



Package leaflet: Information for the user

Dear patient,

please read this leaflet carefully because it contains important information about what you should bear in mind when using this medicinal product. If you have any questions, please contact your doctor or pharmacist.

Active substance

Peppermint oil

Composition

100.0 ml China-Oel contains a medically active substance
100.0 ml peppermint oil.

Pharmaceutical form and content

Essential oil, 10, 25 and 100 ml.

Herbal medicinal product for digestive disorders, for catarrhal diseases of the upper respiratory tract and externally for muscle or nerve pain.

Marketing Authorisation Holder



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Manufacturer

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Therapeutic indications

To be taken for cramp-like complaints of the bile ducts and the gastrointestinal tract, for ingestion or inhalation for colds of the upper respiratory tract, for external use for muscle pain (myalgia) and neuralgiform complaints. A doctor should be consulted for complaints that last longer than a week or recur periodically.

Contraindications

When should you not use China-Oel?

You must not use China-Oel in cases of obstruction of the bile ducts, inflammation of the gall bladder, severe liver damage.

When should you use China-Oel only after consulting a doctor?

The following describes when you should only use China-Oel under certain conditions and with special care. Please consult your doctor about this. This also applies even if the information given was correct in the past. If you suffer from gallstone disease, the medicinal product should only be taken after consulting a doctor.

What do you have to consider during pregnancy and breastfeeding?

The widespread use of peppermint oil as a flavouring and orienting animal experiments have not yet provided any evidence of risks in pregnancy and breastfeeding.

What should be taken into account for infants and small children?

Peppermint oil should not be applied or inhaled by infants and small children (pre-school age) in the area of the face, especially the nose, as asthma-like conditions can occur.

There is insufficient research on the use of this medicinal product in children with digestive disorders. Children under 12 years of age should therefore not take it.

Precautions for use and warnings

What precautions must be taken?

For external use, wash hands thoroughly after use. This will prevent accidental contact of peppermint oil with sensitive parts of the body such as mucous membranes and open wounds or with the eyes.

What do you have to observe in road traffic and when working with machines and when working without a secure grip?

China-Oel has no negative influence on the ability to react in road traffic, when working with machines and when working without a secure footing.

Interactions

Can other drugs influence the effect of China-Oel or be influenced by China-Oel?

Interactions with other drugs are not known.

Dosage instructions and method of administration

The following information applies unless your doctor has prescribed otherwise for China-Oel. Please follow the instructions for use, otherwise China-Oel cannot work properly.

How much and how often should you take China-Oel?

Internal use:

Average daily dose 6 to 12 drops, i.e. 2-3 times a day 3-4 drops each.

For inhalation:

Put 3-4 drops in about 300 ml of hot water, 2-3 times a day.

External use:

Rub a few drops into the affected area of skin.

When and how should you use China-Oel?

Colds of the upper respiratory tract:

Put 3 drops into hot water and, with eyes closed, inhale the vapours deeply (inhale) - drink an additional 2-3 drops in hot water sip by sip. Rub lightly into the chest, neck and throat.

Cramp-like complaints of the bile ducts and the gastrointestinal tract:

Add 3-4 drops to half a glass of warm water and drink on an empty stomach.

Muscle pain (myalgia):

Rub (massage) a few drops on the painful areas, then keep warm with cotton wool or a wool cloth.

Nerve pain-like (neuralgiform) complaints:

Rub a few drops well on the painful areas. In case of neuralgiform complaints in the area of the head, rub a few drops well on the forehead, temples and neck. Dabbing with cold water increases the effect.

Application errors and overdose

China-Oel should not come into contact with eye mucous membranes.

What should be done if China-Oel has been used in excessive quantities (intentional or accidental overdose)?

Taking large quantities of essential oils can cause stomach ache, nausea and vomiting. In severe cases, you may also experience intoxication or drowsiness, cardiac dysfunction and shortness of breath.

In the literature, cases have been described in which the intake of 8 to 9 g of menthol, the main ingredient of peppermint oil (corresponding to about 18 ml of peppermint oil), merely caused nausea and a sensation of cold. Since it is also described in the literature that, especially with sensitive persons, already about 2 g menthol (corresponding to about 1 teaspoonful of peppermint oil) can lead to poisoning, the doctor should be informed immediately in case of any possible poisoning with China-Oel, who will take the necessary measures.

Specific antidotes are not known; under no circumstances should milk or alcoholic beverages be drunk, as this can promote the absorption of essential oils. Excessive inhalation may cause coughing, which will stop quickly after stopping inhalation.

