

Radian B Spray

Active ingredients:

- menthol 1.4%
- acetylsalicylic acid 1.2%
- camphor 0.6%
- methyl salicylate 0.6%

Inactive ingredients and allergens: see section 2 under 'Important information about some of this medicine's ingredients', and section 6 'Additional information'.

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

Use this medicine according to the instructions in the section about dose in this leaflet. Consult your pharmacist if you need further information. Consult your doctor if your symptoms get worse or do not improve.

1. What is this medicine intended for?

This medicine is used to relieve mild rheumatic and muscle pain.

Therapeutic group: methyl salicylate and acetylsalicylic acid are salicylates.

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 in this medicine.
- If you are sensitive to salicylates (for example aspirin) or other nonsteroidal anti-inflammatory medicines (including those taken by mouth).
- On open wounds or on irritated skin. Avoid contact of the product with the eyes and mucous membranes (such as the mouth and the nose).
- If you are pregnant or breastfeeding.
- On children under 12 years old.

Special warnings about using this medicine

- Avoid contact of the product with eyes, mucous membranes (such as the mouth and the nose), face, and sensitive areas. In case of contact, rinse with water immediately.
- Do not inhale the spray.
- Flammable substance; do not use near painted or polished surfaces, fire, naked flame, hot surfaces and confined areas.
- Do not light a cigarette or go near fire until the product has dried completely - risk of severe burns. Flammable substance: 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 bedding may reduce product residues but will not necessarily remove it completely.

Children and adolescents

Do not use on children under 12 years old.

Other medicines and Radian B

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

- warfarin (Coumadin)

Pregnancy and breastfeeding

- Do not use this medicine if you are pregnant or breastfeeding.

Important information about some of this medicine's ingredients

This medicine contains fragrance with Geraniol, Citronellol, Benzyl Benzoate, Eugenol and Citral, which may cause allergic reactions.

This medicine contains 76% v/v ethanol per application. This may cause burning sensation on damaged skin.

3. How to use this medicine?

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

First use: Before use, prime the pump by pressing the spray head several times.

The usual dose for children over 12 years old, adults, and the elderly is:

Spray gently onto the painful area. If necessary, repeat after 10-15 minutes. You may rub it on or massage into the skin, as preferred.

Repeat up to 3 times a day, if necessary, reducing use to twice a day (morning and evening) when the acute symptoms subside.

Do not exceed the recommended dose.

If possible, use after a hot bath. Do not cover the skin immediately after use.

Wash your hands carefully after applying the medicine.

Do not swallow! This medicine is for external use only.

Consult a doctor if your signs of illness persist or get worse.

Overdose

Overdose can cause the following poisoning:

- Salicylate poisoning: can be caused by applying the product to large areas of skin or for prolonged periods and also in the unlikely event of a large quantity being swallowed. Salicylate poisoning is typically associated with:
 - vomiting;
 - dehydration;
 - ringing in your ears (tinnitus);
 - dizziness (vertigo);
 - deafness;
 - sweating;
 - warm extremities with pounding pulses;
 - increased breathing rate and hyperventilation;
 - Uncommon side effects include vomiting blood (hematemesis), extremely high body temperature, hypokalemia (low levels of potassium in the blood), thrombocytopenia (reduced number of platelets), increased INR/PTR, increased blood clotting in blood vessels, kidney failure, and lung edema that is not related to the heart;
 - Central nervous system (CNS) effects including confusion, disorientation, coma, and convulsions are less common in adults than in children.
- Camphor poisoning; may be caused by swallowing the product or by excessive use. The symptoms include:
 - nausea;
 - vomiting;
 - pain in the upper abdomen;
 - headache;
 - dizziness;
 - stinging in the back of the throat;
 - delirium;
 - muscle spasms;
 - epileptic spasms;
 - central nervous system depression;
 - breathing is difficult and breath has a characteristic odor;
 - anuria (kidneys do not produce urine);
 - death from respiratory failure or seizure (status epilepticus);Fatal incidents have been reported in children who received 1 g or more.
- Menthol poisoning: Swallowing significant quantities of menthol causes symptoms similar to camphor poisoning, including:
 - severe abdominal pain;
 - nausea;
 - vomiting;
 - dizziness (vertigo);
 - ataxia (inability to control muscle movement);
 - drowsiness and coma.

If you accidentally apply the medicine to a large area of skin and feel unwell, or if you have swallowed some of it, consult a doctor immediately. Take the product package with you.

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

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using Radian B Spray may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Stop use and consult a doctor as soon as possible if you experience excessive irritation or any other unusual sign.

Side effects

- eczema
- contact dermatitis
- allergic reaction associated with:
 - hives (urticaria-allergic rash)
 - flushing
 - headache

If you experience any side effect, if any side effect gets worse or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: <https://sideeffects.health.gov.il/>

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the product. The expiry date refers to the last day of that month.

Storage conditions

- Store below 25°C. Caution, flammable substance, keep away from heat and fire.

6. Additional information

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

industrial methylated spirit, water, glycerol, citronella oil and ammonia solution 33%.

What the medicine looks like and contents of the pack: 100 ml bottle.

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

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

Revised in April 2021 according to MOH guidelines.

Registration number of the medicine in the Ministry of Health's National Drug Registry: 137-63-24791