#### **ACULAR®**

#### **Consumer Medicine Information (CMI) summary**

The <u>full CMI</u> 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 ACULAR®?

ACULAR® eye drops contain the active ingredient ketorolac trometamol. ACULAR® is used in adults:

- to treat itchy eyes occurring with the condition called seasonal allergic conjunctivitis, and
- to prevent and relieve swelling and redness after cataract surgery.

For more information, see Section <u>1. Why am I using</u> ACULAR®? in the full CMI.

# 2. What should I know before I use ACULAR®?

Check the list of ingredients at the end of the CMI. Do not use ACULAR® if you have ever had an allergic reaction to any of them.

Talk to your doctor before you use this medicine if he/she is not aware that 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 ACULAR®? in the full CMI.

## 3. What if I am taking other medicines?

Some medicines may interfere with ACULAR® and affect how it works, or ACULAR® may interfere with other medicines and affect how they work. 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 ACULAR®?

- Your doctor will advise how many drops to use depending on your condition.
- Use the drops four times per day.
- Your doctor will advise when to start using the drops and when to finish.

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

## 5. What should I know while using ACULAR®?

#### Things you should do

- Remind any doctor, dentist, pharmacist, or optometrist you visit that you are using ACULAR®.
- Continue to use ACULAR® for the time period your doctor tells you.
- Keep all your followup appointments so your condition can be checked.

## Things you should not do

- Do not touch the dropper tip against your eye, eye lid or any surface.
- Do not stop using ACULAR® earlier than instructed or use it for longer than instructed without checking with your doctor.
- Do not use ACULAR® drops while you are wearing soft contact lenses.

Driving or using machines	<ul> <li>Wait for your vision to clear after using ACULAR® before you drive or use machines.</li> </ul>
Drinking alcohol	<ul> <li>There is no information on the effects of using ACULAR® with alcohol.</li> </ul>
Looking after your medicine	<ul> <li>Follow all instructions on the carton and bottle label.</li> <li>Store it in a cool place, below 30°C, away from heat, or sunlight.</li> </ul>

For more information, see Section <u>5. What should I know while using ACULAR®?</u> in the full CMI.

## 6. Are there any side effects?

Stinging and burning of the eye(s) when applying the eye drops (eye pain), blurred vision, infection, swelling at the front of the eye or the iris, red itchy eye(s), irritation of the surface of the eye, , drooping or swollen lid, sensitivity to light, dry eye, lesion on the front of the eye, increased eye pressure, white spots on eye surface, headache, bleeding or swelling of retina, asthma, bronchospasm, severe allergic reaction.

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

## ACULAR® (ack-yoo-lar)

**Active ingredient(s):** *ketorolac trometamol* (keet-oh-roll-ack troh-met-am-ol)

#### **Consumer Medicine Information (CMI)**

This leaflet provides important information about using ACULAR® eye drops. 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 ACULAR®.

#### Where to find information in this leaflet:

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

## 1. Why am I using ACULAR®?

ACULAR® contains the active ingredient ketorolac trometamol.

Ketorolac trometamol works by decreasing prostaglandin E2 levels in the eye. Prostaglandins are normally produced by the body and are thought to be associated with pain, itching and inflammation.

#### **ACULAR®** is used in adults:

- to treat itchy eyes occurring with the condition called seasonal allergic conjunctivitis, and
- to prevent and relieve swelling and redness after cataract surgery.

# 2. What should I know before I use ACULAR®?

## **Warnings**

#### Do not use ACULAR® if:

- you are allergic to ketorolac trometamol, or any of the ingredients listed at the end of this leaflet.
- you have ever had an allergic reaction to aspirin or other similar medicines used for arthritis or pain relief (non-steroidal anti-inflammatory drugs (NSAIDs)).
- the seal around the cap is broken.
- the bottle/packaging shows signs of tampering.
- the product does not look quite right.
- the expiry date on the bottle has passed.