Side effects

What side effects can occur when using China-Oel?

Sensitive persons may experience stomach problems after ingestion. External use may cause burning and reddening of the skin, which will subside after thorough rinsing with water.

In rare cases peppermint oil can also cause allergic skin reactions.

In these cases, treatment should be discontinued and a doctor consulted.

If you observe side effects not listed in this package leaflet, please inform your doctor or pharmacist.

Notes and information on the shelf life of the medicinal product

The expiry date of this package is printed on the label and the folding box. Do not use this package after this date!

After opening the bottle, China-Oel has a shelf life of at least 20 months.

Medicinal product should be kept out of the reach of children.

Status of information: 09.2008

Always store the bottle protected from light in the outer carton.



Things to know about China-Oel

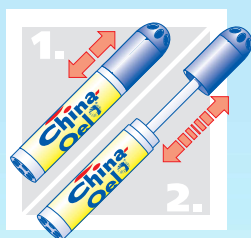
China-Oel - pure peppermint oil from BIO-DIÄT-BERLIN - is the essential oil obtained by steam distillation from the fresh, flowering above-ground parts of *Menthae x piperitae* L.

BIO-DIÄT-BERLIN has developed its own standards for the quality assurance of China-Oel, which are stricter than those required by law. This care guarantees that you receive a herbal medicinal product which is produced by BIO-DIÄT-BERLIN in harmony with nature. This method provides you with a herbal medicinal product that has been tried and tested for decades and has excellent effectiveness and tolerance.

Due to the fact that China-Oel is a natural herbal medicinal product, there can be variations in smell and taste as well as in colour depending on the time of harvest, climatic conditions and cultivation area. **However, this naturally occurring fluctuation does not represent a quality defect, but shows the naturalness of this product without impairing its effectiveness and tolerance.**

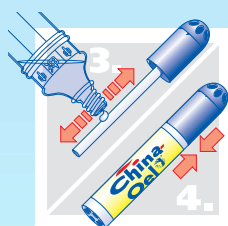
We wish you a good improvement.

Instructions for use of the China-Oel Inhaler



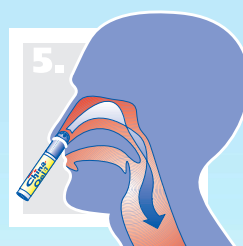
1. Pull off the blue cap top to open the China-Oel Inhaler

2. Pull out the upper part of the cap with the receiving fleece completely.

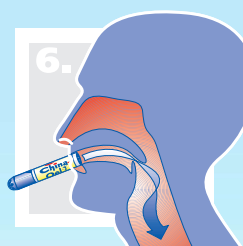


3. Spread 2-3 drops of China-Oel along the fleece tube.

4. Insert the upper part of the cap with receiving fleece into the lower part of the inhaler and close it



5. To treat the nasal cavity: Insert the **blue side** alternately into the nostrils (maximum 1 cm) and breathe in vigorously through the **nose**.



6. To treat the throat: Put the **white side** of the inhaler in your **mouth** (maximum 1 cm) and breathe deeply.

Interesting facts about the China-Oel Inhaler

The China-Oel Inhaler is used for inhalation via the nose or mouth after the inner fibre pen has been sprinkled with the medicinal China-Oel. By inhaling, the China-Oel reaches the mucous membranes of the nose and mouth and by inhaling deeply into the respiratory tract, where it can develop its medicinal effect.

Care and cleaning of the China-Oel Inhaler

After using a China-Oel inhaler, wipe the outside of the inhaler with a fresh cloth and store it in its original packaging.

Travelling with the China-Oel Inhaler

The advantage of the China-Oel inhaler is that China-Oel can be used anytime and anywhere, e.g. in the office, the theatre, in the car or when travelling. The inhaler is easy and unproblematic to use and can be refilled with 2-3 drops of China-Oel at a time.



Important note

Do not use inhalers with clearly visible defects! For reasons of hygiene, an inhaler should only be used by one person at a time. Replace inhaler after max. 30 days of use!

Never swallow the inhaler! Keep away from children! Do not use for children under 12 years of age! When pouring the China-Oel on the fleece tube, make sure that China-Oel does not get into the eyes!



Use of inhalers only until the date indicated on the inhaler and the folding box. You can obtain the inhaler as a 3-pack from the pharmacy under PZN 8763022.

Please report all serious incidents related to the China-Oel Inhaler to the manufacturer and the competent authority in your country.

Status of information: 02/2020.

All information is based on the German version.



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Medical device