



ED 84

10.33 g/15.07 g per 100 g dental emulsion · Chloroxylenol, racemic camphor

Read all of this leaflet carefully before this medicine is administered to you because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- Ask your dentist or pharmacist if you need more information or advice.
- If you get any side effects, talk to your dentist or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a dentist if you do not feel better or if you feel worse after one day.

What is in this leaflet

1. What ED 84 is and what it is used for
2. What you need to know before ED 84 is administered to you
3. How to use ED 84
4. Possible side effects
5. How to store ED 84
6. Contents of the pack and other information

1. What ED 84 is and what it is used for

ED 84 is a dental emulsion for dental use in the oral cavity.

ED 84 is used for temporary disinfection of root canals and for treatment of inflammations of the root tip.

2. What you need to know before ED 84 is administered to you

Do not use ED 84:

- if you are allergic to chloroxylenol, racemic camphor or any of the other ingredients of this medicine (listed in section 6).
- in infants and toddlers up to the age of 2 years.

Warnings and precautions

Talk to your dentist or pharmacist before ED 84 is administered to you.

Children and adolescents

The safety of ED 84 in children and adolescents has not yet been established. ED 84 should therefore be used with caution in children and adolescents.

Other medicines and ED 84

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

There are no known interactions between ED 84 and 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 dentist or pharmacist for advice before using this medicine.

ED 84 should not be used during pregnancy and breast-feeding, unless this is deemed to be clearly necessary by your dentist.

Driving and using machines

ED 84 has no known effects on the ability to drive and use machines.

ED 84 contains Macrogolglycerol hydroxystearate

Macrogolglycerol hydroxystearate may cause skin reactions.

3. How to use ED 84

This medicine is exclusively administered by your dentist.

In the treatment of infected root canals, your dentist will introduce ED 84 into the root canal with a soaked paper point or a pipette.

No adverse reactions are to be expected if ED 84 enters the surrounding (periapical) bone via the root tip, since ED 84 is tissue-compatible.

Before filling a root canal, your dentist will remove residues of ED 84 with paper points, since these would otherwise interfere with the hardening process of the root-filling material.

The duration of treatment should not exceed 2 days, since after that period of time ED 84 loses its efficacy. If a longer duration of treatment is desired, the medicine should be replaced every 2 days.

Shake ED 84 well before each use.

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

4. Possible side effects

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

Not known (cannot be estimated from the available data)

Hypersensitivity reactions (including respiratory distress) in patients sensitized against racemic camphor.

Additional side effects in children and adolescents

In infants and toddlers up to the age of 2 years, racemic camphor may cause a laryngeal spasm, resulting in severe respiratory distress.

Reporting of side effects

If you get any side effects, talk to your dentist or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to the Bundesinstitut für Arzneimittel und Medizinprodukte, Abt. Pharmakovigilanz, Kurt-Georg-Kiesinger-Allee 3, D-53175 Bonn, Germany, website: www.bfarm.de. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store ED 84

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 outer carton and the bottle after "Verwendbar bis". The expiry date refers to the last day of that month.

Keep the bottle in the outer carton in order to protect from light.

6. Contents of the pack and other information

What ED 84 contains

- The active substances are: Chloroxylenol and racemic camphor. 100 g dental emulsion contain 10.33 g chloroxylenol and 15.07 g racemic camphor.
- The other ingredients are: Macrogolglycerol hydroxystearate, purified water.

What ED 84 looks like and contents of the pack

ED 84 is a whitish-milky homogenous and inviscid dental emulsion. ED 84 is available in brown glass bottles with black HDPE screw caps with 10 ml, 30 ml, and 100 ml dental emulsion. Not all pack sizes may be marketed.