## Check with your doctor if you:

have or have had a stomach ulcer

- have or have had problems with your lungs, such as asthma, bronchospasm
- have or have had problems with the surface of your eye (cornea)
- have or have had other eye conditions, such as dry eye syndrome
- have had recent eye surgery
- have diabetes
- have rheumatoid arthritis
- are using topical NSAIDs for any other condition
- have a condition that causes you to bleed or bruise easily
- 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?

## Pregnancy and breastfeeding

Make sure your doctor is aware that you are pregnant or plan to become pregnant or are breastfeeding or intend to breastfeed.

ACULAR® is not recommended in pregnant or breastfeeding women.

#### Children

It is not known if ACULAR® is safe and effective for use in children younger than 12 years of age.

## 3. What if I am taking other medicines?

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

Some medicines may interfere with ACULAR® and affect how it works; while ACULAR® may affect how other medicines work.

Using ACULAR® at the same time as other eye medicines, including similar medicines (NSAIDs) and steroids, may slow down the healing process, after surgery.

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

## 4. How do I use ACULAR®?

#### How much to use

Your doctor will tell you how many drops you need to use each day. Use **ACULAR®** as prescribed by your doctor.

Seasonal allergic conjunctivitis

Use one drop in your eye(s) four times each day.
 Cataract surgery

 Use one to two drops in your eye(s) four times each day.

#### When to use ACULAR®

Seasonal allergic conjunctivitis

 Continue to use the drops as instructed for up to four weeks.

#### Cataract surgery

- Use the drops as instructed starting 24 hours before surgery.
- Continue to use the drops for as long as your doctor advises, which may be up to 4 weeks.

In some instances, ACULAR® needs to be used with other eye drops. Your doctor will let you know which drops, how to use them and how long to use them.

#### How to use ACULAR®

These drops are for topical use only.

- 1. Wash your hands well with soap and water.
- 2. If you wear soft contact lenses, remove them before using ACULAR®.
- 3. Tear off the protective seal on any new bottle and throw the seal away. Remove the lid/cap.
- 4. Hold the bottle upside down in one hand between your thumb and index finger.
- 5. Using your other hand, gently pull down your lower eyelid to form a pouch or pocket.

- 6. Tilt your head back and look up. This might be easier if you are sitting or lying down.
- 7. Put the tip of the bottle close to your lower eyelid. Do not let the tip touch your eye or eyelid.
- 8. Release one drop into the pouch or pocket formed between your eye and eyelid by gently squeezing the bottle.
- 9. If a drop misses your eye, try again, and wipe off any excess that runs down your cheek.
- 10Close your eye. Do not blink or rub your eye.
- 11While 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.
- 12Replace the lid/cap, sealing it tightly.
- 13Wash your hands again with soap and water.
- 14f you wear soft contact lenses, wait 15 minutes before replacing your contact lenses.

## If you forget to use ACULAR®

It is important that you use ACULAR® at the same times each day.

If you forget to use ACULAR® and it is almost time for your next dose, skip the dose you missed and use your next dose when you are meant to.

Otherwise, use the drops as soon as you remember, and then go back to using them as you would normally. If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

Do not use double the number of drops to make up for the dose you missed.

#### If you use too much ACULAR®

Immediately rinse your eyes with warm water.

## If ACULAR® is accidentally swallowed, you should immediately:

- phone the Poisons Information Centre 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 appear to be no signs of discomfort or poisoning.

## 5. What should I know while using ACULAR®?

#### Things you should do

 If you wear soft contact lenses, remove them before using ACULAR® eye drops, and wait at least 15 minutes before inserting them again. The preservative in ACULAR® eye drops (benzalkonium chloride) may be absorbed and cause discolouration of soft contact lenses.

 Tell your doctor if you think your eye(s) is/are not improving while using ACULAR®.

## Call your doctor straight away if you:

- develop problems with your eyes, such as trauma, surgery, infection in the eye(s) or eyelid(s)
- become pregnant while using ACULAR®
   Remind any doctor, dentist, pharmacist, or optometrist you visit that you are using ACULAR®.

