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باسمى ساهى
د. ١٩ / ٧ / ٢٠١٨
Orchazid SDU
Sterile Ophthalmic Solution

النشرة مطابقة لنشرة
المستحضر المرجع
د/ باسمى ساهى
٢٠١٩ / ٥ / ١٦

1. Name of the medicinal product:

Orchazid SDU 0.25 mg/ml, Sterile Ophthalmic Solution in single dose units.

2. Qualitative and quantitative composition:

One ml contains 0.345 mg ketotifen fumarate corresponding to 0.25 mg ketotifen.
For the full list of excipients, see section 6.1.

3. Pharmaceutical form:

Eye drops, solution in single dose units
Clear, colorless ophthalmic solution.

4. Clinical particulars:

4.1 Therapeutic indications:

Symptomatic treatment of seasonal allergic conjunctivitis.

4.2 Posology and method of administration

- Adults, elderly and children (age 3 and older): one drop of **Orchazid SDU** into the conjunctival sac twice a day.
- The contents and dispenser remain sterile until the original closure is broken.
- To avoid contamination do not touch any surface with the dropper tip.
- Safety and efficacy of **Orchazid SDU** in children aged from birth to 3 years have not yet been established.

4.3 Contraindications:

Hypersensitivity to the active substance or to any of the excipients listed in Section 6.1.

4.4 Interaction with other medicinal products and other forms of interaction:

- If **Orchazid SDU** is used concomitantly with other eye medications there must be an interval of at least 5 minutes between the two medications.
- The use of oral dosage forms of ketotifen may potentiate the effect of CNS depressants, antihistamines and alcohol.

Although this has not been observed with **Orchazid SDU** eye drops, the possibility of such effects cannot be excluded.



4.5 Fertility, pregnancy and lactation

- **Pregnancy:**

There are no adequate data from the use of ketotifen eye drops in pregnant women, Animal studies using maternally toxic Oral doses showed increased pre and postnatal mortality, but no teratogenicity. Systemic levels after ocular administration are much lower than after oral use. Caution should be exercised when prescribing to pregnant women.

- **Breastfeeding:**

Although animal data following oral administration show excretion into breast milk, topical administration to human is unlikely to produce detectable quantities in breast milk. **Orchazid SDU** eye drops can be used during lactation.

4.6 Effects on ability to drive and use machines:

Any patient who experiences blurred vision or somnolence should not drive or operate machines.

4.7 Undesirable effects:

Adverse reactions are ranked under heading of frequency, using the following convention:

- *Very common ($\geq 1/10$);
- *common ($\geq 1/100$ to $< 1/10$);
- *uncommon ($\geq 1/1,000$ to $< 1/100$);
- *rare ($\geq 1/10,000$ to $< 1/1,000$).
- * Very rare ($< 1/10,000$), not Known (cannot be estimated from the available data).

At the recommended dose, the following undesirable effects have been reported:

Immune system disorders:

Uncommon: Hypersensitivity

Nervous system disorders:

Uncommon: Headache

Eye disorders:

Common: Eye irritation, eye pain, punctate keratitis, and punctate corneal epithelial erosion.

Uncommon: Vision blurred (during instillation), dry eye, eyelid disorder, conjunctivitis, photophobia, conjunctival haemorrhage.

Gastrointestinal disorders:

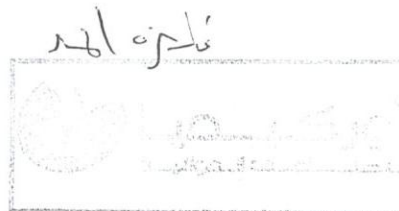
Uncommon: Dry mouth

Skin and subcutaneous tissue disorders:

Uncommon: Rash, eczema, urticaria.

General disorders and administration site conditions:

Uncommon: Somnolence





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Adverse drug reactions from post-marketing experience (frequency not known):

The following post marketing events have also been observed: hypersensitivity reactions including local allergic reaction (mostly contact dermatitis, eye swelling, eyelid pruritis & oedema), Systemic allergic reactions including facial swelling/oedema (in some cases associated with contact dermatitis). And exacerbation of pre-existing allergic conditions such as asthma & eczema.

4.8 Overdose:

No case of overdose has been reported.

