## KETOROLAC MEDSURGE

## **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 KETOROLAC MEDSURGE?

KETOROLAC MEDSURGE contains the active ingredient ketorolac trometamol. KETOROLAC MEDSURGE is used to treat itchy eyes occurring in the condition called seasonal allergic conjunctivitis. They are also used for the relief of swelling and redness after cataract surgery.

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

## 2. What should I know before I use KETOROLAC MEDSURGE?

Do not use if you have ever had an allergic reaction to Ketorolac 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 KETOROLAC MEDSURGE? in the full CMI.

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

Some medicines may interfere with KETOROLAC MEDSURGE 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 KETOROLAC MEDSURGE?

Your doctor will tell you how many drops you need to use each day. Use KETOROLAC MEDSURGE eye drops only as prescribed by your doctor.

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

## 5. What should I know while using KETOROLAC MEDSURGE?

Things you should do	<ul> <li>Remind any doctor or pharmacist you visit that you are using KETOROLAC MEDSURGE.</li> <li>If you wear soft contact lenses, remove them before using KETOROLAC MEDSURGE. Leave your lenses out for at least 15 minutes after putting in the eye drops</li> </ul>
Things you should not do	<ul> <li>Do not stop using this eye drops without first talking to your doctor.</li> <li>Do not give KETOROLAC MEDSURGE eye drops to anyone else, even if they have the same condition as you.</li> </ul>
Driving or using machines	Your vision may blur for a short time after you put in your KETOROLAC MEDSURGE eye drops. If this happens you should wait until you can see well again before you drive or use machinery.
Looking after your medicine	<ul> <li>Keep your eye drops in a cool place where the temperature stays below 25°C, and out of the light.</li> <li>Keep the medicine where children cannot reach it.</li> <li>Do not leave the top/lid off the bottle for any length of time to avoid contaminating the eye drops</li> </ul>

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

## 6. Are there any side effects?

Tell your optical practitioner, doctor or pharmacist as soon as possible if you do not feel well while you are using KETOROLAC MEDSURGE eye drops. KETOROLAC MEDSURGE eye drops can cause blurring of vision, burning and stinging of the eye on instillation, conjunctivitis, pain in the eye and headaches.

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.

## **KETOROLAC MEDSURGE**

ketorolac trometamol

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

This leaflet provides important information about using KETOROLAC MEDSURGE. 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 KETOROLAC MEDSURGE.

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

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

## 1. Why am I using KETOROLAC MEDSURGE?

**KETOROLAC MEDSURGE contains the active ingredient ketorolac trometamol.** KETOROLAC MEDSURGE is a group of nonsteroidal anti-inflammatory drugs (NSAIDs).

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.

KETOROLAC MEDSURGE is used to treat itchy eyes occurring in the condition called seasonal allergic conjunctivitis. They are also used for the relief of swelling and redness after cataract surgery.

# 2. What should I know before I use KETOROLAC MEDSURGE?

#### Warnings

#### Do not use KETOROLAC MEDSURGE 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 certain types of medicines used for arthritis or pain relief (non-steroidal anti-inflammatory drugs)
- 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. If you use this medicine after the expiry date has passed, it may not work effectively.

Do not put the eye drops into your eye(s) while you are wearing soft contact lenses as the preservative benzalkonium chloride) in KETOROLAC MEDSURGE eye drops may be deposited and cause discoloration to soft contact lenses. Contact lenses should be removed prior to using KETOROLAC MEDSURGE eye drops. You can put your soft contact lenses back into your eyes 15 minutes after you have used KETOROLAC MEDSURGE eye drops.

Do not allow the tip of the dispensing container to contact the eye to avoid injury of the eye and contamination of the eye drops

It is not known if KETOROLAC MEDSURGE eye drops are safe and useful for children under 12 years.

These drops are for topical use only.

#### Check with your doctor if you:

- You have had an allergy to any medicines or any other substances, such as foods, preservatives or dyes.
- You are taking any other prescription or nonprescription medicine, particularly those which have an effect on bleeding.
- You have a peptic ulcer or a history of peptic ulcers.
- You have asthma or a history of asthma.
- You have defects of the cornea, sugar diabetes, diseases of the eye (e.g. dry eye syndrome), rheumatoid arthritis, or if you have had recent eye surgery.
- You have a condition that causes you to bleed easily.

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. KETOROLAC MEDSURGE eye drops are not recommended in pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed. KETOROLAC MEDSURGE eye drops are not recommended if you are breastfeeding.

## 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.

It is not expected that KETOROLAC MEDSURGE will interact with other medicines, however you should always ask your optical practitioner, doctor or pharmacist if you have any

concerns about using KETOROLAC MEDSURGE eye drops as well as other medications.

## 4. How do I use KETOROLAC MEDSURGE?

#### How much to take / use

- Your doctor will tell you how many drops you need to use each day. Use KETOROLAC MEDSURGE eye drops only as prescribed by your doctor.
- The usual dose for itchy eyes (seasonal allergic conjunctivitis) is one drop into each eye four times daily for 2-4 weeks.
- The usual dose for use before and after eye surgery for cataract removal is one or two drops into each eye four times daily, starting 24 hours before the surgery and continuing for 2-4 weeks.
- Follow all directions given to you by your doctor carefully. The directions may differ from the information contained in this leaflet.
- If you are using more than one eye drop product, wait
   5 minutes before using the second product.
- 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.

