

 **PACKAGE LEAFLET:**
Information for the patient

EUGENOL

Dental preparation

Solution, drops for local use – 100 %
(Eugenol)

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Eugenol is and what it is used for
2. Before you use Eugenol
3. How to use Eugenol
4. Possible side effects
5. How to store Eugenol
6. Further information

1. WHAT EUGENOL IS AND WHAT IT IS USED FOR
Eugenol has analgesic and antiseptic action and produces local anesthesia.

The bacteriostatic action of Eugenol is against: *Staphylococcus aureus*, *Escherichia coli*, *Pseudomonas aeruginosa* and *Candida albicans*.

It is used in stomatology, frequently mixed with zinc oxide.

It is irritant.

It is used for calming toothaches (a dyed cotton is placed inside the cavity of the affected tooth), in temporary dental fillings with zinc oxide and as a constituent in oral hygiene preparations.

It may be used as flavoring agent.

Clove essence has antihelmintic properties.

Your doctor may have given Eugenol for a different purpose. Ask your doctor if you want to know why you have been given Eugenol.

2. BEFORE YOU USE EUGENOL

Do not use Eugenol if you are hypersensitive (allergic) to this active substance, because allergic reactions may appear, including anaphylaxis.

Take special care with Eugenol

During the use of Eugenol in the cavity of the affected tooth, you must keep in mind not to put it more than once in the same place because it may damage the gingival tissue.

Taking other medicines

Concomitant treatment with other medicines can affect or be affected by Eugenol.

Please contact your doctor or pharmacist if you are taking / using or have recently taken / used other medicines, including those obtained without a prescription.

Don't forget to inform your doctor about the treatment with Eugenol if you get any other medicine during treatment.

Clinically important medical interactions are seen after the systemic absorption of eugenol.

It is especially important that your doctor is informed about the fact that you have been treated with:

- lidocaine as another painkiller: in this case the effect of lidocaine is increased;
- aspirin, anticoagulants (warfarin and heparin), anti-inflammatory drugs (ibuprofen and naproxen): the risk of gums bleeding increases;
- antidiabetics and insulin: eugenol decreases blood sugar levels; in case the use of eugenol in these patients is necessary, they must be monitored;
- antifungals, antihistaminics, antineoplastics: eugenol can interact with them.

Pregnancy and breast-feeding

Ask for the advice of your doctor or pharmacist before you use this medicine. Safety of this medicine in pregnancy and breast-feeding hasn't been confirmed yet, however, it should be avoided during pregnancy and breast-feeding.
C category.

Driving and using machinery

Caution is required during the days you are using Eugenol because eugenol may cause side effects such as: sedation, breath disorders, dizziness. Avoid driving and using machinery.

3. HOW TO USE EUGENOL

Always use Eugenol according to the advice of your doctor or pharmacist. If you are not sure, check with your doctor or pharmacist.

If you feel that the effects of Eugenol are too strong or too weak, talk to your doctor or pharmacist.

Dosage:

- Your dentist will inform you about the amount of Eugenol that you should use and when you should use it. It is important to follow the instructions of your dentist accurately and never change the dose yourself, whatever you feel.
- Ask your dentist or pharmacist if you are not sure about the dose that you should use and how you should do it.

According to the dentist advice, a dyed cotton swab with Eugenol is put in the cavity of the affected tooth. Drops may cause a burning sensation, but this sensation does not last more than several minutes. Otherwise you must consult your doctor or pharmacist.

If you use more Eugenol than you should

If you use more Eugenol than you should, or if the children have taken this medicine accidentally, please contact your doctor, the hospital, or the nearest medical care site to take an opinion on the risk and advice on the action to be taken.

Overdose is possible and side effects that may occur as a result of overdose from Eugenol include symptoms like: convulsions, diarrhoea, nausea, dizziness, accelerated heartbeat, redness of patient's urine.

If you forget to use Eugenol

If you forget to use a dose of Eugenol, use your next dose in its usual time. If it is almost time for the next dose, skip the lost dose.

Do not use a double dose (or higher) to make up a forgotten dose(s).

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

4. POSSIBLE SIDE EFFECTS

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

The most frequent side effects of eugenol are: allergic reactions, itching, vomiting, breathing difficulties, sedation, burning, local damaging of the mouth tissues, damaging of the dental pulp, local loss of sensitivity, high risk of oral cavity damage, sores on the lips.

If any of the above side effects occurs, the treatment with Eugenol should be stopped and you should consult your doctor or pharmacist.

If any of the side effects worsens, or if you notice any side effects not listed in this leaflet, please contact your doctor or pharmacist.

5. HOW TO STORE EUGENOL

Keep out of the reach and sight of children!

Do not use Eugenol after the expiry date stated on the package.

Store between 10° - 25° C!

Do not freeze!

Keep in the original packaging to protect it from light and humidity!

6. FURTHER INFORMATION

What Eugenol contains

The active substance is eugenol bidistilled.

Each plastic vial contains 5 ml eugenol 100%.

Content of the pack

Carton box with one plastic vial.

Explanatory of the illustration icons on the packaging:



Without medical prescription.



Content.



Warning.



Solution, drops.

Marketing Authorisation Holder and Manufacturer:



PROFARMA Sh.a.
Rruga "Myslym Keta"
Tel.: 00355 4 23 89 602
Tirana - ALBANIA

This leaflet was last revised in September 2012.

PAY ATTENTION, all the layers are visible.

If you have to print this document please check or uncheck the specific layers.