## Things you should not do

- Do not touch the dropper tip against your eye, eyelid, or anything else, to avoid contaminating the eye drops and to avoid injury to the eye caused by the tip.
- Do not stop using ACULAR® earlier than instructed or use it for longer than instructed without checking with your doctor.

#### **Driving or using machines**

Wait for your vision to clear after using ACULAR® before you drive or use machines.

## Looking after your medicine

Follow the instructions on the label and carton on how to take care of your medicine properly.

Store it in a cool place below 30°C away from heat or sunlight; for example:

- do not store it in the bathroom or near a sink, or
- do not store it in the car or on window sills.

Keep it where young children cannot reach it.

#### When to discard your medicine

Discard the bottle 4 weeks after first opening it.

#### Getting rid of any unwanted medicine

If your doctor advises that you no longer need to use this medicine or it is out of date, take it 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 optical practitioner, doctor or pharmacist if you have any further questions about side effects.

Side effects listed below could include the symptoms such as eye pain, difficulty reading, sensitivity to light, seeing halos around lights, sudden vision loss, vision getting noticeably worse or blurry, blind or dark spots in vision, seeing flashes or floaters, headache, red or bloodshot eye, eye itching and discharge, and white patch on the front layer of the eyeball.

#### Less serious side effects

Less serious side effects	What to do
Effects on the eye:	Speak to your doctor if
<ul> <li>burning and stinging of the eye(s) when applying eye drops</li> <li>blurred vision</li> <li>itching, redness of the eye(s)</li> </ul>	you have any of these less serious side effects and they worry you.
<ul> <li>irritation of the surface of the eye or feeling of having something in the eye</li> </ul>	
• pain in the eye	
<ul><li>drooping of the upper eyelid</li></ul>	
• swollen eyelid	
<ul> <li>uncomfortable sensitivity to light</li> </ul>	
• dry eye	
<ul><li>changes to vision.</li></ul>	
Effects on the body as a whole:	
• headache.	

## **Serious side effects**

Serious side effects	What to do
Effects on the eye:	Call your doctor straight
<ul> <li>white deposit on the underside of the front part of the eye</li> </ul>	away, if you notice any of these serious side effects.
<ul><li>bleeding of the retina (back of the eye)</li></ul>	
<ul> <li>swelling of the central area of the retina</li> </ul>	
<ul> <li>swelling of the front layer of the eyeball or the coloured part of the eye</li> </ul>	
<ul> <li>white spots on the surface of the eye</li> </ul>	
<ul> <li>a lesion on the front layer of the eyeball</li> </ul>	
<ul> <li>increased pressure in the eye</li> </ul>	
<ul> <li>infection of the eye(s) or surrounding area</li> </ul>	
Body as a whole:	Go straight to the
<ul><li>bronchospasm</li><li>worsening asthma</li></ul>	Emergency Department at your nearest hospital if you notice any of

Serious side effects	What to do
<ul> <li>severe allergic reaction, including swelling of the tongue, lips and throat, difficulty breathing.</li> </ul>	these serious side effects.

Tell your doctor, nurse, 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 to the Therapeutic Goods Administration online at <a href="https://www.tga.gov.au/reporting-problems">www.tga.gov.au/reporting-problems</a> in Australia. 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 using any of your medicines.

## 7. Product details

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

#### What ACULAR® contains

Active ingredient (main ingredient)	ketorolac trometamol
Preservative	benzalkonium chloride
Other ingredients (inactive ingredients)	<ul> <li>disodium edetate</li> <li>hydrochloric acid</li> <li>octoxinol 40</li> <li>purified water</li> <li>sodium chloride</li> <li>sodium hydroxide</li> </ul>

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

#### What ACULAR® looks like

ACULAR® is a clear, colourless to pale-yellow solution. It is supplied in a white opaque plastic dropper bottles with a dropper tip containing 3 mL, 5 mL or 10 mL of liquid which are enclosed in a carton.

(AUST R 63539).

(Not all presentations may be available.)

#### Who distributes ACULAR®?

ACULAR® is distributed in Australia by:

AbbVie Pty Ltd

Mascot NSW 2020

**AUSTRALIA** 

Ph: 1800 252 224

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