

**Core CMI for Drugs Used to Treat Glaucoma** (*text in italics is instructional*)

This core CPI is for both topical and oral dosage forms.

**[Medicine name]**<sup>®</sup> (*if phonetic spelling is required, the Second Edition of the Usability Guidelines suggests using the system outlined in the Webster's International Dictionary*).

Generic name

**Consumer Medicine Information**

*Consumer Name*  
*Consumer Address*  
*Consumer Address*

*Date of Dispensing*

*Pharmacist Name*  
*Pharmacist Address*  
*Pharmacist Address*

**What is in this leaflet<sup>1</sup>**

*Standard information as suggested in Usability Guidelines.*

This leaflet answers some common questions about [Medicine name], (including how to use the eye drops - *if appropriate*). It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits<sup>2</sup>. Your doctor has weighed the risks of you using [Medicine name] against the benefits they expect it will have for you.

**If you have any concerns about using/taking this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.**

You may need to read it again.

**What [Medicine name] is used for**

[Medicine name] is used to lower raised pressure in the eye and to treat glaucoma. Glaucoma is a condition in which the pressure of fluid in the eye may be high. However, some people with glaucoma may have normal eye pressure.

<sup>1</sup> Depending on the length of your CPI, consider using a table of contents (see Usability Guidelines)

<sup>2</sup> Consider reversing "risks" and "benefits"

Glaucoma is usually caused by a build up of the fluid which flows through the eye. This build up occurs because the fluid drains out of your eye more slowly than it is being pumped in. Since new fluid continues to enter the eye, joining the fluid already there, the pressure continues to rise. This raised pressure may damage the back of the eye resulting in gradual loss of sight. Damage can progress so slowly that the person is not aware of this gradual loss of sight. Sometimes even normal eye pressure is associated with damage to the back of the eye.

There are usually no symptoms of glaucoma. The only way of knowing that you have glaucoma is to have your eye pressure, optic nerve and visual field checked by an eye specialist or optometrist. If glaucoma is not treated it can lead to serious problems, including total blindness. In fact, untreated glaucoma is one of the most common causes of blindness.

Although [Medicine name] helps control your glaucoma it does not cure it.

For more information about glaucoma, contact the Glaucoma Foundation of Australia (telephone 9906 6640).

[Medicine name] is used, either alone or in combination with other eye drops/medicines, to lower raised pressure within your eye(s).  
*Mechanism of action:*

[Medicine name] lowers pressure in the eye by reducing the production of fluid.

or

[Medicine name] lowers pressure in the eye by allowing more fluid to flow out from within your eye(s).

or

[Medicine name] lowers the pressure in the eye by decreasing the fluid produced and helping the flow of fluid out of the eye chamber.

[Medicine name] belongs to a family of medicines called beta-blockers/parasympathomimetics/sympathomimetics/alpha-adrenergic agonists.

*Non-approved uses statement:*

Your doctor may have prescribed [Medicine name] for another reason. Ask your doctor if you have any questions about why [Medicine name] has been prescribed for you.

*Statement about addictive properties:*

[Medicine name] is not addictive.

or

There is no evidence that [Medicine name] is addictive.

**Before you use  
[Medicine name]**

[Medicine name]

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## Before you take [Medicine name]

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### *When you must not use/take it*

#### Do not use/take [Medicine name] if:

1. you have an allergy to [Medicine name] or any of the ingredients listed at the end of this leaflet

#### *B-blockers:*

2. you have asthma, or a history of asthma, chronic obstructive lung disease (emphysema) or other breathing problems
3. you have certain heart conditions, such as a very slow heart rate, an irregular heart beat, or heart failure
4. you are breast-feeding<sup>3</sup>  
Your baby may absorb this medicine from breast milk and therefore there is a possibility of harm to the baby.

