Instructions for use: Information for users

China-Oel
1 ml / ml
Liquid

Peppermint oil

For oral administration and for cutaneous use in adults
For inhalation in adults and adolescents aged 12 years and above

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 have 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 a week.

What is in this leaflet

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

1. What China-Oel is and what it is used for

China-Oel is a traditional herbal medicine.

Therapeutic indications
- **External administration**
  Traditional herbal medicine to ease symptoms of cough and colds and to relieve localized muscle pain
- **Inhalation**
  Traditional herbal medicine to ease symptoms of cough and colds
- **Internal administration**
  Traditional herbal medicine to ease mild gastrointestinal symptoms such as flatulence

The medicinal product is a traditional medicine that is registered exclusively for the therapeutic indication based on many years of use.
If symptoms persist or in the event of side effects other than those listed in the leaflet, the user should consult a doctor or another qualified health care professional.

2. What you need to know before you use China-Oel

Do not use China-Oel
- if you are allergic to peppermint oil and/or menthol
- for children under the age of 12 years

Internal administration:
- if you have liver disease (liver disorder), gastric acid deficiency, biliary inflammation, gallstones, or other biliary problems.

Warnings and precautions
If symptoms persist for more than 1 week or in the event of side effects other than those listed in the leaflet, you should see a doctor or another qualified health care professional.
If symptoms worsen when using this medication, immediately contact a doctor or pharmacist.

If you have a cough and cold, you should also contact a doctor if you develop shortness of breath (dyspnea), fever or if you have purulent or bloody sputum.

If used externally, wash your hands after use, to avoid contact with the eyes or sensitive parts of the body such as mucosal linings or open wounds.
Do not apply peppermint oil to damaged or irritated skin.

If you already suffer from heartburn or have a hiatal hernia, symptoms may worsen in some cases when used internally. In this case you should immediately stop using peppermint oil.
Only use peppermint oil with caution if you suffer from gastrointestinal inflammation or ulcers.

When using this medication, avoid other medications that also contain peppermint oil.

Children and adolescents
China-Oel may not be used in all therapeutic indications in children under the age of 12 years.
Menthol (main component in China-Oel) can lead to respiratory arrest and laryngeal spasms in infants and toddlers under the age of 30 months.

There is also insufficient information available on oral and external application of China-Oel in adolescents under the age of 18 years. For this reason, oral and external application is not recommended for adolescents from age 12 up to and including 17 years of age.

Other medicines and China-Oel
Tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use any other medicines.
Interactions between China-Oel and other medications have not been investigated.

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 taking/using this medicine.

Safety during pregnancy and breast-feeding has not been sufficiently investigated. As there is insufficient data, it is not recommended that pregnant and breast-feeding women take China-Oel.

Driving and using machines
Effects on the ability to react are not known. No studies have been carried out on the ability to drive and use machines.

3. How to use China-Oel

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 if you are not sure.

The recommended dose is:

External application (only for adults from 18 years of age)
- Coughs and colds

Massage 2 – 3 drops up to 3 times a day onto the chest or back.
Do not use for longer than 2 weeks!

- Muscular pain
  Massage 2 – 3 drops up to 3 times a day onto the affected site.
  It is recommended not to use the medicine for longer than 2 – 4 weeks.

Inhalation (for adolescents from the age of 12 years and adults)
Adolescents from the age of 12 years and adults add 3 – 4 drops to hot water 2 to 3 times a day, and inhale with eyes closed. The medication can also be inhaled using a nasal stick without adding water. The pack sizes with 25 ml and 100 ml contain a corresponding nasal stick to facilitate controlled inhalation. Do not use for longer than 2 weeks!

Internal administration (only for adults from 18 years of age)
Adults should take 3 – 4 drops (0.08 - 0.12 ml) 2 to 3 times a day in warm water. Do not use for longer than 2 weeks!

If symptoms persist for longer than this or periodically recur, visit a doctor.

Please note that it may take a few seconds for the liquid to pour out of a new bottle. Please hold the bottle upright. Do not shake!

Use in children and adolescents
External and internal use is not indicated in children and adolescents under the age of 18 years. Use as an inhalant in children under the age of 12 years is not indicated (see Section 2 "Do not use China-Oel" and Section "Children and adolescents").

Patients with restricted kidney function
There is insufficient data for specific dose recommendations for restricted kidney function.

If you use more China-Oel than you should
External administration
No cases of overdose have been reported.

Inhalation
Inhalation of larger doses of menthol can lead to dizziness, confusion, muscle weakness, nausea or double vision.

Internal administration
A large oral overdose can lead to severe gastrointestinal complaints, diarrhoea, damage to the mucosal membranes of the intestines, epileptic seizures, unconsciousness, respiratory arrest, nausea, arrhythmia, impaired motor coordination and other problems affecting the central nervous system.
In these cases, gastric lavage should be performed and the patient placed under medical observation to treat symptoms that may arise.

Immediately contact a doctor if you significantly overdose.

If you forget to use China-Oel
Do not use a double dose to make up for a forgotten dose.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Side effects with unknown frequency (frequency cannot be estimated from the available data):

External administration
- Hypersensitivity reactions such as a skin rash, localized skin inflammation (contact dermatitis), eye irritation, burning sensation at the application site. These reactions are generally mild and temporary.
- Irritation to nasal passages after local application

Inhalation
- For hypersensitive individuals: Respiratory paralysis, bronchial and laryngeal spasms

Internal administration
- Menthol odor in the urine and stool, pain when urinating (dysuria) and inflammation of the glans
- Allergic reactions to menthol with headache, slowed heartbeat, muscle tremors, impaired motor coordination (ataxia), severe allergic (anaphylactic) shock, skin redness (erythematous skin rash)
- Heartburn
- Burning sensation around the anus
- Blurred vision
- Nausea, vomiting
- For patients who are hypersensitive to menthol and peppermint oil: Burning sensation in the mouth, repeated blistering (aphthae) in the mouth, lichenoid reactions.

