

PATIENT INFORMATION LEAFLET

Complementary Medicine: Health Supplement

D 34.12 Multiple substance formulation

SCHEDULING STATUS: S0

PROPRIETARY NAME AND PHARMACEUTICAL FORM

TIGER BALM[®] RED, ointment

Read this leaflet carefully before TIGER BALM RED is applied because it contains important information for you.

TIGER BALM RED is available without a doctor's prescription. Nevertheless, you still need to use TIGER BALM RED carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not to share TIGER BALM RED with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 2 weeks.

WHAT TIGER BALM RED CONTAINS

TIGER BALM RED contains natural camphor 11,0 % w/w, levomenthol (menthol) 10,0 % w/w, cajuput oil 7,0 % w/w, dementholised mint oil 6,0 % w/w, clove oil 5,0 % w/w as well as cassia oil, hard paraffin and yellow soft paraffin.

WHAT TIGER BALM RED IS USED FOR

Improves blood circulation in micro vessels. Temporary relief of muscular cramps and rheumatic pain.

BEFORE YOU APPLY TIGER BALM RED**Do not apply TIGER BALM RED**

- if you are allergic (hypersensitive) to any of the ingredients of TIGER BALM RED;
- if you have any sort of skin disease;
- in infants and children less than 2 years of age;
- on broken, irritated or sensitive skin;
- if you are pregnant or breastfeeding (refer to “Pregnancy and breastfeeding”);
- if you have asthma, persistent or chronic cough or other chronic lung conditions;
- if you have epilepsy.

Take special care with TIGER BALM RED

- Avoid use of TIGER BALM RED on the face or near the eyes, mucous membranes, genitals, nose and mouth.
- Avoid exposure of applied area to sunlight.
- Do not bandage areas where you have applied TIGER BALM RED.
- Do not inhale TIGER BALM RED or apply to the nose.
- Do not use TIGER BALM RED 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).
- Do not use with other products containing camphor, menthol, eucalyptol and/or eucalyptus essential oil.

A varied diet is the most effective and safe way to achieve good nutrition, health, body composition as well as mental and physical performance.

If symptoms persist or worsen, reoccur or are accompanied by a fever, rash or persistent headache, discontinue use and consult a relevant healthcare practitioner.

Pregnancy and breastfeeding

Safety in pregnancy and breastfeeding has not been established (refer to “Do not apply TIGER BALM RED”).

Always consult your healthcare professional before using medicines if you are pregnant or breastfeeding your baby.

Taking other medicines with TIGER BALM RED

Always tell your healthcare professional if you are taking or using any other medicine. This includes complementary or traditional medicines. Take special care when using other topical pain-relieving products containing camphor, menthol, eucalyptol and/or eucalyptus essential oil, as this may multiply the dosage effect. Consult your healthcare professional for medical advice when needed.

HOW TO USE TIGER BALM RED

Always apply TIGER BALM RED as per the following instructions (you should check with your healthcare professional, doctor or pharmacist if you are unsure). The product should be handled/applied by adults only.

TIGER BALM RED is for external use only and is harmful if swallowed.

Adults and children over 2 years of age: Apply thinly and evenly to the skin as necessary, up to 3 times a day. Wash your hands after use.

Contact a healthcare professional if your condition worsens or do not improve after 2 weeks.

If you apply more TIGER BALM RED than you should, or swallow it

In the event of an overdose, you may experience some side effects, such as skin irritation. In case of accidental swallowing, urgently contact your doctor or pharmacist; if neither is available, contact the nearest hospital or poison control center. Do not try to induce vomiting.

SIDE EFFECTS

TIGER BALM RED can have side effects.

Not all side effects reported for TIGER BALM RED are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using TIGER BALM RED, discontinue use and consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop using TIGER BALM RED and tell your doctor immediately, or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- Rash or itching, hives, redness, irritation, blistering and/or peeling skin.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to TIGER BALM RED. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Burning pain or discomfort, or blistering at the application site;
- Temporary cessation of breathing, throat spasms or difficulty in breathing in infants and young children.

These side effects may be serious. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequency not known

- Nausea, dizziness and/or headache.

STORING AND DISPOSING OF TIGER BALM RED

STORE ALL MEDICINES OUT OF REACH AND SIGHT OF CHILDREN.

Store in a cool, dry place at or below 30 °C. Keep the jar tightly closed.

Do not use after the expiry date stated on the jar and the carton.

Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

IDENTIFICATION AND PRESENTATION

TIGER BALM RED is a reddish-brown, oily ointment. The ointment is supplied in screw top glass jars containing 19 g or 30 g ointment. Not all pack sizes may be marketed.

REGISTRATION NUMBER

This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

MANUFACTURED BY

Xiamen Tiger Medicals Co. Ltd., for Haw Par Healthcare Ltd., Singapore under licence from Haw Par Corporation Ltd.

Manufacturer's Address: No 289, West Yangguang Road, Haicang District, Xiamen City, Fujian Province, China

NAME AND ADDRESS OF THE PROPOSED HOLDER OF CERTIFICATE OF REGISTRATION

Abex Pharmaceutica (Pty) Ltd; Rubenstein Ridge Suite C, 617 Rubenstein Drive; Moreleta Park; 0181; Tel: +27 (0)12 997 6974

DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET

Edition date: 13 October 2021

MANNER OF GAINING ACCESS TO PROFESSIONAL INFORMATION

For Professional Information, please contact abex.regulatory@abexpharm.com.

TIR/PIL/B