#### *Carbonic anhydrase inhibitors (oral):*

2. you have an allergy to sulphonamide medicines<sup>4</sup>  
The active ingredient of [Medicine name], \_\_\_\_\_, is a sulfur-containing medicine (a sulphonamide). Therefore, if you are allergic to sulfur medicines, such as some antibiotics, you may be allergic to [Medicine name]. Check with your doctor or pharmacist if you are not sure whether you are allergic to sulpha medicines.

3. you have liver problems

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<sup>3</sup> Consider placing breast-feeding statement here or under 'Before you start to use it', depending on wording in PI.

<sup>4</sup> Consider placing sulphonamide allergy statement here on under 'Before you start to take', depending whether a contraindication or precaution.

[Medicine name]

4. you have severe kidney disease
5. you have a deficiency of the adrenal gland (eg, Addison's disease)
6. you have severe lung or breathing problems
7. you have a condition which lowers the levels of potassium or sodium in your blood

8. you have high levels of chloride in your blood

#### *Carbonic anhydrase inhibitors (topical):*

2. you are breast-feeding  
It is not known whether [Medicine name] passes into breast milk.

#### *Pilocarpine/Carbachol/Ecothiopate iodide*

2. you have been diagnosed with a condition known as iritis, an inflammation of the coloured part of the eye
3. you have a certain type of glaucoma called "pupillary block glaucoma", a condition that prevents normal flow of fluid through the pupil

#### *Dipivefrine/Phenylephrine*

2. you have a certain type of glaucoma called angle-closure or narrow-angle glaucoma
3. you have an aneurysm (widening and weakening of blood vessels)

#### *Apraclonidine:*

2. you are currently using or being treated with:

- any monoamine oxidase (MAO) inhibitor or tricyclic antidepressant medicines
- any sympathomimetic medicines. Medicines used to treat asthma, severe headaches or coughs and colds may belong to this family of medicines.

#### *Tampering and expiry date warnings - all products:*

#### Do not use/take [Medicine name] if:

- the seal around the cap is broken
- the bottle/packaging shows signs of tampering
- the expiry date on the bottle/pack/carton has passed.  
If you use this medicine after the expiry date has passed, it may not work.

#### Do not put the eye drops into your eye(s) while you are wearing soft contact lenses.<sup>5</sup>

The preservative in [Medicine name] (benzalkonium chloride) may be deposited in soft contact lenses. You can put your soft contact lenses back into your eyes 15 minutes after you have used [Medicine name].

#### If you are not sure whether you should start using/taking [Medicine name], talk to your doctor.

#### *If use in children a contraindication:*

#### Do not use [Medicine name] in a child (under x years of age - if appropriate).

There is no/not enough experience with the use of [Medicine name] in children.

or

The safety and effectiveness of [Medicine name] in children have not been established.

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<sup>5</sup> Consider placing this information here or under 'Before you start to use it', depending on wording in PI.

or  
[Medicine name] is not recommended for use in children.

The preservative in [Medicine name] (benzalkonium chloride) may be deposited in soft contact lenses.

using [Medicine name] during pregnancy.

**Before you start to use/take it**

**Tell your doctor if:**

- 1. you have had an allergy to any other medicines or any other substances, such as foods, preservatives or dyes.**
- 2. If you have not told your doctor about any of the above, tell them before you use [Medicine name].**

*B-blockers:*

- 3. you are pregnant or intend to become pregnant**  
Your doctor will discuss the possible risks and benefits of using [Medicine name] during pregnancy.

*Alternative:*

Like most medicines, [Medicine name] is not recommended during pregnancy.

- 4. you are breast-feeding or intend to breast-feed**  
Your baby may absorb this medicine from breast milk and therefore there is a possibility of harm to the baby.

*Alternative:*

Your doctor will discuss the possible risks and benefits of using [Medicine name] when breast-feeding.

Like most medicines, [Medicine name] is not recommended while you are breast-feeding.

