

PATIENT INFORMATION LEAFLET

DENCOL 8.71% gel spray

For intraoral use.

- **Active substance(s):** Each 1 g gel contains 87.1 mg choline salicylate
- **Excipient(s):** Chlorhexidine gluconate, glycerin, sorbitol (70%) (E420), povidone K90, polyoxyl 40 hydrogenated castor oil, citric acid monohydrate and deionised water

Read this PATIENT INFORMATION LEAFLET carefully before you start using this medicine, because it contains important information for you.

- *Keep this leaflet. You may need to read it again.*
- *If you have any further questions, please ask your doctor or pharmacist.*
- *This medicine has been prescribed for you only. Do not pass it on to others.*
- *If you go to a doctor or hospital during the use of this medicine, inform your doctor about this.*
- *Follow the instructions in this leaflet exactly. Do not use **higher or lower** doses than the dose which was recommended for you.*

What is in this leaflet:

1. *What DENCOL is and what it is used for?*
2. *What you need to know before you use DENCOL?*
3. *How to use DENCOL?*
4. *Possible side effects*
5. *How to store DENCOL?*

1. What DENCOL is and what it is used for?

- DENCOL is a gel spray containing 87.1 mg choline salicylate in 1 gram in a plastic bottle with a spray cap, which is applied externally into the mouth and has analgesic effect.
- DENCOL is used as a pain reliever in inflammations and wounds in the mouth, in the relief of pain in pressure and wound sites caused by dental prostheses and jaw orthopaedic devices, and in teething pain in children older than 6 months..

2. What you need to know before you use DENCOL?

DO NOT use DENCOL

- Babies under 6 months of age
- Do not use if you are allergic to choline salicylate or the components of DENCOL

Warnings and precautions

NOT USED WITHOUT CONSULTING DOCTOR IN CHILDREN AND ADOLESCENTS WITH THE SYMPTOMS OF VIRAL FLU OR CHICKEN POX BECAUSE OF THE REYE SYNDROME, A RARE BUT SERIOUS DISEASE CAUSED BY THE USE OF ASPIRIN-LIKE DRUGS.

- Do not use during pregnancy without consulting your doctor.

- In patients under 16 years of age, do not use in case of viral flu/cold or chickenpox without consulting a physician.

If these warnings apply to you, even if at any time in the past, please consult your doctor.

DENCOL with food and drink

No interaction with food and drinks.

Pregnancy

Consult your doctor or pharmacist before taking this medicine.

Use under the supervision of your doctor when necessary during pregnancy.

Consult your doctor or pharmacist immediately if you recognize that you are pregnant during your treatment.

Breast-feeding

Consult your doctor or pharmacist before taking this medicine.

Since DENCOL can pass into milk, do not use during breastfeeding unless recommended by a doctor.

Driving and using machines

No adverse effects on the ability to drive and use machines have been reported.

Important information about some of the excipients of DENCOL

Since DENCOL contains sorbitol (70%) (E420), if you have been told by your doctor that you have an intolerance (intolerance) to some sugars, contact your doctor before taking this medicinal product.

As this medicine contains polyoxyl 40 hydrogenated castor oil, it may cause nausea and diarrhoea and skin reactions.

Other medicines and DENCOL

It is not used together with products containing aspirin (acetylsalicylic acid) in young children.

If you currently have been receiving or have recently received any prescription or nonprescription medicine, please notify your doctor or pharmacist about these.

3. How to use DENCOL?

• Instructions for use and dosage/frequency of administration:

Unless otherwise recommended by a doctor, use 1 puff 4 times a day.

It should be used at night before going to bed and before meals.

• Route of administration and method:

DENCOL is for oral use only.

Squeeze 1 puff onto a cotton pad or a clean finger and gently massage the affected area.

• Different age groups:

Use in children:

It is not suitable for use in babies under 6 months of age.

It can be used every 6 hours depending on the severity of the pain.

Use with the advice of a doctor in children under 16 years of age with suspected viral influenza or chickenpox.

Use in elderly:

The safety and efficacy of DENCOL in elderly patients have not been studied.

• **Special cases of use:**

Renal/Hepatic failure:

The safety and efficacy of DENCOL in patients with renal and hepatic failure have not been studied.

If you have impression that the effect of DENCOL is very strong or weak, tell a doctor or pharmacist.

If you use more DENCOL than you should:

If you take more DENCOL than you should, tell your doctor or pharmacist.

If you forget to use DENCOL:

Do not take a double dose to make up for a forgotten dose.

Continue taking the recommended dose again at the next usual time of intake.

If you stop using DENCOL:

None.

4. Possible side effects?

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

If you notice any of the followings stop taking DENCOL and immediately inform your doctor or go to the nearest emergency department:

- Sudden shortness of breath, skin rash, swelling of the face and/or tongue (anaphylaxis)
- Hypersensitivity reactions
- Allergic reactions

All of these are very serious side effects of unknown frequency. If you have any of these, you are seriously allergic to DENCOL. You may need urgent medical attention or hospitalisation.

Side effects were listed by frequency as following:

Very common: may affect more than 1 in 10 people

Common: may affect up to 1 in 10 people

Uncommon: may affect up to 1 in 100 people

Rare: may affect up to 1 in 1,000 people

Very rare: may affect up to 1 in 10,000 people

Not known: frequency cannot be estimated from the available data.

Rare:

- Dizziness
- Loss of balance
- Excessive drop in blood pressure
- Shortness of breath
- Wheezing

- Vomiting with loss of consciousness
- Hives (urticaria)
- Itching
- Skin rash

In children under 16 years of age with suspected viral influenza or chickenpox, vomiting with loss of consciousness may occur.

This is a very serious side effect. It may cause narrowing of the airways (bronchospasm) and asthma attack in susceptible patients. You may need urgent medical attention or hospitalisation.

All of these very serious side effects are very rare.

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

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via clicking “Reporting of Drug Side Effects” icon on the website www.titck.gov.tr or Turkish Pharmacovigilance Center (TUFAM) by calling the phone number 0 800 314 00 08 for side effects reporting line. By reporting side effects, you can help provide more information on the safety of this medicine.

5. 5. How to store DENCOL?

Keep this medicine out of the sight and reach of children in its original packaging.

Store at room temperature below 25°C.

Use in accordance with expiry date.

Do not use this medicine after the expiry date which is stated on the label or package.

Do not use DENCOL if you notice any defects in the product and/or its packaging.

Do not throw away drugs that have expired or are not used! Give to the collection system determined by the Ministry of Environment and Urbanism.

Marketing Authorization Holder:

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This patient information leaflet was last approved on 01/04/2018.