Patient leaflet in accordance with the pharmacists' regulations (preparations) - 1986

This medicine is supplied without physician's prescription

Radian[®] B Muscle Rub Cream

Active ingredients:

Menthol2.54%Camphor1.43%Methyl salicylate0.42%Capsicum oleoresin0.005%

Inactive ingredients and allergens: See under "*Important information about some of the medicine's ingredients*" in section 2 and section 6 "*Additional information*".

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your physician or pharmacist.

Use this product according to the instructions in the section about dose in this leaflet. Consult the pharmacist if you need further information.

1. What is this medicine intended for?

The medicine is indicated for relief of rheumatic pain and mild muscle pain. **Therapeutic group:** methyl salicylate which belongs to the salicylate group.

2. Before using this medicine

Do not use this medicine:

- If you are sensitive (allergic) to the active ingredients or to any of the other ingredients that this medicine contains.
- If you are allergic to salicylates (e.g. aspirin), or to any other nonsteroidal anti-inflammatory drug.
- On open wounds, irritated skin, face, eyes and sensitive areas.
- In children under the age of 6 years.

Special warnings regarding use of the medicine

- Do not allow contact of the product with the eyes. In case of contact, rinse with water immediately.
- Avoid contact of the product with mucosal tissue (such as the mouth and the nose).
- Do not light a cigarette or go near open flames: there is a risk of severe burns. Fabric (clothing, bed and table linen, etc.) that has been in contact with this product burns more easily and is a serious fire hazard. Laundering the clothing and linen may reduce product residues but will not necessarily remove them completely.

Children and adolescents

Do not use in children under 6 years old.

Radian B and other medicines

If you are taking or have recently taken other medicines, including nonprescription medicines and dietary supplements, tell the physician or the pharmacist. Particularly if you are taking:

• warfarin (Coumadin).

Pregnancy and breastfeeding

• If you are pregnant or breastfeeding, consult a physician before using the medicine. .

Important information about some of the medicine's ingredients

This medicine contains cetostearyl alcohol, lanolin, and 0.91% sodium lauryl sulfate which may cause local skin reactions (such as contact dermatitis, stinging or burning sensations) or increased skin reactions caused by other products when used on the same area.

3. How should you use the medicine?

Check with the physician or the pharmacist if you are not sure about your dose or about how to take this medicine.

The usual dosage in children over 6 years old, adults, and the elderly is: Apply on the painful area and massage into the skin. Use sparingly on tender skin.

For strained and stiff muscles it is best used after a hot bath.

If necessary, repeat up to 3 times a day, reducing to twice a day (morning and evening) when the acute symptoms have gone away.

Do not exceed the recommended dose.

Wash your hands thoroughly after you apply the medicine. Do not cover the skin immediately after use.

Do not swallow! The medicine is intended for external use only.

Contact the physician if your signs of illness persist or get worse.

Overdose

- Salicylate poisoning may be caused after the product is applied to large areas of skin or for prolonged periods. It may also occur in the unlikely event of large quantities being swallowed. Common features of salicylate poisoning are:
 - o vomiting,
 - o dehydration,
 - o ringing in your ears (tinnitus),
 - o dizziness (vertigo),
 - o deafness,
 - o sweating,
 - o warm extremities with bounding pulses,
 - o increased respiratory rate and hyperventilation,

- Uncommon reactions include vomiting blood (hematemesis), extremely high fever, hypokalemia (low blood levels of potassium), thrombocytopenia (platelet deficiency), increased INR/PTR, excessive clotting in the blood vessels, kidney failure, and fluid in the lungs that is not related to the heart.
- Central nervous system effects including confusion, disorientation, coma, and convulsions. Less common in adults than in children.
- Camphor poisoning: may be caused by swallowing the product or by excessive use. The symptoms include:
 - \circ nausea,
 - o vomiting,
 - o pain in your upper abdomen,
 - o headache,
 - \circ dizziness,
 - o burning in the back of the throat,
 - o delirium,
 - o muscle twitching,
 - epileptiform convulsions,
 - o central nervous system depression and coma,
 - o breathing is difficult and breath has a characteristic odor,
 - o anuria (kidneys do not produce urine),
 - o death from respiratory failure or status epilepticus.
 - Fatal events have been reported in children who received 1 g or more.
- Menthol poisoning: Swallowing significant quantities of menthol is reported to cause symptoms similar to camphor poisoning, including:
 - o acute abdominal pain,
 - o nausea,
 - o vomiting,
 - o dizziness (vertigo),
 - o ataxia (inability to control muscle movements),
 - \circ drowsiness and coma.

If you accidentally apply this medicine to a large area of skin and you feel unwell, or if you swallow some, see a physician straight away. Take the product package with you.

If a child has accidentally swallowed the medicine, go to a hospital emergency room immediately and bring the medicine package with you.

Do not take medicines in the dark! Check the label and the dose <u>each</u> <u>time</u> you take a medicine. Wear glasses if you need them.

If you have any other questions regarding use of the medicine, consult the physician or the pharmacist.

4. Side effects

As with any medicine, use of Radian[®] B Muscle Rub may cause side effects in some of the users. Do not be alarmed by the list of side effects. You may not experience any of them.

Stop treatment and consult a physician if the following side effects persist:

• Excessive irritation (rare),

Other side effects:

- contact dermatitis,
- eczema,
- allergic reactions such as: rash, headaches or flushing.

If you experience any side effect, if any of the side effects get worse, or if you suffer from a side effect not mentioned in the leaflet, you should consult the physician.

You can report side effects to the Ministry of Health (MoH) by following the link 'Reporting Side Effects of Medication' on the MoH home page (<u>www.health.gov.il</u>) which links to an online form for reporting side effects, or by following this link:

https://sideeffects.health.gov.il/

5. How to store the medicine?

- Prevent poisoning! This medicine and all other medicines should be kept in a closed place out of the reach and sight of children and/or infants in order to prevent poisoning. Do not induce vomiting without an explicit instruction from the physician.
- Do not use the medicine after the expiry date (exp. date) appearing on the package and tube. The expiry date refers to the last day of that month.

Storage conditions

- Store below 25°C. Caution, flammable product, keep away from fire!
- Use within 56 days of opening.

6. Additional information

In addition to the active ingredients, the medicine also contains:

water, Argobase S1 (contains lanolin, lanolin alcohol, cetostearyl alcohol, liquid paraffin), emulsifying wax (containing sodium laurilsulfate and cetostearyl alcohol), white petroleum jelly, industrial methylated spirit, imidurea, dichlorobenzyl alcohol.

What the medicine looks like and contents of the package: 40 or 100 g tube. Not all pack sizes may be marketed.

Registration holder's name and address: Devries & Co. Ltd., Habarzel 32 st., Tel-Aviv.

Manufacturer' name and address: Thornton & Ross Ltd., Huddersfield, West Yorkshire, HD7 5QH, UK.

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Registration number of the medicine in the National Drug Registry of the Ministry of Health: 137.01.22841