- 5. you have or have had any medical conditions, especially the following:**
  - heart disease
  - lung disease
  - diabetes mellitus or sugar diabetes
  - an overactive thyroid gland
  - generalised muscle weakness
- 6. you wear soft contact lenses**

[Medicine name]

*Carbonic anhydrase inhibitors:*

- 3. you are pregnant or intend to become pregnant, or are breast-feeding or intend to breast-feed.**
- Like most medicines, [Medicine name] is not recommended to be used during pregnancy or while breast-feeding. [Medicine name] passes into breast milk. Your doctor will decide if you should take [Medicine name].
- 5. you have or have had any medical conditions, especially the following:**
  - liver or kidney disease
  - any breathing difficulties or lung problems

*Pilocarpine/Carbachol/Ecothiopate iodide:*

- 3. you are pregnant or intend to become pregnant**  
Your doctor will discuss the possible risks and benefits of using [Medicine name] during pregnancy.
- 4. you are breast-feeding or intend to breast-feed**  
Your doctor will discuss the possible risks and benefits of using [Medicine name] when breast-feeding.
- 5. you have or have had any medical conditions, especially the following:**
  - Parkinson's disease
  - high blood pressure
  - an obstruction of the urinary tract
  - any heart disease
  - any breathing difficulties or lung problems, eg asthma
  - peptic ulcers

*Dipivefrine/Phenylephrine:*

- 3. you are pregnant or intend to become pregnant**  
Your doctor will discuss the possible risks and benefits of

- 4. you are breast-feeding or plan to breast-feed**  
Your doctor will discuss the possible risks and benefits of using [Medicine name] when breast-feeding.
- 5. you have or have had any medical conditions, especially the following:**

- heart disease
- high blood pressure
- thyroid problems
- diabetes mellitus or sugar diabetes

*Apraclonidine:*

- 3. you are pregnant or intend to become pregnant**  
Your doctor will decide if you should use [Medicine name].
- 4. you are breast-feeding or intend to breast-feed**  
Your baby may absorb this medicine from breast milk and therefore there is a possibility of harm to the baby.
- 5. you have or have had any medical conditions, especially the following:**

- depression
- any disease affecting the veins or arteries of the brain
- any disease affecting the veins or arteries in other areas of the body
- heart problems, including high blood pressure
- Raynaud's syndrome. This is a condition marked by numbness, tingling and colour change (white, blue, then red) in the fingers when they are exposed to cold.
- kidney or liver problems
- a certain type of glaucoma called angle-closure or narrow-angle glaucoma

**Taking other medicines**

**Tell your doctor if you are taking any other medicines, including any that you buy without a**

## prescription from your pharmacy, supermarket or health food shop.

Some medicines and [Medicine name] may interfere with each other. These include:

### *B-blockers:*

- tablets for high blood pressure or heart conditions, including a group of medicines called beta-blockers
- reserpine, another medicine used to treat high blood pressure (*NB - reserpine no longer available in Australia*)
- digoxin, a medicine used to treat heart failure
- other medicines or eye drops for glaucoma
- *Carbonic anhydrase inhibitors:*
- aspirin, in high doses
- salicylate-containing medicines which are used to relieve pain
- digoxin, a medicine used to treat heart failure
- phenytoin, a medicine used to treat epilepsy
- corticosteroids such as prednisone, cortisone
- ACTH, a hormone given by injection
- tablets used to treat diabetes
- warfarin, a medicine used to prevent blood clots
- methotrexate, a medicine used to treat some cancers and arthritis
- medicines to treat high blood pressure
- tablets used to treat glaucoma

### *Pilocarpine/Carbachol/Ecothiopate iodide:*

- other medicines or eye drops for glaucoma

### *Dipivefrine/Phenylephrine:*

- medicines for high blood pressure, including propranolol, methyl dopa, reserpine
- guanethidine, a medicine used for certain heart conditions

- certain medicines to treat depression, such as monoamine oxidase inhibitors and tricyclics
- anticholinergic medicines, such as atropine, benztropine, benzhexol, biperiden, procyclidine, orphenadrine

### *Apraclonidine:*

- medicines used to treat high blood pressure
- medicines used to treat some heart problems
- any sedative-type medicines, including alcohol and antihistamines

These medicines may be affected by [Medicine name], or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while using [Medicine name].

