SCHEDULING STATUS S4

1. NAME OF THE MEDICINE

NOVESIN WANDER ™ 0,4 %, 0,4 g oxybuprocaine HCl per 100 ml, sterile eye drops

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100 mL contains oxybuprocaine as oxybuprocaine HCl 0,4 g.

Preservative: chlorhexidine acetate 0,01 % *m/v*

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Sterile eye drops.

Clear, colourless to pale yellowish, aqueous solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

- Local anaesthetic:

  - for tonometry.

  -In cases of glaucoma, measurements of the angle of the anterior chamber.

  -In contact lens fitting.

  -for examinations of the fundus of the eye with a slit lamp.

  -It is extremely suitable for preparing patients for subconjunctival and retrobulbar injections and for diagnostic punctures of the anterior chamber.

-For minor surgery such as the removal of pterygiums, chalazions and small tumours of the eyelids or conjunctiva.

-for preparation for cataract operations when combined with other suitable local measures (retrobulbar injection, possibly also cocaine or procaine).

4.2 Posology and method of administration

Posology

A single instillation of 1 or 2 drops produces within 60 seconds a sufficient degree of anaesthesia to permit tonometry. A further drop after 90 seconds provides adequate anaesthesia for the fitting of contact lenses.
Three drops at 90 second intervals produce sufficient anaesthesia after 5 minutes for a foreign body to be removed from the corneal epithelium.

Do not exceed the recommended dose.

Paediatric population

The safety and efficacy of NOVESIN WANDER 0,4 % in children under the age of two years have not yet been established (see section 4.4).

Method of administration

Topical.

4.3 Contraindications

Hypersensitivity to oxybuprocaine, chlorhexidine acetate or to any of the inactive ingredients of NOVESIN WANDER 0,4 % (see and section 6.1).

4.4 Special warnings and precautions for use

Indiscriminate use can lead to severe corneal damage. To be used under strict medical supervision for a short duration only. The anaesthetised eye should be protected from dust and bacterial contamination.

Paediatric Population

NOVESIN WANDER 0,4 % may not be used in children under the age of 2 years.

4.5 Interactions with other medicines and other forms of interaction

No data available.

4.6 Fertility, pregnancy and lactation

Pregnancy

The safety of this preparation in pregnancy has not been established.

Breastfeeding

The safety of this preparation in lactation has not been established.

Fertility

No data available

4.7 Effects on ability to drive and use machines

No data available.

4.8 Undesirable effects

Slight hyperaemia of short duration. In therapeutic concentrations epithelial lesions are rare but note warning for indiscriminate use. Occasional hypersensitivity reactions such as eczema of the eyelid or allergic conjunctivitis are encountered. A mild burning sensation may be experienced on instillation.

NOVESIN WANDER 0,4 % may cause methaemoglobinaemia.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care professionals are asked to report any suspected adverse reactions 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.

4.9 Overdose

In the event of overdosage, side effects can be precipitated and/or be of increased severity. See section 4.8.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacological classification: A 15.4 Ophthalmic preparations. Others.

Oxybuprocaine is a surface-active anaesthetic, which abolishes the sensitivity of an intact surface. It belongs to the benzoate group and acts in the same way as cocaine.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Boric acid

Chlorhexidine acetate

Hydrochloric acid (for pH-adjustment)

Water for injection.

6.2 Incompatibilities

No data available.

6.3 Shelf life

Unopened: 36 months

6.4 Special precautions for storage

Store at or below 25 °C.

Do not use for more than 30 days after opening.

6.5 Nature and contents of container

3ml 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.

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Adcock Ingram Limited

1 New Road,

Erand Gardens,

Midrand, 1685

Customer Care: 0860 ADCOCK / 232625

8. REGISTRATION NUMBER(S)

H1270 (Act 101 of 1965)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

01 March 1982

10. DATE OF REVISION OF THE TEXT

14 September 2021

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