PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

MINIMS® OXYBUPROCAINE HYDROCHLORIDE 0,4 %

Eye drops, solution in single-dose container

Read all of this leaflet carefully before you are given MINIMS® Oxybuprocaine Hydrochloride

- 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.

What is in this leaflet

1. What MINIMS® Oxybuprocaine Hydrochloride eye drops are and what they are used for
2. What you need to know before you use MINIMS® Oxybuprocaine Hydrochloride eye drops
3. How to use MINIMS® Oxybuprocaine Hydrochloride eye drops
4. Possible side effects
5. How to store MINIMS® Oxybuprocaine Hydrochloride eye drops
6. Contents of the pack and other information

1. What MINIMS® Oxybuprocaine Hydrochloride eye drops are and what they are used for

MINIMS® Oxybuprocaine Hydrochloride is a surface anaesthetic.

It is used when needing to measure your intraocular pressure (applanation tonometry) and for the fitting of contact lenses.

2. What you need to know before you use MINIMS® Oxybuprocaine Hydrochloride eye drops

MINIMS® Oxybuprocaine Hydrochloride should not be administered to you if:

- you are hypersensitive (allergic) to oxybuprocaine or any of the other ingredients of MINIMS® Oxybuprocaine Hydrochloride (listed in section 6).
- you have heart disease
- you have hyperthyroidism (your thyroid gland is producing too much thyroxine/hormones)
- you have injuries, wounds or ulcers on your eye.

Take special care with MINIMS® Oxybuprocaine Hydrochloride:

You may experience systemic effects of steroids following the use of MINIMS® Oxybuprocaine Hydrochloride eye drops, but this is unlikely due to the reduced absorption of topical eye drops.

Other medicines and MINIMS® Oxybuprocaine Hydrochloride

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

Pregnancy, breastfeeding and fertility

The use of MINIMS® Oxybuprocaine Hydrochloride eye drops during pregnancy and breastfeeding should be avoided.

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 using this medicine.

Driving and using machines

You may experience blurred vision when you instil MINIMS® Oxybuprocaine Hydrochloride into your eye. Wait until your vision clears before driving or using machinery.

3. How to use MINIMS® Oxybuprocaine Hydrochloride eye drops

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

Dosage

Adults and Children: The normal dose is 1 to 3 drops as directed by your eye specialist.

Method of administration

You will not be expected to use MINIMS® Oxybuprocaine Hydrochloride eye drops. It will be dropped into your eye(s) by a person who is qualified to do so.

If you use more MINIMS® Oxybuprocaine Hydrochloride than you should

Since a health care provider will administer MINIMS® Oxybuprocaine Hydrochloride eye drops, they will control the dosage. However, in the event of overdosage your doctor will manage the overdose.

If you forget to use MINIMS® Oxybuprocaine Hydrochloride

Since a health care provider will administer MINIMS® Oxybuprocaine Hydrochloride eye drops, it is unlikely that the dose will be missed.

4. Possible side effects

MINIMS® Oxybuprocaine Hydrochloride can have side effects.

Not all side effects reported for MINIMS® Oxybuprocaine Hydrochloride are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using MINIMS® Oxybuprocaine Hydrochloride eye drops, please consult your health care provider for advice.

If any of the following happens, stop using MINIMS® Oxybuprocaine Hydrochloride eye drops and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the lips, mouth or throat and eyes, which may cause difficulty in swallowing or breathing.
- rash or itching
- fainting

These are very serious side effects. If you have them, you may have had a serious reaction to MINIMS® Oxybuprocaine Hydrochloride eye drops. You may need urgent medical attention or hospitalisation.

Consult your doctor if you notice any of the following changes in your eyesight:

- eye pain
- eye irritation

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. 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.

You can also report side effects directly to the company, using the following e-mail address: PV-SouthAfrica@bausch.com

By reporting side effects, you can help provide more information on the safety of MINIMS® Oxybuprocaine Hydrochloride.

5. How to store MINIMS® Oxybuprocaine Hydrochloride

- Store all medicines out of reach of children.
- Store in a refrigerator between 2 – 8 °C
- Protect from light.
- Keep the units in the outer carton.
- Do not freeze.
- Do not use after the expiry date stated on the carton or unit.
- Discard each Minims unit after single use.
- 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 MINIMS® Oxybuprocaine Hydrochloride contains

- The active substance is Oxybuprocaine Hydrochloride.
- Each dispensing unit of 0,5 ml contains 2 mg Oxybuprocaine Hydrochloride (0,4 % *m/v*)
- The other ingredients are hydrochloric acid (for pH adjustment) and purified water.

What MINIMS® Oxybuprocaine Hydrochloride looks like and contents of the pack

MINIMS® Oxybuprocaine Hydrochloride is an eye drops solution in a single-dose container.

The eye drops are a clear, colourless solution, reasonably free from visible particulate matter.

MINIMS® Oxybuprocaine Hydrochloride eye drops are provided in a sealed conical shaped polypropylene tube (unit), fitted with a polypropylene twist and pull-of cap. Each unit contains approximately 0,5 ml of solution.

Each unit is individually overwrapped in a polypropylene/paper sachet. The sachets are packed in cartons of 20 units.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

The Professional Information is available on the company website,

www.bausch.co.za, or may be requested telephonically: +27 10 025 2100.