Important information. Please read carefully

ABCROM

Eye drops

Composition

Sodium Cromoglicate B.P..... 2.0%w/v
Benzalkonium chloride as preservative..... 0.01%w/v
Disodium Edetate.....0.1%w/v
Aqueous vehicle.....qs

Pharmacological properties

ABCROM contains Sodium Cromoglicate, a mast cell stabilizer. Primary mode of action is inhibition of the degranulation of sensitized mast cells which occurs after exposure to specific antigens. Sodium Cromoglicate acts by inhibiting the release of histamine and SRS-A (slow-reacting substance of anaphylaxis) from the mast cell.
Symptomatic response to therapy (decreased itching, tearing, redness, and discharge) is usually evident within a few days, but longer treatment for up to six weeks is sometimes required. Once symptomatic improvement has been established, therapy should be continued for as long as needed to sustain improvement.
Sodium Cromoglicate has no intrinsic vasoconstrictor, antihistamine, or anti-inflammatory activity.

Indications

ABCROM is indicated in the prevention and treatment of acute, seasonal and perennial allergic conjunctivitis.

Dosage

The dose is 1-2 drops in each eye 4-6 times a day at regular intervals. Or use as directed by a doctor. If required, corticosteroids may be used concomitantly with ABCROM

Contraindications

ABCROM is contraindicated in those patients who have shown hypersensitivity to Sodium Cromoglicate or to any of the other ingredients

Precautions

Patients may experience a transient stinging or burning sensation following application of ABCROM
The recommended frequency of administration should not be exceeded (see Dosage)
Users of contact lenses should refrain from wearing lenses while exhibiting the signs and symptoms of vernal kerato conjunctivitis, vernal conjunctivitis, or vernal keratitis. Do not wear contact lenses during treatment with ABCROM
Avoid using in pregnancy unless benefits outweigh the risks.
Caution should be exercised when administered to a nursing woman.

Side effects

The most frequently reported adverse reaction attributed to the use of ABCROM on the basis of reoccurrence following re-administration, is transient ocular stinging or burning upon instillation.
The following adverse reactions have been reported as infrequent events. It is unclear whether they are attributed to the drug: watery eyes; itchy eyes; dryness around the eye; puffy eyes; eye irritation; and styes.
Immediate hypersensitivity reactions have been reported rarely and include dyspnea, edema, and rash.

Presentation

Clear, colorless to pale yellow solution in sterile plastic dropper bottles of 10ml and 5ml enclosed in protective carton with leaflet.

Shelf life

The manufacturing and expiry dates are indicated on the packing.

Storage

Store below 30º C but do not freeze, protect from light.
Discard after the expiration date or 4 weeks after opening the bottle.

KEEP OUT OF REACH OF CHILDREN.

Direction for use

Tighten the cap on the nozzle
The spike in the cap will pierce the tip of the vial.
Dispense drops with gentle pressure.

Replace the cap after every use.

Warning

1. If irritation persists or increases, discontinue the use and consult a physician.
2. Do not touch the vial tip or other dispensing tip to any surface since this may contaminate the solution.
3. Use the solution within four weeks after opening the vial.

Wash your hands well before use.

1. Remove the outer cap.
2. Tilt the head back and pull the lower lid of the eye down to form a pocket.
3. Hold the container between the thumb and middle finger of the other hand, turn the container upside down near to the eye, and try not to touch the eye.
4. Apply enough pressure to the container to release one to two drops
5. Close the eye and keep it closed for one to two minutes
6. If you think you have missed the eye, then insert another drop.
7. Repeat in the other eye if you have been instructed to use this preparation in both eyes.
8. Replace the outer cap on the container, try not to touch the applicator tip with the fingers as you do so.
9. Wash your hands

For further information, please consult your pharmacist or physician

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