

Package Leaflet: Information for the User

Oxybuprocaine Agepha 4 mg/ml eye drops, solution

oxybuprocaine hydrochloride

Read all of this leaflet carefully before you start using 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.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Oxybuprocaine Agepha is and what it is used for

This medicine is an anaesthetic for external use in adults.

It is intended to locally anaesthetise the surface of the eye for short ophthalmological procedures.

2. What you need to know before you use Oxybuprocaine Agepha

Do not use Oxybuprocaine Agepha

- if you are hypersensitive (allergic) to oxybuprocaine or to any of the ingredients of Oxybuprocaine Agepha (listed in section 6);
- if you are hypersensitive (allergic) to other local anaesthetics which belong to the same group of active substances (p-aminobenzoic acid).

Warnings and precautions

Take special care with Oxybuprocaine Agepha

If you wear contact lenses; remove your contact lenses prior to instillation and wait until the anaesthetic effect has fully subsided before putting them back on the eye (also see **3. How to use Oxybuprocaine Agepha**).

In patients with a history of allergies, heart diseases, asthma, overactive thyroid gland (hyperthyroidism) and liver diseases as well as in elderly patients.

If you have an inflamed eye, as red eyes greatly increase the passage into the blood stream through the surface of the eyes.

Long-term and repeated use

Oxybuprocaine Agepha is only intended for short-term use by a physician. Repeated, uncontrolled use may lead to serious damage of the cornea of the eye. The same applies with long-term use.

Children and adolescents

The safety and efficacy of Oxybuprocaine Agepha in children and adolescents has not been established.

Other medicines and Oxybuprocaine Agepha

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines or eye drops, including medicines or eye drops obtained without a prescription.

Sulfonamides (contained in certain antibiotics): The efficacy of these antibiotics may be reduced.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice. Your doctor will tell you whether you can be given Oxybuprocaine Agepha or not.

Driving and using machines

This medicine may impair your ability to react as well as your ability to drive. Using Oxybuprocaine Agepha may impair your vision and therefore also your ability to react in traffic and to operate machines. Do not drive vehicles or operate tools or machinery before this effect has subsided.

3. How to use Oxybuprocaine Agepha

The recommended dose is 1 eye drop before the examination or procedure; this dose can be repeated if necessary.

Method of application

For use on the eye. (For instillation into the eye to be examined)

The doctor or eye specialist will put the drops in your eye for you. You may be asked to press on the inner corners of your eyelid for 1-2 minutes. This will help stop the solution draining into your nose and throat. This is especially advisable in the elderly and population at risk.

Your eye will remain numb for about one hour, depending on how many drops you received. Avoid touching the eye until the anaesthetic has worn off.

If you have other eye drops to instill, you should wait at least 15 minutes before administering them.

If you received more Oxybuprocaine Agepha than you should, an overdose is very unlikely to occur.

If you suddenly feel unwell after receiving the drops, tell your doctor or eye specialist or contact your nearest emergency department immediately.

Notice for people wearing contact lenses

Remove your contact lenses before instilling the drops into the eye and wait for at least one hour after instillation - until the anaesthetic effect has fully subsided - before putting them back on the eye. Failure to follow this advice may lead to corneal damage.

If you use more Oxybuprocaine Agepha than you should

Overdose: Intoxication with local/topical anaesthetics, especially when administered via the oral route, may trigger the following symptoms: muscle twitching, seizures, drop in blood pressure, fainting, cardiac arrhythmias, cardiac arrest caused by conduction disturbances, respiratory paralysis.

In such cases, consult a doctor immediately.

Instructions for healthcare professionals

You will find information on overdosage at the end of the prescribing information.

If you have any further questions on the use of this medicinal product, ask your doctor or pharmacist.

4. Possible Side Effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

You must contact a doctor immediately if you experience any of the following symptoms of a serious allergic/anaphylactic reaction: swelling, rash, itching, hives, difficulty breathing, chills, hot flushes, headache, general malaise, nausea, restlessness, fast heart rate or low blood pressure (occurring with an unknown number of users).

Other side effects that may occur:

Common (may affect up to 1 in 10 people):

The most common side effect is local irritation. Other common side effects are temporary burning after instillation, corneal damage with repeated use.

Rare (may affect up to 1 in 1,000 people):

Tremors, blurred vision, slow heart rate, low blood pressure, dizziness.

Not known (frequency cannot be estimated from the available data):

Eye allergy, allergic blepharitis (eyelid inflammation). Symptoms of eye allergy and allergic blepharitis can be itchy, red and swollen eyelids, red eyes, irritated and watery eyes, burning or stinging eyes, scales and crusts on the edge of the eyelashes, similar to dandruff, sensitivity to light.

Reporting of side effects

If you get any 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 directly to HPRC Pharmacovigilance

Website: www.hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Oxybuprocaine Agepha

This medicine does not require any special storage conditions.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and bottle label after EXP. The expiry date refers to the last day of that month.

To be used within 4 weeks after first opening.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Oxybuprocaine Agepha contains

- The active substance is oxybuprocaine hydrochloride
Each ml contains 4 mg oxybuprocaine hydrochloride
- The other ingredients are: Boric acid, Chlorhexidine diacetate, Hydrochloric acid (for pH adjustment), Water for injections

What Oxybuprocaine Agepha looks like and contents of the pack

Oxybuprocaine Agepha 4 mg/ml eye drops, solution is a clear, colourless solution in a plastic bottle. Each pack contains one bottle of 10 ml.

Marketing Authorisation Holder

AGEPHA Pharma s.r.o.
Diaľničná cesta 5,
Senec 903 01,
Slovakia

This medicine is authorised in the Member States of the European Economic Area under the following names:

| Country | Product Name |
|-------------|---|
| Austria | Novain 4 mg/ml Augentropfen, Lösung |
| Croatia | Ophtesia 4 mg/ml kapi za oko, otopina |
| Denmark | Oxybuprocainhydrochlorid "Agepha" |
| Estonia | Novain 4 mg/ml silmatilgad, lahus |
| Finland | Obupro 4 mg/ml silmätipat, liuos |
| Hungary | Oxybuprocaine hydrochloride AGEPHA 4 mg/ml oldatos szemcsepp |
| Iceland | Novain 4 mg/ml augndropar, lausn |
| Ireland | Oxybuprocaine Agepha 4 mg/ml eye drops, solution |
| Latvia | Oxybuprocaine hydrochloride Agepha 4 mg/ml acu pilieni, šķīdums |
| Lithuania | Novain 4 mg/ml akių lašai (tirpalas) |
| Netherlands | Obupro 4 mg/ml oogdruppels, oplossing |
| Norway | Obupro 4 mg/ml øyedråper, oppløsning |
| Poland | Novain, 4 mg/mL, krople do oczu, roztwór |

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| Portugal | Novain 4 mg/ml colírio, solução |
| Spain | Oxibuprocaína hidrócloruro Agepha 4 mg/ml colirio en solución |
| Sweden | Obupro 4 mg/ml ögondroppar, lösning |

This leaflet was last revised in October 2024

The following information is intended for physicians and healthcare personnel only:

Therapy of intoxication

Immediate respiratory and blood circulation management (intubation and artificial ventilation), cardiovascular stimulation, infusions (no adrenaline!). In case of cardiac arrest, external cardiac massage and electro-stimulation is to be performed. In case of seizures, ultra-short-acting barbiturates or diazepam should be given (long-acting barbiturates should not be administered due to the risk of respiratory depression).