

PACKAGE LEAFLET: INFORMATION FOR THE USER

ANGAL S LEMON

2 mg + 0,5 mg / ml, Oromucosal spray

CHLORHEXIDINE, LIDOCAINE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking 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, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

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

1. WHAT ANGAL S LEMON IS AND WHAT IS IT USED FOR

Angal S Lemon is a spray with local effect in the mouth and pharynx.

Angal S Lemon oromucosal spray is antiseptic (local antimicrobial activity) and local painkiller.

Angal S Lemon oromucosal spray is recommended for:

treatment of symptoms of sore throat, redness in the throat, discomfort in the throat accompanied with irritability

in case of a bacterial infection accompanied with fever, additional treatment is necessary.

Angal S Lemon oromucosal spray contains no sugar and is therefore suitable for diabetics (people with diabetes).

2. BEFORE YOU TAKE ANGAL S LEMON

Do not take ANGAL S LEMON

- If you are allergic to any ingredient of Angal S Lemon spray. All ingredients can be found in section 6.
- If your child is younger than 5 years.

Take special care with ANGAL S LEMON

Talk to your doctor or pharmacist before using Angal S Lemon spray.

Angal S Lemon oromucosal spray should not be used over a long period of time, without interruption or repeatedly. Limit its use to clearly necessary relief of pain and irritation.

In case of overdose (more than one bottle per day) there is a small risk of impaired control over the swallowing reflex.

Angal S Lemon oromucosal spray contains alcohol and propylene glycol. Please also read the section "Angal S Lemon oromucosal spray contains alcohol and propylene glycol."

If you use other medicines, please read the section "Taking other medicines".

Contact your doctor if any of the above applies to you or if anything like that applied to you in the past.

Children

Angal S Lemon spray should not be used in children younger than 5 years.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription and herbal medicines. Do not use Angal S Lemon spray with medicines for the treatment of mild forms of Alzheimer's disease (gradual and permanent loss of memory, orientation and language capability), such as cholinesterase inhibitors (medicines for treating dementia).

During the administration of ANGAL S LEMON you should not simultaneously use other antiseptics.

Pregnancy and breast-feeding

Before you start using Angal S Lemon spray, talk to your doctor or pharmacist if you are pregnant, planning to become pregnant or are breastfeeding.

Angal S Lemon spray contains alcohol. Please read part "Angal S Lemon oromucosal spray contains alcohol, and propylene glycol."

If you follow previously mentioned precautions, Angal S Lemon oromucosal spray may be used during pregnancy or breastfeeding. Tell your doctor that you are using this medicine.

Driving and using machines

It is not likely that ANGAL S LEMON will affect your ability to drive and use machines.

Other warnings

Angal S Lemon oromucosal spray contains alcohol and propylene glycol

Angal S Lemon oromucosal spray contains alcohol (29.7% by volume of ethanol), ie. a maximum of 108 mg per 5 sprays, equivalent to 2.7 ml of beer or 1.1 ml of wine per 5 sprays. This is unfavorable for people suffering from alcoholism. It requires caution in pregnant and breastfeeding women, children and high risk groups, such as patients with liver disease or epilepsy.

Angal S Lemon oromucosal spray contains propylene glycol, which can cause symptoms similar to the use of alcohol.

3. HOW TO TAKE ANGAL S LEMON

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.

Recommended dosage:

Adults and children over 12 years: 3-5 sprays on the sore spot, 6-10 times a day.

Children from the age of 5: half the dose of adults, meaning 2-3 sprays on the sore spot, 3-5 times a day.

Point the nebulizer towards the pharynx and press the top of the dispenser.

This medicine should not be used over long periods of time. Contact your doctor if symptoms worsen or do not improve after 3-4 days.

If you use more ANGAL S LEMON than you should

If you take more of this medicine than you should, talk to a doctor or go to a hospital straight away. This medicine contains only small portion of the toxic dose. If used properly, the risk of overdose is very small. Symptoms of overdose are: restlessness, tinnitus, breathing difficulties, cardiac arrhythmia (abnormal rhythm of the heart) and reduced control over the swallowing reflex.

If you forget to use ANGAL S LEMON

No special precautions are required.

If you stop using ANGAL S LEMON

No special precautions are required

Talk to your doctor or pharmacist if you have any additional questions.

4. POSSIBLE SIDE EFFECTS

Like all medicines, **ANGAL S LEMON** can cause side effects, although not everybody gets them. Side effects are classified according to frequency: very common: 1 / 10; common: (1/10 - 1/100), uncommon (1/100 - 1/1000); rare (1 / 1,000 to 1 / 10,000); very rare (1 / 10,000), Not known: frequency cannot be determined from the available data.

When used in the recommended manner, Angal S Lemon spray is well tolerated.

Very rare: allergic reactions on the skin and mucous membranes.

In the case of prolonged and continuous application you may experience brown coloration of teeth. However, this brown color is easy to remove.

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

5. HOW TO STORE ANGAL S LEMON

Keep out of the reach and sight of children.

Do not store above 25 °C.

Do not use **ANGAL S LEMON** after the expiry date which is stated on the label, 1 year from the date of manufacture.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What ANGAL S LEMON contains

The active substances are chlorhexidine digluconate and lidocaine hydrochloride.

The other ingredients are:

Lemon flavor

Sucralose

Glycerol

Propylene glycol

Citric acid monohydrate

Ethanol
Purified water.

What ANGAL S LEMON looks like and contents of the pack

Angal S Lemon oromucosal spray is available in a bottle with a pump for dispersing which contains 30 ml of oromucosal spray.

Regime of dispensing

The medicine is issued without doctor's prescription.

Manufacturer

Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Slovenia

Manufacturer of the medicinal product

Laboratoria Qualiphar N.V./S.A., Rijksweg 9, B-2880 Bornem, Belgium
Lek farmacevtska družba dd, Veroškova 57, Ljubljana, Slovenia