

SCHEDULING STATUS

S3

Ketorolac Drops Pharma-Q, 0,5 % Eye drops, solution

Ketorolac trometamol

Sugar free

Read all of this leaflet carefully before you start using Ketorolac Drops Pharma-Q

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- Ketorolac Drops Pharma-Q has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What Ketorolac Drops Pharma-Q is and what it is used for
2. What you need to know before you use Ketorolac Drops Pharma-Q
3. How to use Ketorolac Drops Pharma-Q
4. Possible side effects
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1. What Ketorolac Drops Pharma-Q is and what it is used for

Ketorolac Drops Pharma-Q belongs to a group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs). The active ingredient in Ketorolac Drops Pharma-Q is ketorolac trometamol.

Ketorolac Drops Pharma-Q is used to relieve inflammation following surgery on the eye in adults.

2. What you need to know before you use Ketorolac Drops Pharma-Q

Do not use Ketorolac Drops Pharma-Q:

- if you are allergic (hypersensitive) to ketorolac trometamol or any of the other ingredients of Ketorolac Drops Pharma-Q (listed in section 6).
- if you are allergic to aspirin or any other similar medicine
- if you are a child as the safety and effectiveness in children have not been established.
- if you are pregnant or breastfeeding your baby.
- Ketorolac Drops Pharma-Q should not be used while wearing soft contact lenses.

Warnings and precautions

Talk to your doctor before using Ketorolac Drops Pharma-Q:

- If you suffer from, or have in the past suffered from:
 - viral or bacterial infections of the eye,
 - bleeding tendencies (for example, anaemia) or stomach ulcers,
 - diabetes,
 - rheumatoid arthritis
 - dry eye syndrome
 - asthma after using non-steroidal anti-inflammatories
 - or if you have had any recent or repeated eye surgeries.
 - Anastomotic leakage (abdominal leakage due to a connection made surgically between parts of the intestine)

Children

Ketorolac Drops Pharma-Q is not recommended for use in children.

Other medicines and Ketorolac Drops Pharma-Q:

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

If you use Ketorolac Drops Pharma-Q with another eye medicine, leave at least 5 minutes between putting in Ketorolac Drops Pharma-Q and the other medicine.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other healthcare professional for advice before using Ketorolac Drops Pharma-Q.

Pregnancy

Ketorolac Drops Pharma-Q should not be used during pregnancy. Tell your doctor if you are, you think you might be or are planning to become pregnant.

Breastfeeding

The active ingredient ketorolac trometamol may pass into breast milk. Ketorolac Drops Pharma-Q should not be used during breastfeeding.

Driving and using machines:

Ketorolac Drops Pharma-Q may cause temporary blurred vision. Do not drive or use machinery until the symptoms have cleared.

Ketorolac Drops Pharma-Q contains benzalkonium chloride

Ketorolac Drops Pharma-Q contains 0,1 mg benzalkonium chloride in each millilitre which is equivalent to 0,1 mg/mL. Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. You should remove contact lenses before using this medicine and put them back 15 minutes afterwards.

Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disorders of the cornea (the clear layer at the front of the eye). If you feel abnormal eye sensation, stinging or pain in the eye after using Ketorolac Drops Pharma-Q, talk to your doctor.

3. How to use Ketorolac Drops Pharma-Q

Do not share medicines prescribed for you with any other person.

Always use Ketorolac Drops Pharma-Q exactly as your doctor has instructed. You should check with your doctor or pharmacist if you are unsure.

The recommended dose is 1 drop into the affected eye(s), 3 times a day, starting 24 hours before surgery and continuing after eye surgery. Your doctor will tell you how long your treatment with Ketorolac Drops Pharma-Q will last.

The proper application of your eye drops is very important.

Instil one drop of the solution between the eye globe and the lower eyelid while pulling the lower eyelid gently downwards and looking upwards. If you are using other eye drops, wait 15 minutes between applications.

If you have any questions ask your doctor or pharmacist.