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## How to use [Medicine name]

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*This information will be product specific, consistent with the approved PI. The following order of information is suggested, but will depend upon the particular product and the amount of information. These headings and information are suggested but may not be necessary in all cases:*

### **How much to use/take**

*Include dosage ranges, usual doses for each indication or patient group, or a general statement that the dose will depend on the patient and will be determined by the doctor.*

**Your doctor will tell you how many drops/tablets you need to use/take each day. Use/take [Medicine name] only when prescribed by your doctor.**

**Follow all directions given to you by your doctor carefully.**

They may differ from the information contained in this leaflet.

**Use [Medicine name] every day, at about the same time each day, unless your doctor tells you otherwise.**

Using your eye drops at the same time each day will have the best effect on your eye pressure. It will also help you remember when to use the eye drops.

**After using [Medicine name], wait at least 5 minutes before putting any other eye drops in your eye(s).**

**If you are being changed from one eye drop to another, follow your doctor's instructions carefully as to when to stop the old drops and when to start the new drops.**

### **How to use it**

You may find it easier to put drops in your eye while you are sitting or lying down.

**If you are wearing soft contact lenses, remove them before putting the drops in your eye.**

To open a **new** bottle of [Medicine name], first tear/twist off the protective seal from the bottle. The seal will break and you can pull it off and then throw it away.

### **For bottles that are *squeezed*:**

1. Wash your hands well with soap and water.
2. Shake the bottle. (*if appropriate*)
3. Remove the lid/cap.
4. Hold the bottle upside down in one hand between your thumb and forefinger/index finger.
5. Using your other hand, gently pull down your lower eyelid to form a pouch/pocket.
6. Tilt your head back and look up.
7. Put the tip of the bottle close to your eye. Do not let it touch your eye.
8. Release one drop onto your eye by gently squeezing the bottle.

or

8. Put the tip of the bottle close to your lower eyelid. Do not let it touch your eye.
9. Release one drop into the pouch/pocket formed between your eye and eyelid by gently squeezing the bottle.
10. Close your eye. Do not blink or rub your eye.
11. While your eye is closed, place your index finger against the inside corner of your eye and press against your nose for about two minutes. This will help to stop the medicine from draining through the tear duct to the nose and throat, from where it can be absorbed into other parts of your body. Ask your doctor for more specific instructions on this technique. *(if appropriate)*
12. Replace the lid/cap, sealing it tightly.
13. Wash your hands again with soap and water to remove any residue.

For bottles that are **tapped or pressed**:

1. Wash your hands well with soap and water.
2. Shake the bottle *(if appropriate)*
3. Remove the lid/cap.
4. Hold the bottle upside down in one hand between your thumb and middle finger.
5. Using your other hand, gently pull down your lower eyelid to form a pouch/pocket.
6. Tilt your head back and look up.
7. Put the tip of the bottle close to your eye. Do not let it touch your eye.
8. Release one drop onto your eye by gently tapping or pressing the base of the bottle with your index finger/forefinger.

or

8. Put the tip of the bottle close to your lower eyelid. Do not let it touch your eye.
9. Release one drop into the pouch/pocket formed between your eye and eyelid by gently tapping or pressing the base of the bottle with your index finger/forefinger.
10. Close your eye. Do not blink or rub your eye.

11. While your eye is closed, place your index finger against the inside corner of your eye and press against your nose for about two minutes. This will help to stop the medicine from draining through the tear duct to the nose and throat, from where it can be absorbed into other parts of your body. Ask your doctor for more specific instructions on this technique. *(if appropriate)*
12. Replace the lid/cap, sealing it tightly.
13. Wash your hands again with soap and water to remove any residue.

Wait 15 minutes before replacing your contact lenses.

You may feel a slight burning sensation in the eye shortly after using the eye drops.

