

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using ALCAINE?

ALCAINE contains the active ingredient proxymetacaine hydrochloride. ALCAINE is used to temporarily numb or block the feeling of pain in your eye(s).

For more information, see Section 1. Why am I using ALCAINE? in the full CMI.

2. What should I know before I use ALCAINE?

Do not use if you have ever had an allergic reaction to ALCAINE or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use ALCAINE? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ALCAINE and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use ALCAINE?

- The usual dose of ALCAINE is one to two drops in your eye(s). This may be repeated every 5-10 minutes, for up to 3 doses.
- ALCAINE is only to be used by your doctor during a medical procedure.

More instructions can be found in Section 4. How do I use ALCAINE? in the full CMI.

5. What should I know while using ALCAINE?

Things you should do	 Remind any doctor or pharmacist you visit that you are using ALCAINE. Keep all your medical appointments so your progress can be checked. Keep your eye(s) covered and protected.
Things you should not do	Do not touch or rub your eye while your eye is numb because you may scratch the surface of your eye and damage it.
Driving or using machines	Be careful before you drive or use any machines or tools as ALCAINE may temporarily blur your vision.
Looking after your medicine	 Store in a refrigerator between 2°C to 8°C. Do not freeze. Protect from light. Do not use the product on more than one person. Discard the container 4 weeks after opening. Discard any unused product.

For more information, see Section 5. What should I know while using ALCAINE? in the full CMI.

6. Are there any side effects?

All medicines can have side effects although not everybody gets them. The most common side effects of ALCAINE include irritation, stinging and burning feeling in the eye, redness or watery eyes, increased blinking. Less common side effects can include dilated pupils causing blurred vision, drying and splitting of the skin on fingertips, a severe, immediate allergic reaction on the surface of the eye.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

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ALCAINETM

Active ingredient(s): proxymetacaine hydrochloride

Consumer Medicine Information (CMI)

This leaflet provides important information about using ALCAINE. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ALCAINE.

Where to find information in this leaflet:

- 1. Why am I using ALCAINE?
- 2. What should I know before I use ALCAINE?
- 3. What if I am taking other medicines?
- 4. How do I use ALCAINE?
- 5. What should I know while using ALCAINE?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using ALCAINE?

ALCAINE contains the active ingredient proxymetacaine hydrochloride. ALCAINE (proxymetacaine hydrochloride) belongs to a group of medicines called local anaesthetics.

ALCAINE Eye Drops are only to be used by your doctor during eye procedures.

ALCAINE is used by your doctor to temporarily numb or block the feeling (anaesthetise) of pain in your eye(s) during short-term medical procedures. These procedures can include measuring the pressure in your eye, cataract surgery, removing stitches or a foreign body from your eye e.g. a bit of dirt.

The numbing effect of ALCAINE will wear off quickly, usually about 15 minutes after the last drop is put in your eye(s).

Ask your doctor if you have any questions or concerns about why this medicine has been used on your eye(s).

Your doctor may have prescribed it for another reason.

What should I know before I use ALCAINE?

Warnings

Do not use ALCAINE if:

 you are allergic to proxymetacaine hydrochloride, or any of the ingredients listed at the end of this leaflet.
 Always check the ingredients to make sure you can use this medicine.

- Do not use ALCAINE if you have an allergy to any other local anaesthetics.
- Some of the symptoms of an allergic reaction may include:
 - shortness of breath
 - wheezing or difficulty breathing
 - swelling of the face, lips, tongue, or other parts of the body
 - o rash, itching or hives on the skin.
- Do not use ALCAINE after the expiry date printed on the pack or if the seal around the pack is broken or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.
- ALCAINE has been developed for use in the eye only. It is not to be swallowed or injected.
- If you are not sure whether you should be given ALCAINE talk to your doctor.

Check with your doctor if you:

- have any other medical conditions, especially:
 - o Epilepsy
 - Heart problems
 - Lung or breathing problems
 - Myasthenia gravis (a disease of the muscles causing drooping eyelids, double vision, difficulty in speaking and swallowing and sometimes muscle weakness in the arms or legs)
- have ever experienced a reaction to any other local anaesthetics
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

ALCAINE is not recommended for use in pregnancy. Your doctor will discuss the possible risks and benefits of using ALCAINE during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed. Your doctor will discuss the possible risks and benefits involved.

Long term use

- may lessen the anaesthetic effect so that more of the medicine is needed to produce the numbing effect
- it may also damage the surface of the eye, cause an eye infection or permanent loss of sight.

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Protect your eyes

It is very important that you protect your eyes from irritating chemicals, avoid touching or rubbing your eye(s) until the numbness has worn off.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins, or supplements that you buy without a prescription from your pharmacy, supermarket, or health food shop.

