Minims® Tetracaine (Amethocaine)

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 Minims® Tetracaine (Amethocaine)?

Minims[®] Tetracaine (Amethocaine) contains the active ingredient tetracaine (amethocaine) hydrochloride. Minims[®] Tetracaine (Amethocaine) is used to numb or block the feeling of pain in your eye(s) during short-term medical procedures.

For more information, see Section 1. Why am I using Minims® Tetracaine (Amethocaine)? in the full CMI.

2. What should I know before I use Minims® Tetracaine (Amethocaine)?

Do not use if you are allergic to tetracaine (amethocaine), any other local anaesthetic or any of the ingredients listed at the end of this CMI. Do not use if you are being treated with a group of medicines called sulphonamides. Do not use in premature babies. Do not use this medicine continuously for a long period of time. 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 Minims® Tetracaine (Amethocaine)? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Minims® Tetracaine (Amethocaine) 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 Minims® Tetracaine (Amethocaine)?

- Your doctor will instill Minims® Tetracaine (Amethocaine) eye drops into your eye(s) before starting a procedure on your eye(s).
- The usual dose is one drop instilled into the eye.
- The number of times your doctor will put drops in your eye(s) will depend on the type and length of the procedure to be performed.

More instructions can be found in Section <u>4. How do I use Minims</u> <u>Tetracaine (Amethocaine)?</u> in the full CMI.

5. What should I know while using Minims® Tetracaine (Amethocaine)?

Things you should do	Protect your numb eye from dust particles, which could cause infections.		
Things you should not do	Do not touch or rub your eye while your eye is numb.		
Driving or using machines	 Be careful before you drive or use any machines or tools until you know how Minims® Tetracaine (Amethocaine) affects you. Keep the patch that your doctor puts on your eye until normal feeling returns. Do not drive or operate hazardous machinery until you regain clear vision. 		
Looking after your medicine	• Your doctor will keep Minims® Tetracaine (Amethocaine) in a refrigerator (2-8°C). The eye drops should not be frozen or exposed to strong light.		

For more information, see Section 5. What should I know while using Minims® Tetracaine (Amethocaine)? in the full CMI.

6. Are there any side effects?

All medicines can have side effects. If they do occur, they are usually minor and temporary. Do not be alarmed by this list. You may not experience any of them.

Less serious side effects include: stinging or burning sensation in the eye, blurred vision or decreased vision, watery eyes, pain, swelling, redness, itching, eye fatigue, sensitivity to light and the feeling of having something in the eye. Serious side effects that require urgent medical attention include: grey appearance of the cornea and symptoms of an allergic reaction.

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.

Minims® Tetracaine (Amethocaine)

Active ingredient: Tetracaine (Amethocaine) hydrochloride

Consumer Medicine Information (CMI)

This leaflet provides important information about using Minims® Tetracaine (Amethocaine). 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 Minims® Tetracaine (Amethocaine).

Where to find information in this leaflet:

- 1. Why am I using Minims® Tetracaine (Amethocaine)?
- 2. What should I know before I use Minims® Tetracaine (Amethocaine)?
- 3. What if I am taking other medicines?
- 4. How do I use Minims® Tetracaine (Amethocaine)?
- <u>5.</u> <u>What should I know while using Minims® Tetracaine (Amethocaine)?</u>
- 6. Are there any side effects?
- 7. Product details

1. Why am I using Minims® Tetracaine (Amethocaine)?

Minims® Tetracaine (Amethocaine) contains the active ingredient tetracaine (amethocaine) hydrochloride.

Minims® Tetracaine (Amethocaine) belongs to a class of medicines called local anaesthetics.

Minims® Tetracaine (Amethocaine) is used to numb or block the feeling of pain in your eye(s) during short-term medical procedures. These procedures may include: measuring the pressure in your eye, inserting contact lenses, removing foreign bodies from your eye(s) and other minor operations on your eye(s).

2. What should I know before I use Minims® Tetracaine (Amethocaine)?

Warnings

Do not use Minims® Tetracaine (Amethocaine) if:

- You are allergic to tetracaine (amethocaine), any other local anaesthetic or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- You are being treated with a group of medicines called sulphonamides.

Check with your doctor if:

- You have had an allergy to any other medicines, foods, preservatives or dyes.
- You have any other medical conditions.
- You 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 <u>6</u>. Are there any side effects?

This medicine has been developed for use in the eye only. It should not be swallowed or injected.

Pregnancy and breastfeeding

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

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Elderly

Minims® Tetracaine (Amethocaine) should be used with caution in the elderly.

Infants

Minims® Tetracaine (Amethocaine) should not be used in premature babies.

Long-term Use

Do not use Minims® Tetracaine (Amethocaine) continuously for a long period of time.

