

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S1

UNIVERSAL NASAL DROPS (Solution)

Phenylephrine hydrochloride

Naphazoline nitrate

Contains preservatives:

Chlorbutol 0,5 % m/v

Nipasept 0,15 % m/v

Read all of this leaflet carefully because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- Do not share UNIVERSAL NASAL DROPS with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 5 days.

What is in this leaflet

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

1. What UNIVERSAL NASAL DROPS are and what it is used for

UNIVERSAL NASAL DROPS contains the active ingredients phenylephrine and naphazoline. They are nasal decongestants which help relieve a blocked or stuffy nose caused by cold, hay fever, sinus infection or other allergic reactions.

2. What you need to know before you use UNIVERSAL NASAL DROPS

Do not use UNIVERSAL NASAL DROPS

- if you are hypersensitive (allergic) to phenylephrine, naphazoline or any of the other ingredients of UNIVERSAL NASAL DROPS (listed in section 6).
- If you are on treatment with a monoamine oxidase inhibitor for depression or within 14 days of stopping such medication.
- If you are pregnant or breastfeeding.
- If you have high blood pressure, a problem with your thyroid or any heart problems.

Warnings and precautions

Take special care with UNIVERSAL NASAL DROPS:

- Do not use this medicine for more than 5 days.
- If your symptoms do not clear up, contact your doctor.
- Frequent or prolonged use of this medicine may cause the original symptoms to re-appear, by a rebound action of the lining of the nose in some cases.
- Do not use the same bottle of UNIVERSAL NASAL DROPS for more than one person, as the infection may spread.
- Use caution when treating children as UNIVERSAL NASAL DROPS, as they be more sensitive to the effects of this medicine.
- Use caution and check with your doctor before using this medicine, if you have any of the following:
 - High blood pressure
 - A problem with your thyroid
 - Any type of heart disease or irregular heart rate
 - Diabetes
 - Glaucoma, which is a condition of the eye involving nerve damage
 - Prostate problems
 - If you are undergoing any procedure that requires you to receive an anaesthetic.

Other medicines and UNIVERSAL NASAL DROPS

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor if you are taking any of the following:

- Treatment for high blood pressure, as the effect of these medicines may be reduced or it may produce unwanted side effects, e.g. prazosin, doxazosin, atenolol, propranolol, guanethidine, reserpine, methyldopa.
- Maprotiline, or other medicines used to treat depression, as UNIVERSAL NASAL DROPS may interfere with how these medicines work.
- Digoxin, used to for heart conditions and to regulate heart rate, as UNIVERSAL NASAL DROPS may interfere with how this medicine works.

Pregnancy, breastfeeding and fertility

UNIVERSAL NASAL DROPS should not be used if you are pregnant or breastfeeding your baby.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor, pharmacist or other health care provider for advice before using this medicine.

Driving and using machines

UNIVERSAL NASAL DROPS may cause dizziness. It is not always possible to predict to what extent UNIVERSAL NASAL DROPS may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which UNIVERSAL NASAL DROPS affects you.

3. How to use UNIVERSAL NASAL DROPS

Do not share medicines prescribed for you with any other person.

Always use UNIVERSAL NASAL DROPS as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist, or nurse if you are not sure.

The usual dose is two or three drops in each nostril, every four hours. Do not use more often than every 4 hours.

If you have the impression that the effect of UNIVERSAL NASAL DROPS is too strong or too weak, tell your doctor or pharmacist.

If you use more UNIVERSAL NASAL DROPS than you should

In the event of overdosage, or accidental ingestion, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to use UNIVERSAL NASAL DROPS

Use the drops as soon as you remember. Do not use a double dose to make up for forgotten doses.

4. Possible side effects

UNIVERSAL NASAL DROPS can have side effects.

Not all side effects reported for UNIVERSAL NASAL DROPS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using UNIVERSAL NASAL DROPS, please consult your health care provider for advice.

If any of the following happens, stop using UNIVERSAL NASAL DROPS and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching.

These are all very serious side effects. If you have them, you may have had a serious reaction to UNIVERSAL NASAL DROPS. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following side effects:

- Reduced appetite
- Extreme thirst, feeling tired or weak, blurred vision – may indicate a change in your blood sugar levels.
- If you feel confused, anxious, irritable, experience hallucinations.
- Difficulty sleeping, weakness, sweating
- Headache, dizziness
- A faster heart beat, pounding heart, chest pain
- Fainting, flushing, severe headaches with dizziness
- Difficulty breathing, stuffy nose or runny nose

- Nausea, vomiting, increased production of saliva
- Difficulty or pain when passing urine
- Dryness, burning or stinging in the mouth and throat, runny nose with sneezing.

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

Reporting of side effects

If you/your child get/s side effects, talk to your/your child's doctor or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website or to Acino Pharma via email on drugsafety_ZA@acino.swiss. By reporting side effects, you can help provide more information on the safety of UNIVERSAL NASAL DROPS.

5. How to store UNIVERSAL NASAL DROPS

Store all medicine out of reach of children.

Store at or below 25 °C and away from light.

6. Contents of the pack and other information

What UNIVERSAL NASAL DROPS contains

- The active substances are phenylephrine hydrochloride and naphazoline nitrate.
- Each 1 ml of solution contains 2,5 mg phenylephrine hydrochloride and 0,25 mg naphazoline nitrate.
- The other ingredients are chlorbutol, Nipasept, sodium chloride, sodium metabisulphite and purified water.

What UNIVERSAL NASAL DROPS look like and contents of the pack

UNIVERSAL NASAL DROPS is a clear, colourless solution.

The nasal drops are packed in 15 ml amber glass bottles, closed with a black plastic screw cap dropper, incorporating a glass dropper pipette and rubber teat.

Pack sizes: 1 bottle

Holder of Certificate of Registration

Acino Pharma (Pty) Ltd.

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Access to the corresponding Professional Information

The professional information can be found in the packaging of UNIVERSAL NASAL DROPS.