**If this persists, or is very uncomfortable, contact your doctor or pharmacist.**

**Be careful not to touch the dropper tip against your eye, eyelid or anything else to avoid contaminating the eye drops.** Contaminated eye drops may give you an eye infection.

#### **How to take it**

Swallow [Medicine name] with a glass of water.

#### **How long to use/take it**

[Medicine name] helps control your condition but does not cure it. Therefore [Medicine name] must be used/taken every day. Continue using [Medicine name] for as long as your doctor prescribes. For some people [Medicine name] may have been prescribed for a short time before or after eye surgery.

#### **If you forget to use/take it**

*As per Usability Guidelines*

**If it is almost time for your next dose, skip the dose you missed and use/take your next dose**

**when you are meant to. Otherwise, use the drops/take the tablets as soon as you remember, and then go back to using/taking them as you would normally.**<sup>6</sup>

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

**Do not use double the amount to make up for the dose that you missed.**

*Oral:*

**Do not take a double dose to make up for the dose that you missed.**

If you have trouble remembering to use your eye drops/take your medicine, ask your pharmacist for some hints.

*Topical:*

**If you use too much (overdose)**

**If you accidentally put several drops in your eye(s), immediately rinse your eye(s) with warm water.**

**If you think that you or anyone else may have swallowed any or all of the contents of a bottle of [Medicine name], immediately telephone your doctor or Poisons Information Centre<sup>7</sup> (telephone 13 11 26) for advice, or go to casualty at your nearest hospital. Do this even if there are no signs of discomfort or poisoning<sup>8</sup>.**

If [Medicine name] is accidentally **swallowed** you may feel .....*(list symptoms in P1)*.

<sup>6</sup> These two sentences are in reverse order from that recommended in the Usability Guidelines.

<sup>7</sup> Consider including NZ details - National Poisons Information Centre (telephone 03 4747000).

<sup>8</sup> The reference to casualty and urgent medical attention could be left out, depending on the type of product.

Oral:

### **If you take too much (overdose)**

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, or go to casualty at your nearest hospital, if you think that you or anyone else may have taken too much [Medicine name]. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you take too much [Medicine name], you may feel ..... (list symptoms in P1)

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### **While you are using [Medicine name]**

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#### **Things you must do**

**Have your eye pressure checked when your eye specialist says, to make sure [Medicine name] is working.**

**If you wear soft contact lenses, remove them before using [Medicine name]. Leave your lenses out for at least 15 minutes after putting in the eye drops.**

The preservative in [Medicine name] (benzalkonium chloride) may be deposited in soft contact lenses.

**If you develop an eye infection, receive an eye injury, or have eye surgery tell your doctor.**

Your doctor may tell you to use a new container of [Medicine name] because of possible contamination of the old one, or may advise you to stop your treatment with [Medicine name].

**If you become pregnant while using [Medicine name] tell your doctor immediately<sup>9</sup>.**

**If you are about to be started on any new medicine tell your**

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<sup>9</sup> The need to use "immediately" will depend on the product.

**doctor and pharmacist that you are using [Medicine name].**

#### **Things you must not do**

**Do not give [Medicine name] to anyone else, even if they have the same condition as you.<sup>10</sup>**

**Do not stop using [Medicine name] without first talking to your doctor.**

If you stop using your eye drops, your eye pressures may rise again and damage to your eye may occur.

#### **Things to be careful of**

**Be careful driving or operating machinery until you know how [Medicine name] affects you.**

[Medicine name] generally does not cause any problems with your ability to drive a car or operate machinery. However, [Medicine name] may cause blurred vision/ dizziness/ drowsiness/ tiredness in **some** people. Make sure you know how you react to [Medicine name] or that your vision is clear before driving a car or operating machinery.

*Carbonic anhydrase inhibitors (oral):*

**Have your potassium levels checked when your doctor says.**

This medicine may cause a loss of potassium from your body. Having the right amount of potassium in your body is very important. Your doctor may want to increase your potassium in your diet or take a potassium supplement. Do not alter your diet or take a supplement without talking to your doctor first, as it can also be harmful to have too much potassium.

