOLATUM DEEP HEAT SPRAY

Store all medicines out of reach of children.

Store at or below 25 °C and protect from direct sunlight.

Do not pierce or burn, even when empty.

Do not spray on a naked flame or any incandescent material.

Do not use after the expiry date stated on the aerosol can.

Return all unused medicine to your pharmacist.

6 Content of the pack and other information

What MENTHOLATUM DEEP HEAT SPRAY contains

The active substances per 100 g spray are 1,59 g methyl nicotinate, 4,59 g 2-hydroxyethyl salicylate, 4,59 g ethyl salicylate and 0,99 g methyl salicylate.

The other ingredients are butane B46 and isopropyl alcohol.

What MENTHOLATUM DEEP HEAT SPRAY looks like and contents of the pack

MENTHOLATUM DEEP HEAT SPRAY is a pressurised aerosol multi-dose dispenser for administration as a topical spray. The spray is a clear liquid with characteristic smell of methyl salicylate.

MENTHOLATUM DEEP HEAT SPRAY is presented in pressurised aerosol multi-dose dispensers with contents of 150 ml and 250 ml.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

The PI can be found online under Mentholatum SA's website:

https://www.mentholatum.co.za/product-information/.