

Package leaflet: Information for the user

Tiger Balm White Ointment

cajuput oil, camphor, levomenthol, clove oil

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- 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 listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 2 weeks.
- You must talk to a doctor if your muscular aches and pains worsen or do not improve after 2 weeks or if your headaches last for 24 hours or keep coming back over the next week.

What is in this leaflet

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

1. What Tiger Balm is and what it is used for

- Tiger Balm can be used by adults and children over 2 years of age to give temporary relief from minor muscular aches and pains.
- Tiger Balm can also be used by **adults only** for the treatment of tension headache. This is the kind of headache that you may get when your head, neck and shoulder muscles become tense due to tiredness, overwork or emotional strain. If you are not sure whether you have a tension headache **contact your doctor or pharmacist** for advice.
- You must talk to a doctor if your muscular aches and pains worsen or do not improve after 2 weeks or if your headaches last for 24 hours or keep coming back over the next week.

2. What you need to know before you use Tiger Balm

Do not use Tiger Balm

- If you are allergic (hypersensitive) to camphor, menthol, clove oil or cajuput oil or any of the other ingredients of Tiger Balm (listed in Section 6).
- If you have asthma or other lung diseases that can result in severe breathing difficulties.
- If the type of headache you have is not the tension type. A tension headache is usually restricted to a slight dull ache on both sides of the head and pressure of a cap-like pain around the forehead, neck and shoulder regions only. If you are not sure whether you have a tension headache contact your doctor or pharmacist for advice.
- If your headache lasts for a long time in one area, is severe or involves any other symptoms such as sickness, dizziness, a migraine, changes in vision, is on one side of your head only, or occurs when you first wake up and/or following strenuous exercise you should talk to your

doctor or pharmacist immediately. You should seek medical advice if your headache is different to any headache that you have had before.

- If you have any sort of skin disease.
- In children less than two years of age.
- On open wounds or on inflamed or irritated skin.

You must contact a doctor if your muscular aches and pains worsen or do not improve after 2 weeks.

Warnings and precautions

- Keep Tiger Balm away from the delicate and moist linings in or around the eyes, mouth, nose, vagina (the birth canal) and the urethra (the tube that carries urine from the bladder).
- Do not bandage areas where you have applied Tiger Balm.
- Do not inhale Tiger Balm or apply to the nose.
- 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 Tiger Balm

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

- Avoid excessive use if you are pregnant or breast-feeding.

3. How to use Tiger Balm

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist or nurse if you are not sure.

Tiger Balm White is for external use only.

Follow the recommended instructions below and wash hands after use:

- **For muscular aches and pains (Adults and children aged 2 years and older):** rub gently on the affected parts of the skin as necessary, usually 2 or 3 times a day.
- If your condition does not improve after two weeks or gets worse, seek medical advice. **Do not use on children under two years of age.**
- **For tension headaches (Adults only):** Apply the ointment onto the forehead or temples and lightly rub in a circular motion. You should use a pea-sized amount of ointment, just enough to cover the area being treated. Repeat this application after 30 minutes and after one hour if your headache has not got better. If your symptoms last continuously for 24 hours or if they keep coming back over the next 7 days, seek medical advice. If you are not sure whether you have a tension headache **contact your doctor or pharmacist** for advice.
- **Do not use Tiger Balm to treat headaches in children.**

Use in children

- **Do not use on children under two years of age.**
- **Do not use Tiger Balm to treat headaches in children.**
- In the case of accidental swallowing of Tiger Balm by a child, it is important to consult a physician without delay who can provide any necessary treatment. Do not try to induce vomiting.

If you forget to use Tiger Balm

Do not apply a double quantity to make up for a forgotten application.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Tiger Balm can cause side effects, although not everybody gets them.

Frequency not known (cannot be estimated from the available data).

- Tiger Balm may occasionally cause irritation to the skin, such as rashes or contact dermatitis. If this occurs, discontinue use and seek medical advice immediately.
- It is important not to use Tiger Balm near the nose of babies or young children, as other similar products have been reported to cause difficulties or disturbances in normal breathing, falling unconscious or severe allergic reactions (significant fall in blood pressure and/or swelling of the voice box).
- Burns at application site.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below).

HPRA 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 Tiger Balm

Keep this medicine out of the sight and reach of children.

Do not store above 25°C.

Do not use Tiger Balm after the Expiry date which is stated on the base of the jar and the 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.

6. Contents of the pack and other information

What Tiger Balm contains

- The active substances are cajuput oil 13.0% w/w, camphor 11.0% w/w, levomenthol 8.0% w/w and clove oil 1.5% w/w.
- The other ingredients are dementholised mint oil, yellow soft paraffin and hard paraffin.

What Tiger Balm looks like and contents of the pack

Tiger Balm White is a whitish, oily ointment. The ointment is supplied in tins containing 4g or 8g or in screw top jars containing 19g or 30g. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Chefaro Ireland DAC

The Sharp Building
Hogan Place
Dublin 2
Ireland

Manufacturer (site of batch release in EEA):

Omega Pharma International, Venecoweg 26, B-9810 Nazareth, Belgium.

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