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### **Side effects**

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*An all inclusive list of side effects has been developed. The italic text in brackets indicates the medical*

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<sup>10</sup> The Usability Guidelines suggest including this statement under "Before you use/take it", but consider including it here under "While you are using [Medicine name]".

*term in the Product Information. The side effects can be grouped as appropriate. The list does not mean all companies are disclosing the same side effects. The side effects for a particular product will depend on the Product Information and the company's disclosure policy. The list enables a consistent approach in the way the side effects are described.*

**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using [Medicine name].**

[Medicine name] helps most people with high eye pressure and glaucoma, but it may have unwanted side effects in a few people. (If appropriate - If you are over 65 years of age you may have an increased chance of getting side effects.)

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

*Alternative:*

**Check with your doctor as soon as possible if you have any problems while taking [Medicine name], even if you do not think the problems are connected with the medicine or are not listed in this leaflet.**

Like other medicines, [Medicine name] can cause some side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

**Ask your doctor or pharmacist to answer any questions you may have.**

**Tell your doctor if you notice any of the following and they worry you:**

- allergic reactions including redness and swelling of the eye/s, swelling of the eyelids and surrounding area, discomfort, watering eye/s,

- feeling of something in the eye/s, itching (*hypersensitivity*)
- blurred vision (*blurred vision, cataract, corneal staining*)
- problems seeing clearly (*decreased visual acuity*)
- double vision (*diplopia*)
- irritation or feeling of having something in the eye (*ocular irritation, ocular pain, ocular discomfort, foreign body sensation*)
- dry eyes, or irritation or feeling of having something in the eye (*dry eyes*)
- sore eye and blurred vision (*corneal punctate keratitis*)
- small images floating through or across your vision (*transient pigment floaters*)
- burning and stinging of the eye/s (*burning and stinging*)
- discharge, itching of the eye/s, crusty eyelashes (*conjunctivitis, itching sensation*)
- watering of the eye/s (*tearing*)
- redness of the eye/s (*redness, hyperaemia*)
- swelling of the eyelids (*eyelid inflammation, eyelid oedema*)
- excessive sensitivity to bright light (*photophobia*)
- raising of the upper eyelid (*lid retraction*)
- poor night vision (*reduced visual acuity in poor illumination*)
- short sightedness (*myopia*)
- whitening of the non-coloured part of the eye (*blanching*)
- squinting or blinking of the eyelids
- headache (*headache*)
- feeling sick (nausea) (*nausea*)
- bitter taste (*bitter taste*)
- dizziness (*dizziness*)
- tiredness, lack of energy (*lethargy*)
- tiredness (*fatigue*)
- weakness (*asthenia*)
- dry nose (*dry nose*)
- runny nose (*rhinitis*)
- numbness or tingling in the fingers or toes (*paraesthesia*)
- dry mouth (*dry mouth*)
- changes in sensation of taste or smell (*taste perversion*)
- thirst (*thirst*)
- vomiting (*vomiting*)
- loss of appetite (*anorexia*)
- constipation (*constipation*)
- diarrhoea (*diarrhoea*)

- inability to sleep (*insomnia*)
- confusion (*confusion*)
- irritability (*irritability*)
- flushing (*flushing*)
- ringing or buzzing in the ears (*tinnitus*)
- drowsiness (*sedation*)
- loss of weight (*loss of weight*)
- mood changes such as depression or nervousness (*depression, nervousness*)
- feeling of a lump in the throat (*globus hystericus*)
- sore mouth or tongue (*glossitis*)
- skin rash (*dermatitis, contact dermatitis*)
- hair loss or thinning (*alopecia*)
- aching or painful muscles, not caused by exercise (*myalgia*)

These are usually mild side effects that may occur occasionally.

or

These side effects are usually mild.