Some medicines may interfere with ALCAINE and affect how it works.

Telling your doctor is particularly important if you are currently using any medicines called "cholinesterase inhibitors".

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ALCAINE.

Your doctor will advise you and decide whether or not to give you ALCAINE.

4. How do I use ALCAINE?

How much to use

- Your doctor will put the correct number of drops of ALCAINE into your eye(s) before starting the procedure on your eye(s).
- Your doctor will not write a prescription for ALCAINE for your own use. ALCAINE has been specifically developed to help a doctor numb the feeling in your eye(s) while attending to your eye(s).
- The usual dose of ALCAINE is one to two drops in your eve(s).
- The number of times you will be given ALCAINE during
 the procedure will depend on the type and length of
 procedure to be performed. For example, your doctor
 will put one to two drops into your eye(s) just before
 measuring the pressure in your eye. However, if you
 are to have minor surgery such as removal of stitches
 your doctor will put one to two drops in your eye(s)
 every 5 to 10 minutes for up to three doses.

When to use ALCAINE

ALCAINE is only to be used by your doctor during an eye procedure.

If you are given too much ALCAINE

The doctor giving you ALCAINE will be experienced in the use of local anaesthetics, so it is unlikely that you will be given too much.

If too many drops have been put in accidentally in your eye(s) immediately rinse your eye(s) with water.

If you think that you or someone else has swallowed too much ALCAINE, you may need urgent medical attention.

You should immediately:

phone the Poisons Information Centre in Australia

(by calling 13 11 26), or

- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using ALCAINE?

Things you should do

- You must protect your anaesthetised eye(s) from dust particles, which could cause infection.
- If you are wearing soft contact lenses, you will be asked to remove them prior to instillation of the drops by your doctor. You may put your soft contact lenses back into your eyes after the numbing effect has worn off and at least 15 minutes after you have been given ALCAINE

Things you should not do

Do not touch or rub your eye(s) while they are numb. You may scratch the surface of the eye and damage it. Your doctor will put a patch over your eye after finishing the procedure to protect your eye and stop you from touching it.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how ALCAINE affects you and your vision.

As with any eye medicines, temporary blurred vision or another visual disorder may affect your ability to drive or use machinery in some people. If blurred vision occurs, wait until your vision is clear before you drive or use machines or tools.

Looking after your medicine

ALCAINE will be stored by your doctor or pharmacist under the recommended conditions.

- Store in a fridge between 2°C and 8°C
- Do not freeze
- Protect from light

When to discard your medicine (as relevant)

ALCAINE should be used in a single patient only.

Do not use if seal is broken.

Do not use if the liquid is discoloured.

Discard the container 4 weeks after opening.

Getting rid of any unwanted medicine

Do not use any medicine after the expiry date.

Unwanted medicines can be taken to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
 In or around the eye (ocular): Irritation, stinging and burning feeling in the eye Redness or watery eyes Increased winking Dilated pupils causing blurred vision 	Speak to your doctor if you have any of these less serious side effects and they worry you.
Body as a whole: • Feel unwell Skin: • Drying and splitting of the skin on fingertips	

Serious side effects

Serious side effects	What to do
 Allergic reaction: Shortness of breath Wheezing or difficulty breathing Swelling of the face, lips, tongue or other parts of the body Rash, itching or hives on the skin Redness and swelling of the eye(s), eyelid(s) and or the areas surrounding the eye(s) 	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.
Breathing:	side effects.
Shortness of breathWheezing or difficulty breathing	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side affects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor, nurse, or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What ALCAINE contains

Active ingredient (main ingredient)	proxymetacaine hydrochloride 0.5% (5 mg in 1 mL)
Other ingredients (inactive ingredients)	benzalkonium chloride (as a preservative) glycerol
	purified water hydrochloric acid and/or sodium hydroxide to adjust pH
Potential allergens	ALCAINE does not contain: gluten, latex, corn/corn derivatives, mercury, dyes, sulfa, sulfites or sulfate, phthalates (DEHP/PVC), dairy, eggs, BSE/TSE, and alcohol.

Do not use this medicine if you are allergic to any of these ingredients.

What ALCAINE looks like

ALCAINE eye drops is a sterile, clear liquid that comes in a 15 mL dropper bottle. (AUST R 24299).

Who distributes ALCAINE

ALCAINE is distributed in Australia by:

Alcon Laboratories (Australia) Pty Ltd

ABN 88 000 740 83054

15 Talavera Road

Macquarie Park NSW 2113

Telephone: 1800 224 153

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You should ensure that you speak to your doctor to obtain the most up to date information on the medicine.

You can also obtain a copy of the most up to date leaflet from your pharmacist. The updates may contain important information about the medicine and its use of which you should be aware.

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