If hypersensitivity reactions occur, do not use China-Oel again.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to the Federal Institute of Drugs and Medical Devices, Pharmacovigilance Department, Kurt-Georg-Kiesinger-Allee 3, D-53175 Bonn, website: www.bfarm.de.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store China-Oel

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

Do not use this medicine after the expiry date which is stated on the label and carton after “expiry date” or “use by”. The expiry date refers to the last day of that month.

Do not store above 25 °C.
Store in the original package to protect the contents from light.

Shelf life after opening: 12 months

Never dispose of medicines via waste water (e.g. do not flush down the toilet or pour down the sink). Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment. Further information is available at www.bfarm.de/arzneimittelentsorgung.

6. Contents of the pack and other information

What China-Oel contains
- The active substance is: peppermint oil.
  1.0 ml China-Oel contains 1.0 ml peppermint oil.
- Excipients: none

What China-Oel looks like and contents of the pack
- Round 5 ml clear glass bottle in an outer carton
- Characteristic 10 ml clear glass bottle in an outer carton

- Characteristic 25 ml clear glass bottle with an nasal stick in an outer carton
- Characteristic 100 ml clear glass bottle with 3 nasal sticks in an outer carton

Marketing Authorisation Holder and Manufacturer
mibe GmbH Arzneimittel
Münchener Str. 15
06796 Brehna

This leaflet was last revised in October 2024.

This is a translation. All information is based on the German version.

(Additional information and instructions for use for the nasal stick)

Important information about China-Oel

China-Oel contains pure peppermint oil, an essential oil extracted by steam distillation from the fresh flowering above-ground parts of *Menthae x piperitae L.*

Because China-Oel is a natural herbal medicine, the scent, taste and colour may fluctuate depending on when and where the crop is harvested and the prevailing climate. This natural fluctuation is not, however, a quality deficiency.

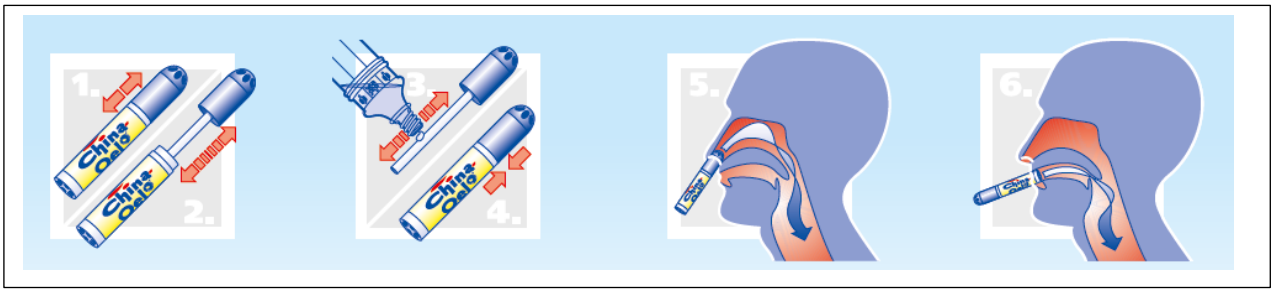
We wish you a speedy recovery.

Important information about the nasal stick
The China-Oel nasal stick is used for inhalation through the nose or mouth after sprinkling the inside felt wick with the medicinal China-Oel.

Cleaning and maintaining the China-Oel nasal stick
After using a China-Oel nasal stick, rub the outside clean with a clean cloth and ideally store in the original packaging.

Out and about with the China-Oel nasal stick
The advantage of the China-Oel nasal stick is that China-Oel can be used anywhere, be it the office, the theatre, the car or on a trip. The nasal stick is easy to use and is filled each time with 3 drops of China-Oel.

Instructions for use for the China-Oel nasal stick



1. Pull off blue cap top to open the China-Oel nasal stick.
2. Fully pull out the upper part of the cap with the non-woven fiber wick.
3. Add 3 drops of China-Oel along the non-woven fiber tube.
4. Introduce the upper part of the cap with the non-woven fiber wick into the bottom part of the nasal stick and close.
5. To treat the nasal area:
6. Insert the **blue side** into each nostril (no higher than 1 cm) and breathe in deeply through your **nose**.
7. To treat the throat area:
8. Put the **white side** of the nasal stick into your **mouth** (no more than 1 cm) and breathe in deeply.

Important note

Do not use the nasal stick if it is obviously damaged! For hygienic reasons, a nasal stick should only be used by one person. Replace the nasal stick after max. 30 days. Never swallow! Keep in a safe place away from children! Not to be used by children under the age of 12 years! When drizzling the China-Oel onto the non-woven fiber tube, take care to ensure that China-Oel does not get into your eye!

Only use nasal sticks until the date printed on the nasal stick and the folding box.

The nasal stick is available as a pack of 3 from your pharmacy under PZN 8763022.

Please report any serious events associated with the China-Oel nasal stick to the manufacturer and the responsible authorities in your country.

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CE 0297
Medical device