**Tell your doctor immediately if you notice any of the following:**

- a loss of feeling to the surface of the eye (*decreased corneal sensitivity*)
- pupils of differing sizes (*anisocoria*)
- reduced colour vision (*colour vision defects*)
- blurred vision, halos around light (*corneal oedema*)
- dizziness and light-headedness, which may be due to low blood pressure (*hypotension*)
- severe dizziness, spinning sensation (vertigo) (*vertigo*)
- sudden onset of severe headache, which may be due to high blood pressure (*high blood pressure*)
- fast or irregular heart beat, also called palpitations (*palpitations*)
- skin rash (*rash*)
- itching (*pruritus*)
- swelling of face, hands or feet (*peripheral oedema*)
- need to urinate more often than usual (*urinary frequency*)
- sudden severe back pain, which may be caused by kidney stones (*renal colic*)
- bruising or bleeding more easily than normal (*thrombocytopenia*)

- signs of frequent or worrying infections such as fever, sore throat, severe chills or mouth ulcers (*agranulocytosis, leukopenia*)
- blood in the urine (*haematuria*)
- lack of co-ordination (*ataxia*)
- tremor (*tremor*)

These are serious side effects. You may need urgent medical attention. Serious side effects are rare.

**If any of the following happen, stop using [Medicine name] and tell your doctor immediately or go to casualty at your nearest hospital:**

- wheezing, difficulty in breathing (*bronchospasm, exacerbation of asthma, respiratory failure, pulmonary distress*)
- shortness of breath (*dyspnoea, heart failure*)
- very slow pulse (*bradycardia*)
- irregular heart beat (*arrhythmia, ventricular arrhythmia*)
- slow or irregular heart beat (*heart block*)
- chest pain (*cardiac arrest, chest pain*)
- seizures or fits (*convulsions*)
- fainting (*syncope*)
- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing (*angioedema*)
- severe and sudden onset of pinkish, itchy swellings on the skin, also called hives or nettlerash (*urticaria*)
- severe skin reaction which starts with painful red areas, then large blisters and ends with peeling of layers of skin. This is accompanied by fever and chills, aching muscles and generally feeling unwell. (*toxic epidermal necrolysis*)

These are very serious side effects. You may need urgent medical attention. These side effects are rare.

**Other side effects not listed above may also occur in some**

**patients. Tell your doctor if you notice any other effects.**

Do not be alarmed by this list of possible side effects. You may not experience any of them.<sup>11</sup>

*Alternative:*

Most people do not experience any of them.

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## **After using [Medicine name]**

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### **Storage**

*This information will be product specific. See general statements in Usability Guidelines, including:*

**Keep your eye drops in a cool place where the temperature stays below 25°C/30°C. Do not freeze the eye drops.**

**Do not store it or any other medicine in the bathroom or near a sink. Do not leave it in the car or on window sills. Do not carry the eye drops in pockets of your clothes.** Heat and dampness can destroy some medicines.

**Keep it where children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

**Do not leave the top/lid off the bottle for any length of time to avoid contaminating the eye drops.**

**Do not use the eye drops if the solution is discoloured brown (or other colour if appropriate).**

### **Disposal**

**Write the date on the bottle when you open the eye drops and throw out any remaining solution after four weeks/28 days.**

Eye drops contain a preservative which helps prevent germs growing in the solution for the first four weeks after opening the bottle. After this time there is a greater risk that the drops may become contaminated and cause an eye infection. A new bottle should be opened.

**If your doctor tells you to stop using the eye drops or they have passed their expiry date, ask your pharmacist what to do with any remaining solution.**

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## **Product description**

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*This information will be product specific. The Usability Guidelines suggest the following order:*

### **What it looks like**

### **Ingredients**

Active ingredient:

Inactive ingredients:

### **Manufacturer/Supplier**

*Include:*

*Name and address of sponsor*

*ARTG number*

*Date of preparation*

***The statements in this core document are optional. Some may not be appropriate for a given CMI. In order to achieve consistency, however, CMI writers are encouraged to use these statements and follow the Usability Guidelines wherever possible.***

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<sup>11</sup> Consider placing this statement at the beginning of this section.