

Patient Leaflet in Accordance with the Pharmacists' Regulations (Preparations) -1986

This medicine is sold without a doctor's prescription

Tiger Balm Red, Tiger Balm White Ointment

Active ingredients:

Tiger Balm Red contains (w/w):

Camphor 11%, Menthol 10%, Cajuput oil 7%, Dementholized mint oil 6%, Clove oil 5%

Tiger Balm White contains (w/w):

Dementholized mint oil 16%, Cajuput oil 13%, Camphor 11%, Menthol 8%, Clove oil 1.5%

For the list of the additional ingredients, see section 6.

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any further questions, please refer to the doctor or pharmacist.

Use this medicine according to the instructions in the dosage section in this leaflet. Consult the pharmacist if you require additional information. Refer to a doctor if the symptoms worsen or do not improve after 7 days.

1. What is the medicine intended for?

The ointment is intended for temporary relief of muscular pains.

2. Before using the medicine

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredients or to any of the additional ingredients the medicine contains (for a list of the additional ingredients, see section 6).
- You have asthma or other respiratory system diseases that can result in severe breathing difficulties.
- You have any type of skin disease.
- Do not use the ointment on open wounds or on inflamed or irritated skin.
- Do not use in children under 2 years of age.

Special warnings concerning use of the medicine

- Do not apply to damaged, wounded or irritated skin. In any case you experience signs of skin injury on the applied area (e.g., pain, swelling, appearance of blisters, burns), stop the use and refer to the doctor immediately!
- Avoid contact with and around the eyes, mucous membranes and other sensitive areas such as the mouth, nose, vagina and the urethra.
- Do not inhale and do not apply inside the nostrils.
- If there is a need for bandaging do not tighten it.
- Wash hands immediately after use.
- Do not smoke or go near naked flames, as there is a risk of severe burns. Fabrics (such as clothing, bedding, dressings) that have been in contact with the ointment might burn more easily thus posing a serious fire hazard. Washing these fabrics may not totally remove the ointment.

Children and adolescents: The medicine is not intended for children under 2 years of age.

Drug interactions:

If you are taking or have recently taken any other medicines, including non-prescription medicines and nutritional supplements, please tell the doctor or pharmacist.

Pregnancy and breastfeeding:

If you are pregnant, think you are pregnant, are planning a pregnancy or are breastfeeding, consult the doctor or pharmacist before using the medicine. Avoid excessive use during pregnancy or breastfeeding time period.

3. How to use the medicine?

Check with the doctor or pharmacist if you are not certain about the dosage and the manner of treatment with the medicine.

The standard dosage is usually:

Apply gently to the painful area of the skin as necessary (usually 2 to 3 times a day).

Do not exceed the recommended dose.

If there is no improvement in your condition within 7 days, or if there is any deterioration, refer to the doctor.

Attention:

This medicine is intended for external use only. Avoid contact with the eyes, mucous membranes, wounded skin and other sensitive areas. See also section 'Special warnings concerning use of the medicine'.

The ointment might stain the clothing.

Manner of use:

Apply gently to the painful area. In order to avoid an allergic reaction, perform a test on a small area before use.

Wash hands immediately after use. See also section 'Special warnings concerning the use of the medicine'.

If you have accidentally taken a higher dosage: if you used an overdose or if a child accidentally swallowed the medicine, proceed immediately to a doctor or a hospital emergency room, and bring the package of the medicine with you. Excessive use may cause irritation of the skin.

If you forgot to use the medicine, do not apply a double dose to make up for it.

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

If you have further questions concerning the use of the medicine, consult the doctor or pharmacist.

4. Side effects

As with any medicine, the use of Tiger Balm may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Stop treatment and refer to the doctor immediately if the following side effects appear:

Irritation to the skin such as rash or allergic reactions including contact dermatitis, burning at the application site.

The frequency of these side effects is not known.

Additional side effects

Side effects of unknown frequency (effects whose frequency has not yet been determined):

- Burning sensation at the application site.
- It is important to not use the ointment near or inside the nose of babies and small children, as it has been reported that the ingredients of the ointment might cause

difficulties or disturbances in breathing, loss of consciousness and/or severe allergic reactions (including a significant drop in the blood pressure and/or swelling of the throat).

If a side effect appears, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Side effects may be reported to the Ministry of Health by clicking on the link "Report on side effects following medicinal treatment" on the homepage of the Ministry of Health website (www.health.gov.il) which leads to an online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il/>

5. How to store the medicine?

- **Avoid poisoning!** This medicine, and any other medicine, must be stored in a closed place out of the reach and sight of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** store below 25°C. After the first opening of the jar, the ointment may be used for 6 months, but no later than the expiry date imprinted on the package.

6. Additional information

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

Hard paraffin, yellow soft paraffin.

Tiger Balm Red also contains: cinnamon oil.

What does the medicine look like and what does the package contain?

A whitish-transparent (Tiger Balm White) or reddish-brown (Tiger Balm Red) ointment in a glass jar of 19 g.

Manufacturer: Haw Par Healthcare Ltd., Singapore

Registration holder: Rafa Laboratories Ltd., P.O. Box 405, Jerusalem 9100301

Medicine registration number in the National Medicines Registry of the Ministry of Health:

Tiger Balm Red: 1272230565

Tiger Balm White: 1272330566

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