

Loteprednol Etabonate Cas No. : 82034-46-6

This medication is used to treat eye conditions (e.g., conjunctivitis, allergies) and following eye surgery. It belongs to a class of drugs known as corticosteroids. Loteprednol works by relieving swelling and itching.

Active Pharmaceuticals Ingredients Manufacturers



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# Taj Pharmaceuticals Ltd.

## Loteprednol Etabonate

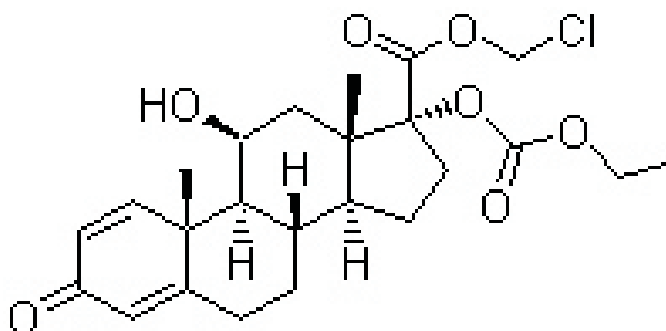
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#### Systematic (IUPAC) name

Chloromethyl 17-ethoxycarbonyloxy-11-hydroxy-10,13-dimethyl-3-oxo-7,8,9,11,12,14,15,16-octahydro-6H-cyclopenta[a]phenanthrene-17-carboxylate

Molecular Formula C<sub>24</sub>H<sub>31</sub>ClO<sub>7</sub>  
 Molecular Weight 466.96  
 CAS Registry Number 82034-46-6  
 ATC code S01BA14  
 PubChem 444025  
 DrugBank APRD01078



#### Chemical data

Formula C<sub>24</sub>H<sub>31</sub>ClO<sub>7</sub>  
 Mol. mass 466.951 g/mol

#### DOSAGE

Do not wear soft contact lenses while you are using this medicine..

Decrease use gradually as symptoms improve.

To help clear up your eye infection completely, keep using loteprednol and tobramycin for the full time of treatment, even if your symptoms have disappeared.

To use

\* First, wash your hands. Tilt your head back and, pressing your finger gently on the skin just beneath the lower eyelid, pull the lower eyelid away from the eye to make a space. Drop the medicine into this space. Let go of the eyelid and gently close the eyes. Do not blink. Keep the eyes closed and apply pressure to the inner corner of the eye with your finger for 1 or 2 minutes to allow the medicine to be absorbed by the eye.

\* If you think you did not get the drop of medicine into your eye properly, use another drop.

\* To keep the medicine as germ-free as possible, do not touch the applicator tip to any surface (including the eye). Also, keep the container tightly closed.

#### Dosing

The dose of this medicine will be different for different patients. Follow your doctor's orders or the directions on the label. The following information includes only the average doses of this medicine. If your dose is different, do not change it unless your doctor tells you to do so.

The amount of medicine that you take depends on the strength of the medicine. Also, the number of doses you take each day, the time allowed between doses, and the length of time you take the medicine depend on the medical problem for which you are using the medicine.

For ophthalmic suspension dosage form (eye drops)

For eye disorders:

Adults—Use one or two drops into the affected eye every four to six hours. Your doctor may have you use the drops more frequently during the first day or two and will probably have you space the doses further apart as the eye gets better

Children—Use and dose must be determined by your doctor.



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**Loteprednol  
Etabonate**  
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### SIDE EFFECTS

Along with its needed effects, a medicine may cause some unwanted effects. Although not all of these side effects may occur, if they do occur they may need medical attention.

Check with your doctor immediately if any of the following side effects occur:

More common

- \* Increased intraocular pressure
- \* Painful irritation of the clear front part of the eye

Less common

- \* Blurred vision or blue-green halos seen around objects
  - \* Blurred vision or other changes in vision
  - \* Decreased vision
  - \* Discharge from the eye
  - \* Dry eyes
  - \* Eyelid burning, redness, itching, pain, or tenderness
  - \* Fast heartbeat
  - \* Fever
  - \* Hives
  - \* Hoarseness
  - \* Irritation and swelling of the eye
  - \* Itching
  - \* Joint pain
  - \* Lid itching and swelling
  - \* Pain in eye
  - \* Rash
  - \* Redness of skin
  - \* Redness of eyelid
  - \* Sensitivity of eyes to light
  - \* Shortness of breath
  - \* Stiffness or swelling
  - \* Swelling of eyelids, face, lips, hands, or feet
  - \* Tightness in chest
  - \* Troubled breathing or swallowing
  - \* Wheezing
- Incidence not known
- \* Redness of eye
  - \* Tearing



Some side effects may occur that usually do not need medical attention. These side effects may go away during treatment as your body adjusts to the medicine. Also, your health care professional may be able to tell you about ways to prevent or reduce some of these side effects. Check with your health care professional if any of the following side effects continue or are bothersome or if you have any questions about them:

More common

- \* Burning
- \* Dry eyes
- \* Headache
- \* Increased sensitivity of eyes to light



\* Itching

\* Stinging

Other side effects not listed may also occur in some patients. If you notice any other effects, check with your healthcare professional.

## PRECAUTIONS

If you will be using this medicine for more than few weeks, an ophthalmologist (eye doctor) should examine your eyes at regular visits to make sure it does not cause unwanted effects.

If your eye infection does not improve or if your condition becomes worse, check with your doctor.

For ophthalmic use only. The initial prescription and renewal of the medication order beyond 14 days should be made by a physician only after examination of the patient with the aid of magnification, such as slit lamp biomicroscopy and, where appropriate, fluorescein staining.

If signs and symptoms fail to improve after two days, the patient should be re-evaluated.

If this product is used for 10 days or longer, intraocular pressure should be monitored even though it may be difficult in children and uncooperative patients

## DRUG DESCRIPTION

Each mL contains

Actives: Loteprednol Etabonate 5 mg (0.5%) and Tobramycin 3 mg (0.3%). Inactives: Edetate Disodium, Glycerin, Povidone, Purified Water, Tyloxapol, and Benzalkonium Chloride 0.01% (preservative). Sulfuric Acid and/or Sodium Hydroxide may be added to adjust the pH to 5.7-5.9. The suspension is essentially isotonic with a tonicity of 260 to 320 mOsmol/kg.

This medicine, in the form of eyedrops, is used to treat inflammation of the eyes caused by allergies, bacteria, viruses, or eye surgery. Loteprednol Etabonate is an eye drop medicine that is used to treat certain eye inflammation and where there is a bacterial infection of the eye or the chance of a bacterial infection in the eye. Loteprednol Etabonate contains a corticosteroid medicine and an antibiotic medicine.

Loteprednol Etabonate has not been approved for use in children.

Note /Government Notification: These chemicals are designated as those that are used in the manufacture of the controlled substances and are important to the manufacture of the substances. For any (Control Substance) products Import and Export \*\*\* subjected to your country government laws /control substance ACT.

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The Controlled Substances Act (CSA) was enacted into law by the Congress of the United States as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970.[1] The CSA is the federal U.S. drug policy under which the manufacture, importation, possession, use and distribution of certain substances is regulated. The Act also served as the national implementing legislation for the Single Convention on Narcotic Drugs

This document plus the full buyer/ prescribing information, prepared for health professionals can be found at:

<http://www.tajapi.com>

or by contacting the sponsor, Taj Pharmaceuticals Limited., at:

91 022 30601000.

This leaflet was prepared by  
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