#### When to use KETOROLAC MEDSURGE

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

#### How to use KETOROLAC MEDSURGE

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

To open a new bottle of KETOROLAC MEDSURGE eye drops first tear off the protective seal from the bottle. The contents are sterile if the seal is intact. The seal will break and you can pull it off and then throw it away.

- Wash your hands well with soap and water.
- Remove the lid/cap
- Hold the bottle upside down in one hand between your thumb and forefinger or index finger.
- Using your other hand, gently pull down your lower eyelid to form a pouch or pocket.
- Tilt your head back and look up.
- Put the tip of the bottle close to your lower eyelid. Do not let it touch your eye.
- Release one drop into the pouch or pocket formed between your eye and eyelid by gently squeezing the bottle.
- Close your eye. Do not blink or rub your eye.
- 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.
- Replace the lid/cap, sealing it tightly.
- Wash your hands again with soap and water to remove any residue.

Wait 15 minutes before replacing your contact lenses.

Be careful not to touch the dropper tip against your eye, eyelid or anything else to avoid contaminating the eye drops.

#### How long to use KETOROLAC MEDSURGE

Continue using KETOROLAC MEDSURGE eye drops for as long as your doctor prescribes. The usual length of use is 2-4 weeks

#### If you forget to use KETOROLAC MEDSURGE

KETOROLAC MEDSURGE should be used regularly at the same time each day.

If 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 amount to make up for the dose that you missed.

#### If you use too much KETOROLAC MEDSURGE

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 KETOROLAC MEDSURGE eye drops drink fluids to dilute and

#### You should immediately:

- phone the National Poisons Centre by calling 0800
   POISON (0800 764 766), 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 KETOROLAC MEDSURGE?

## Things you should do

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 KETOROLAC MEDSURGE eye drops because of possible contamination of the old one or may advise you to stop your treatment with KETOROLAC MEDSURGE eye drops.

If you become pregnant while using KETOROLAC MEDSURGE eye drops tell your doctor immediately.

If you wear soft contact lenses, remove them before using KETOROLAC MEDSURGE eye drops. Leave your lenses out for at least 15 minutes after putting in the eye drops.

Tell your doctor if your condition gets worse or does not get better while using KETOROLAC MEDSURGE eye drops.

If you are about to start any new medicine tell your doctor and pharmacist that you are using KETOROLAC MEDSURGE eye drops.

#### Things you should not do

- Do not stop using this medicine suddenly without first talking to your doctor.
- Do not give KETOROLAC MEDSURGE eye drops to anyone else, even if they have the same condition as you.

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

Be careful before you drive or use any machines or tools until you know how KETOROLAC MEDSURGE affects you.

Your vision may blur for a short time after you put in your KETOROLAC MEDSURGE eye drops. If this happens you should wait until you can see well again before you drive or use machinery.

KETOROLAC MEDSURGE eye drops are not expected to cause any problems with your ability to drive a car or operate machinery. However, as a general precaution be careful driving or operating machinery until you know

#### Looking after your medicine

- Keep your eye drops in a cool place where the temperature stays below 25°C.
- Do not leave the top/lid off the bottle for any length of time to avoid contaminating the eye drops.

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

Keep it where children cannot reach it.

#### When to discard your medicine

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. Getting rid of any unwanted medicine

## 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

Less serious side effects	What to do
<ul> <li>burning and stinging of the eye on instillation</li> <li>blurring of vision</li> <li>infection of the eye or surrounding areas</li> <li>inflammation of the front layer of the eyeball or the coloured part of the eye</li> <li>conjunctivitis (scratching, foreign body sensation, itching, redness)</li> <li>local allergic reactions, such as red eye, stinging of the eye</li> <li>irritation of the surface of the eye or feeling of having something in the eye</li> <li>pain in the eye</li> <li>drooping of the upper eyelid</li> <li>swollen eyelid</li> <li>uncomfortable sensitivity to light</li> <li>eye dryness</li> <li>a lesion on the front layer of the eyeball</li> <li>increased pressure in the eye</li> <li>white spots on the surface of the eye</li> <li>headaches</li> <li>visual disturbance</li> <li>hypersensitivity.</li> </ul>	Speak to your doctor if you have any of these less serious side effects and they worry you.

### Serious side effects

Serious side effects	What to do
<ul> <li>white deposit on the underside of the front part of the eye</li> <li>bleeding of the retina</li> <li>swelling of the central area of the retina</li> <li>burning eye</li> <li>itchy eye</li> <li>eye injury.</li> </ul> The above side effects were	straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of
observed in one patient during a controlled clinical study.	these 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

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any

suspected adverse reactions <a href="https://nzphvc.otago.ac.nz/reporting/">https://nzphvc.otago.ac.nz/reporting/</a>

Always make sure you speak to your doctor 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 KETOROLAC MEDSURGE contains

Active ingredient (main ingredient)	Ketorolac trometamol
Other ingredients (inactive ingredients)	sodium chloride, edetate disodium octoxinol 40 water for injections sodium hydroxide and/or hydrochloric acid may be added to adjust pH
Preservative	Benzalkonium chloride

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

#### What KETOROLAC MEDSURGE looks like

KETOROLAC MEDSURGE is clear, colourless to pale yellow, sterile solution, supplied in a white opaque plastic LDPE bottle with a dropper tip and HDPE screw cap.

#### Who distributes KETOROLAC MEDSURGE

Medsurge Pharma Limited PO Box 331054 Takapuna Auckland 0622

Telephone: 0800 788 261

Marketed and Distributed by Medsurge Healthcare.



Telephone: 1300 788 261 Website: <u>www.medsurgehc.com</u>

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