If you have the impression that the effect of Ketorolac Drops Pharma-Q is too strong or too weak, tell your doctor or pharmacist.

If you use more Ketorolac Drops Pharma-Q than you should

Overdose is unlikely to occur via the recommended method of administration. If, by accident, anyone drinks Ketorolac Drops Pharma-Q, drink fluids to dilute and contact your doctor.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to use Ketorolac Drops Pharma-Q

If you forget a dose apply it as soon as you remember, unless it is almost time for your next dose, in which case you should miss out the forgotten dose. Then take your next dose as usual and continue with your normal routine. Do not use a double dose to make up for forgotten individual doses.

If you stop using Ketorolac Drops Pharma-Q

Ketorolac Drops Pharma-Q should be used as advised by your doctor. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Ketorolac Drops Pharma-Q can have side effects.

Not all side effects reported for Ketorolac Drops Pharma-Q are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using Ketorolac Drops Pharma-Q, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop using Ketorolac Drops Pharma-Q and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching.

These are all very serious side effects. If you have them, you may have had a serious reaction to Ketorolac Drops Pharma-Q. You may need urgent medical attention or hospitalisation.

Side effects related to the cornea (the surface of the eye) may be more likely if Ketorolac Drops Pharma-Q is used for longer than two weeks or if you are using topical steroid drops at the same time or if you have a related eye condition. You should see your doctor immediately if you experience pain, increased irritation in the eye or changes in vision.

Tell your doctor if you notice any of the following:

Frequent:

- Irritation of the eye, stinging and/or burning in the eye, eye pain.
- Allergic reaction, eye and/or eyelid swelling/puffiness, itchy eyes, red eye, infection of the eye, inflammation of the eye (surface or inside), bleeding of the retina, swelling of central retina (light-sensitive layer of the eye).

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PHARMA-Q HOLDINGS (PTY) LTD.
Ketorolac Drops Pharma-Q (ketorolac trometamol, Eye drops)

- Headache.
- Accidental injury caused by the tip of the dropper touching the eye.
- Increased pressure in the eye, blurred and/or diminished vision.

Less frequent:

- Inflammation or damage to the front clear layer of the eye, eye dryness and/or watery eyes.

Frequency unknown:

- Damage on the surface of the eye such as thinning, erosion, degradation of cell(s).
- Abdominal leakage due to the surgical anastomosis fails (it is one of the serious complications of bowel surgery).
- Difficulty in breathing or wheezing, aggravation of asthma.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse.

You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of Ketorolac Drops Pharma-Q.

5. How to store Ketorolac Drops Pharm-Q

Store all medicines out of reach of children.

- Store at or below 25 °C.
- Keep in original container until required for use.
- Do not use after the expiry date stated on the carton and label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What Ketorolac Drops Pharma-Q contains

The active substance is ketorolac trometamol.

Ketorolac Drops Pharma-Q contains ketorolac trometamol 5 mg/mL.

Preservatives:

Benzalkonium chloride 0,01 % *m/v*

Disodium edetate 0,1 % *m/v*

The other ingredients are:

Benzalkonium chloride, disodium edetate, hydrochloric acid (to adjust pH), octoxynol 40, sodium chloride, sodium hydroxide (to adjust pH), water for injection.

What Ketorolac Drops Pharma-Q looks like and contents of the pack

Ketorolac Drops Pharma-Q is a clear, colourless to pale yellow solution practically free from particles.

Contents of the pack:

5 mL pack:

5 mL of Ketorolac Drops Pharma-Q solution is filled in a 5 mL 3-piece container: white opaque low density polyethylene (LDPE) container with white opaque LDPE open nozzle and grey high density polyethylene (HDPE) screw caps.

10 mL pack:

10 mL of Ketorolac Drops Pharma-Q solution is filled in a 10 mL 3-piece container: white opaque low density polyethylene (LDPE) container with white opaque LDPE open nozzle and grey high density polyethylene (HDPE) screw caps.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

Can be obtained on SAHPRA's website