

PACKAGE LEAFLET: INFORMATION FOR THE USER

ANGAL S

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

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

The box contains 30 ml of solution in a bottle with a mechanical sprayer.

Each ml of solution contains 2.0 mg of chlorhexidine digluconate and 0.5 mg of lidocaine hydrochloride.

ANGAL S has a twofold effect, because it contains two active substances: has antimicrobial and local effect against pain. It is used in relieving pain of sore throat, reducing the risk of developing severe bacterial infections and alleviating pain.

ANGAL S does not contain sugar, so it can also be used by patients suffering from diabetes.

ANGAL S is recommended to relieve the symptoms of sore throat (painful swallowing, irritation).

2. BEFORE YOU TAKE ANGAL S

Do not take ANGAL S

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

Take special care with ANGAL S

- If you are prone to hypersensitivity reactions
- If you have a fever, severe pain in the throat and difficulty swallowing. In this case, consult a doctor.

Patients with liver disease and epilepsy can use medicine with a warning that a single dose for adults and adolescents older than 12 years contains 140 mg of ethanol, equivalent to 3.5 ml of beer and 1.5 ml of wine. ANGAL S contains levomenthol and therefore should be carefully given to young children who have a history of convulsions.

Avoid applying the medicine near the eyes.

You should not consume food and drinks, and brush your teeth for at least one hour after administration.

This medicinal product contains 41.6 vol% ethanol (alcohol), ie up to 140 mg per single maximum dose for adults and children over 12 years of age (equivalent to 3.5 ml of beer or 1.5 ml of wine per dose) and 84 mg per maximum single dose for children from 5 to 12 years of age (equivalent to 2.1 ml of beer or 0.9 ml of wine).

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.

During the administration of ANGAL S you should not simultaneously use other local antiseptics. This does not apply to Angal pastilles that contain the same active substances.

ANGAL S should not be taken simultaneously with medicines that hinder the activity of the enzyme acetylcholinesterase (such as neostigmine, pyridostigmine and distigmin).

Pregnancy and breast-feeding

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

Driving and using machines

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

Other warnings

Glycerol in high doses can cause headache, stomach problems or indigestion.

3. HOW TO TAKE ANGAL S

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.



Lift the nozzle of the spray away from the container until it is horizontal.

Aim the spray at the sore area of your mouth or throat and press down on the pump to release one spray. During spraying hold your breath.

If ANGAL S Spray was not used for some time, it is recommended to clean the spray head after the last administration in the following manner:

1. Turn the bottle with spray tube upside down and press spray head until the spray tube is completely empty (that the solution can no longer spray).
2. Spray tube should be placed in a glass of hot water for a few minutes.
3. While the bottle is facing down tighten spray head on the dry spray tube

After using it, the tube must be turned downward to block the spray head.

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.

The use of the medicine in children younger than 5 years is not recommended.

The maximum single dose for adults and children over 12 years contains small doses of alcohol, less than 140 mg and 84 mg for children aged 5-12 years.

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 than you should

If you use more of this medicine than you should, talk to a doctor or go to a hospital straight away. When using high doses (more than 1 bottle per day) you may rarely experience problems with swallowing (reduced control over the swallowing reflex).

Signs of overdose that can occur are: restlessness, tinnitus, yawning, difficulty in breathing, heart rhythm disorders, changes in the value of blood pressure, rapid movements of the eyeballs and spasms of skeletal muscles.

4. POSSIBLE SIDE EFFECTS

Like all medicines, **ANGAL S** can cause side effects, although not everybody gets them.

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

Very rarely may appear signs of hypersensitivity on the skin, for example, irritation and rashes.

If you notice any side effects indicated in the following list, stop taking the medicine and tell your doctor or pharmacist:

- swelling of the hands, feet, wrists, face, lips, tongue or neck which can cause disorder in swallowing and breathing
- rash
- urticaria
- loss of consciousness.

These are serious side effects. They indicate severe allergic reaction to the medicine. In this case, emergency medical care is needed.

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

Keep out of the reach and sight of children.

Do not store above 25 °C.

Do not use **ANGAL S** after the expiry date which is stated on the label, 5 years from the date of manufacture.

6. FURTHER INFORMATION

What ANGAL S contains

The active substances are: chlorhexidine digluconate and lidocaine hydrochloride.

One pressure spray (83.1 mg, corresponding to 0.085 ml) contains 0.17 mg of chlorhexidine digluconate and 0.04 mg of lidocaine hydrochloride.

Excipients: levomenthol, essential oil, glycerol, sodium saccharin, citric acid monohydrate, 43 vol.% Ethanol, purified water.

One pressure spray (83.1 mg, corresponding to 0.085 ml) contains 28 mg (0.035 ml) of ethanol.

The maximum single dose for adults (5 pressure spray wand) contains 140 mg (0.177 ml) of ethanol.

What ANGAL S looks like and contents of the pack

ANGAL S 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