SCHEDULING STATUS

S4

NOVESIN WANDER 0,4 %, 0,4 g oxybuprocaine HCl per 100 mL, Sterile eye drops
Oxybuprocaine HCl

Read all of this leaflet carefully before you start using NOVESIN WANDER 0,4 %

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- NOVESIN WANDER 0,4 % has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What NOVESIN WANDER 0,4 % is and what it is used for
2. What you need to know before you use NOVESIN WANDER 0,4 %
3. How to use NOVESIN WANDER 0,4 %
4. Possible side effects
5. How to store NOVESIN WANDER 0,4 %
6. Contents of the pack and other information

1. What NOVESIN WANDER 0,4 % is and what it is used for

NOVESIN WANDER 0,4 % contains oxybuprocaine which is an anaesthetic that numbs the surface of the eye temporarily.

NOVESIN WANDER 0,4 % is used by your doctor or eye specialist as an anaesthetic to numb the eye(s) for:

- Eye examinations.
- Preparation for injections into the eye.
- Minor eye operations or preparation of eye operations.
- Contact lense fitting.

2. What you need to know before you use NOVESIN WANDER 0,4 %

Do not take NOVESIN WANDER 0,4 %

- If you are allergic to oxybuprocaine, chlorhexidine or any of the other ingredients listed in section 6.

Warnings and precautions

Talk to your doctor or health care provider before taking or being given NOVESIN WANDER 0,4 %.

Take special care with NOVESIN WANDER 0,4 %:

- If you have had any hypersensitivity (allergic) reactions (including hives, swelling of the face, lips, tongue, and/or throat which may cause difficulty in breathing or swallowing) to

other local anaesthetics in the past.
- When your eye has been numbed it is important not to rub it and to keep it free of dust and infection.
- NOVESIN WANDER 0,4 % may only be used under strict medical supervision for a short duration. This means that NOVESIN WANDER 0,4 % is not intended for long term use.
- Indiscriminate use (use without care, incorrect use or unsupervised use) can lead to severer damage of the protective outer layer of the eye (cornea).
- If you are pregnant.
- If you are breastfeeding.

Children
NOVESIN WANDER 0,4 % may not be used in children under the age of two years. For more information, talk to your doctor.

Other medicines and NOVESIN WANDER 0,4 %
No information is available.
Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

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

Pregnancy
The safety of this medicines in pregnancy has not been established.
Do not use NOVESIN WANDER 0,4 % if you are pregnant unless your doctor considers it necessary.

Breastfeeding
The safety of this medicines in breastfeeding has not been established.
Do not use NOVESIN WANDER 0,4 % if you are breastfeeding unless your doctor considers it necessary.

Driving and using machines
It is not always possible to predict to what extent NOVESIN WANDER 0,4 % may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which NOVESIN WANDER 0,4 % affects them.

3. How to use NOVESIN WANDER 0,4 %

Do not share medicines prescribed for you with any other person.
Always use NOVESIN WANDER 0,4 % exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The amount of NOVESIN WANDER 0,4 % used will vary, depending on the procedure decided by your doctor.
A single instillation of one or two drops numbs the eye sufficiently within 60 seconds to measure the pressure inside your eye.
A further drop after 90 seconds numbs the eye sufficiently for fitting of contact lenses.
Three drops at 90 second intervals sufficiently numbs the eye after 5 minutes to allow minor operations to be performed.

Do not exceed the recommended dose.

If you use more NOVESIN WANDER 0,4 % than you should

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

In overdose, you may experience side effets and/or they may increase in severity. See section 4 for side effects.

If a health care provider administers NOVESIN WANDER 0,4 % he or she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

4. Possible side effects

NOVESIN WANDER 0,4 % can have side effects.
Not all side effects reported for NOVESIN WANDER 0,4 % are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking NOVESIN WANDER 0,4 %, please consult your health care provider for advice.

NOVESIN WANDER 0,4 %, may cause:

- Increased blood flow to the eye for a short duration (dilation and redness of the blood vessels in the lining of the white part of the eye). This is also called hyperaemia.
- Lesions (damage or scars) on the cornea (the clear, protective outer layer of the eye) when used without care, incorrectly use or unsupervised.
- Occasional hypersensitivity reactions such as eczema (red swollen skin) of the eyelid or allergic conjunctivitis (inflammation causing redness, itching, swelling, tearing, and stringy discharge).
- A mild burning sensation when the drops are first put in.
- Methaemoglobinaemia (condition affecting the ability of redblood cells to carry oxygen which causes symptoms such as headache, dizziness, shortness of breath, nausea, poor muscle coordination, and blue-colored skin). Methaemoglobinaemia can be life-threatening, but fully reversible with early treatment.

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

Reporting of side effects
If you get side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the **6.04 Adverse Drug Reaction Reporting Form**, found online under SAHPRA"s publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of NOVESIN WANDER 0,4 %.

5. How to store NOVESIN WANDER 0,4 %
Store all medicines out of reach of children.
Store at or below 25 °C.
Do not use more than 30 days after opening.
Do not use after the expiry date.
Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information
What NOVESIN WANDER 0,4 % contains
The active substance is oxybuprocaine.
Each 100 mL contains oxybuprocaine as oxybuprocaine hydrochloride 0,4 g.

The other ingredients are boric acid, chlorhexidine acetate, hydrochloric acid and water for injection.

What NOVESIN WANDER 0,4 % looks like and contents of the pack
NOVESIN WANDER 0,4 % is a clear, colourless to pale yellowish, aqueous solution.

3 ml of NOVESIN WANDER 0,4 % is packed in a 5 mL white LDPE plastic dropper bottle with a clear LLDPE dropper insert and a yellow HDPE screw cap.

Holder of Certificate of Registration
Adcock Ingram Limited
Address
1 New Road,
Erand Gardens,
Midrand, 1685
Customer Care: 0860 ADCOCK / 232625

This leaflet was last revised in
14 September 2021

Registration number
South Africa: H 1270 (Act 101 of 1965)

Botswana:

S2 Novesin Wander 0,4% (5 mL): B9323435

Namibia:

NS2: Novesin Wander 0,4%: 14/15/0403 (Act No. 13 of 2003)

adcock ingram