Oral ingestion of the contents of a 5ml bottle would be equivalent to 1.25mg of ketotifen which is 60% of a recommended oral daily dose for a 3 year old child. Clinical results have shown no serious signs or symptoms after oral ingestion of up to 20mg of ketotifen.

5. Pharmacological properties:

5.1 Pharmacodynamic properties:

Pharmacotherapeutic group : Ophthalmological , other anti-allergics.

Ketotifen is a histamine H1 receptors antagonist. In vivo animal studies and in vitro studies suggest the additional activities of mast cell stabilization and inhibition of infiltration, activation and degranulation of eosinophils.

5.2 Pharmacokinetic properties:

*In a pharmacokinetic study conducted in 18 healthy volunteers with Ketotifen eye drops, plasma levels of ketotifen after repeated ocular administration for 14 days were in most cases below the limit of quantitation (20pg/ml) after oral administration, ketotifen is eliminated biphasically with an initial half-life of 3 to 5 hours and a terminal half-life of 21 hours. About 1% of the substance is excreted unchanged in the urine within 48 hours and 60 to 70% as metabolites. The main metabolite is the practically inactive ketotifen N-glucuronide.

Every time you use **Orchazid SDU**:

1. Wash your hands.
2. Take the strip of containers.
3. Detach one single-dose container from the strip.
4. Make sure that the solution is in the bottom part of the single-dose container.

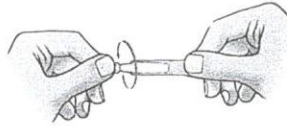


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open the container, twist off the tab.



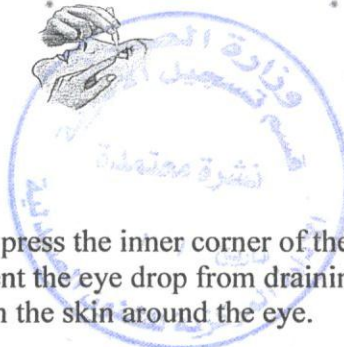
7. Tilt your head backwards.

8. Place the tip of the container close to your eye.



9. Pull the lower eyelid downwards and look up.

10. Gently squeeze the container and let one drop fall into the space between the lower eyelid and the eye.



11. Close your eye for a moment and press the inner corner of the eye with your finger for about one minute. This helps to prevent the eye drop from draining down the tear duct.

12. Wipe off any excess solution from the skin around the eye.



*If a drop misses your eye, try again.

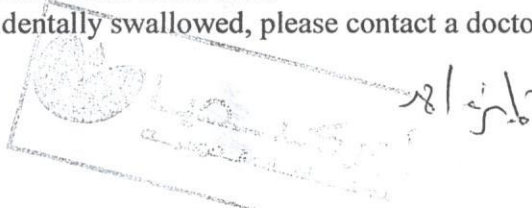
*If your doctor has told you to use drops in both eyes, repeat steps 7 to 12 for your other eye.

*The contents of one single-dose container are sufficient for both eyes. Discard the opened container with any remaining contents immediately after use.

*If you use other medicines in the eye, leave at least 5 minutes between putting in **Orchazid SDU** and the other medication.

*If you use more **Orchazid SDU** than you should, it is unlikely to cause you any serious harm. Put in your next dose at the usual time.

*If the medicine is accidentally swallowed, please contact a doctor for advice.



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if you forget to use Orchazid SDU, use a single drop as soon as you remember, and then go back to your regular routine. Do not use a double dose to make up for a forgotten dose.

6. Pharmaceutical particulars:

6.1 List of excipients:

- Glycerol.
- Sodium Citrate.
- Citric Acid (~~anhydrous~~).
- Sodium Hydroxide/Hydrochloric acid.
- Water for injections

6.2 Incompatibilities:

Not applicable.

6.3 Shelf life & Storage:

Store at temperature not exceeding 30° before opening & after opening, the remaining amount discarded directly after use.

6.4 Nature and contents of container:

Carton box containing 30 units of LDPE (low density polyethylene) plastic bottle containing 0.4 ml solution + insert leaflet.

6.5 Special precautions for disposal and other handling:

No special requirements.

7. Marketing authorization holder:

Orchidia Pharmaceutical Industries

Produced By

Orchidia Pharmaceutical Industries