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 and Minims® Tetracaine may interfere with each other. These medicines may be affected by Minims® Tetracaine (Amethocaine) or may affect how well it works. These include:

- Special dyes that your doctor may use to stain your eyes for examination.
- A group of medicines called sulphonamides.
- A group of medicines called anticholinesterases.
- A medicine called suxamethonium.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Minims® Tetracaine (Amethocaine).

4. How do I use Minims® Tetracaine (Amethocaine)?

Your doctor will not give you a prescription for your own use. This medicine has been specifically developed for use by your doctor to numb the feeling in your eye(s) while he/she is attending to your eye(s), and not for long-term use.

How much to use

 The usual dose is one drop into your eye(s) before starting a procedure on your eye(s). The number of times your doctor will put drops in your eye(s) will depend on the type and length of the procedure to be performed.

How to use Minims® Tetracaine (Amethocaine)

- Your doctor will put the correct number of drops of Minims® Tetracaine (Amethocaine) into your eye(s) before starting a procedure on your eye(s).
- If you are wearing contact lenses, you will be asked to remove them before putting in the eye drops. You may put your contact lenses back into your eye after the numbness has worn off or when you doctor tells you to.
- In children, the doctor may compress the small part of the child's eye near the corner of his/her nose for a minute during and following the instillation of the drops.

If you use too much Minims® Tetracaine (Amethocaine)

Minims® Tetracaine (Amethocaine) can damage the surface of the eye or cause vision loss if it is used too much or too often, especially if your eye is already damaged.

The doctor giving you Minims® Tetracaine (Amethocaine) will be experienced in its use, so it is unlikely that you will be given an overdose.

If too many drops have accidentally been put into your eye(s):

- Immediately rinse your eye(s) with plenty of warm water or saline and continue rinsing for at least 15 minutes (if you are wearing contact lenses, remove them before the rinse).
- A further examination should be performed if irritation, pain or swelling continue beyond 15 minutes.

Accidental swallowing of the solution is unlikely to cause any bad side effects due to the low content of tetracaine (amethocaine).

If you think that you or anyone else may have swallowed any or all of the contents of the container of Minims® Tetracaine (Amethocaine), you should immediately:

- phone the Poisons Information Centre (in Australia, call 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 Minims® Tetracaine (Amethocaine)?

Things you should do

 Protect your numb eye from dust particles, which could cause infections.

Things you should not do

Do not touch or rub your eye while your eye is numb.

Your eye(s) may remain numb for up to one hour after the last drop is put in.

Your doctor will put a patch over your eye after finishing the procedure to protect your eye from dust and bacterial contamination and stop you from touching it, scratching the surface of the eye and damaging it.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Minims® Tetracaine (Amethocaine) affects you.

Keep the patch that your doctor puts on your eye until normal feeling returns. Do not drive or operate hazardous machinery until you regain clear vision.

Looking after your medicine

Your doctor will keep Minims® Tetracaine (Amethocaine) in a refrigerator (2-8°C). The eye drops should not be frozen or exposed to strong light.

When to discard your medicine

Your doctor will discard each single dose unit and any remaining solution in it immediately after use. He/she will not save unused contents.

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 or pharmacist if you have any further questions about side effects.

Less serious side effects

 Stinging or burning sensation	Speak to your
(that may last for up to 30	doctor if you
seconds after instillation of the	have any of
drops) Blurred vision or decreased vision Watery eyes Pain Swelling Redness Itching Eye fatigue	these less serious side effects and they worry you.

Less serious side effects		What to do
•	Feeling of having something in	
	the eye	

Serious side effects

Serious side effects	What to do
Eyes: Grey appearance of the cornea (the clear and shiny part at the front of your eye) Symptoms of an allergic reaction, such as: 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	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.

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 effects you experience, you can report side effects online (in Australia, go to 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 or pharmacist before you decide to stop taking any of your medicines.

7. Product details

What Minims® Tetracaine (Amethocaine) contains

Active ingredient	tetracaine (amethocaine) hydrochloride (0.5% or 1% w/v)	
(main ingredient)		
Other ingredients	Purified water	
(inactive ingredients)	Hydrochloric acid	

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

The eye drops do not contain any preservatives.

What Minims® Tetracaine (Amethocaine) looks like

Minims® Tetracaine (Amethocaine) comes in single-dose units (tubes) containing 0.5 mL of a clear, colourless solution. Each tube is wrapped in a polyester/paper blister. The blisters are packed in cartons of 20 units.

Minims® Tetracaine (Amethocaine) is available in two strengths: 0.5% w/v (AUST R 32252) and 1% w/v (AUST R 32254).

Who distributes Minims® Tetracaine (Amethocaine)

In Australia, Minims® Tetracaine (Amethocaine) is supplied by:

Bausch & Lomb (Australia) Pty Ltd

Level 2, 12 Help Street

Chatswood, NSW 2067

Phone: 1800 251 150

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