Sunday, May 24, 2026

Direct Healthcare Professional Communication (DHPC)

Availability of Approved English Package Leaflet for Imported ZYKLOLAT EDO® (Cyclopentolate Hydrochloride 1%) Eye Drops Solution and Important Safety Information

Dear Healthcare Professional,

Sada Al Dawa Medical Warehouse Company in agreement with Saudi Food and Drug Authority (SFDA) would like to inform healthcare professionals about the availability of an approved English package leaflet for ZYKLOLAT EDO® 1% Eye Drops Solution containing Cyclopentolate Hydrochloride 10 mg/ml (1%).

This communication aims to support the safe and appropriate use of imported ZYKLOLAT EDO® batches distributed to healthcare institutions within the Kingdom of Saudi Arabia.

Summary

- Imported ZYKLOLAT EDO® packs contain the original package leaflet in German language only.
- An approved English package leaflet legalized by the manufacturer is attached for healthcare professional reference.
- Healthcare professionals should review the attached English leaflet before prescribing, dispensing, or administrating.
- Suspected adverse drug reactions should be reported to the SFDA National Pharmacovigilance Center through the Saudi Vigilance System.

Background

ZYKLOLAT EDO® 1% Eye Drops Solution (Cyclopentolate Hydrochloride 10 mg/ml) is manufactured by Dr. Gerhard Mann Chem.-Pharm. Fabrik GmbH and marketed in Germany.
According to the approved SPC/package leaflet, ZYKLOLAT EDO® is indicated:

- To switch off the close focus of the eye (cycloplegia) for an objective determination of ametropia (refraction determination)
- For pupil dilation (mydriasis) for diagnostic purposes
- To treat inflammation of the iris (iritis), iris and ciliary body (iridocyclitis), choroid (choroiditis) and cornea (keratitis)
- To prevent or break up adhesions between the iris and the lens of the eye.

Due to temporary shortages within governmental healthcare institutions in the Kingdom of Saudi Arabia, the product was imported through an authorized distributor in Germany following SFDA approval procedures.

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The imported batches were distributed through NUPCO warehouses to healthcare institutions across the Kingdom.

As the original package leaflet enclosed with the imported product is available only in German language, an approved English package leaflet legalized by the manufacturer has been provided to facilitate safe and appropriate product use by healthcare professionals.

Advice for Healthcare Professionals

- Review the attached approved English package leaflet before prescribing, dispensing, or administering the product.

Call for Reporting

Healthcare professionals are encouraged to report any suspected adverse drug reactions associated with the use of ZYKLOLAT EDO® to the Saudi Food and Drug Authority (SFDA) National Pharmacovigilance Center through the Saudi Vigilance System.

SFDA barcode for reporting:

tracking.drug@sfda.gov.sa

Website: https://ade.sfda.gov.sa

Email: npc.drug@sfda.gov.sa

Telephone: 19999

Company Information

Dr. Gerhard Mann Chem.-Pharm. Fabrik GmbH
Brunsbütteler Damm 165–173
13581 Berlin, Germany
Email: kontakt@bausch.com

Yours sincerely,
Pharmacist: Tarek Mansour
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This document is approved by The Executive Directorate of Pharmacovigilance, at Saudi Food and Drug Authority (SFDA).

version 1.0 - approved by SFDA: May 2026

Package leaflet: Information for patients

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Zyklolat EDO®

10.0 mg/ml eye drops, solution in single-dose container
cyclopentolate hydrochloride

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- **Keep the leaflet. You might want to read it again.**
- **If you have any further questions, ask your doctor or pharmacist.**
- **This medicine has been prescribed for you personally. Do not pass it on to others. It can harm other people, even if they have the same symptoms as you.**
- **If you get any side effects, talk to your doctor or pharmacist. This also applies to side effects that are not listed in this leaflet. See section 4.**

What is in this leaflet

1. What is cyclolate EDO® and what is it used for?

Cyclolate EDO® is a cycloplegic and mydriatic.

Cyclolate EDO® is applied:
- **to switch off the close focus of the eye (cycloplegia) for an objective determination of ametropia (refraction determination)**
- **for pupil dilation (mydriasis) for diagnostic purposes**
- **to treat inflammation of the iris (iritis), iris and ciliary body (iridocyclitis), choroid (choroiditis) and cornea (keratitis)**
- **to prevent or break up adhesions between the iris and the lens of the eye.**

In the case of inflammation, the need for appropriate additional medication (such as, if necessary, anti-inflammatory drugs and/or antibiotics) must be taken into account.

2. What you should know before using Zyklolat EDO® observe?

Cyclolate EDO® must not be used:
- **if you are allergic to cyclopentolate or any of the other ingredients of this medicine (listed in section 6).**
- **with increased intraocular pressure (especially in narrow-angle glaucoma)**
- **in sensitive patients, especially infants, premature babies, young children, adults over 65 years of age and patients with Down's syndrome and children with brain damage**

Notes: Note possible systemic effects.

Warnings and Precautions
Talk to your doctor or pharmacist before using Zyklolat EDO® use.

Take special care when using Zyklolat EDO® is required:

- in dry nasal mucosa inflammation
- **with an accelerated heart rate**
- **if you have heart failure**
- **with mechanical narrowing of the gastrointestinal tract**
- **in case of intestinal obstruction due to paralysis of the small intestine**
- **with inflammatory dilatation of the colon**
- **in case of muscle weakness**
- **if you have an overactive thyroid gland**
- **in acute pulmonary edema and**
- **in the case of narrowing of the urinary tract**

Note for contact lens wearers
Contact lenses must be removed before applying the eye drops and may not be reinserted for at least 15 minutes.

Application of Zyklolat EDO® together with other medicines
Tell your doctor or pharmacist if you are taking or using any other medicines, have recently taken or used any other medicines or might take or use any other medicines.

The effects of other drugs (e.g. antihistamines, phenothiazines, tricyclic and tetracyclic antidepressants, amantadine, quinidine, disopyramide, metoclopramide) on the nervous system may be increased.
Please note that this may also apply to medicines you have used recently.

pregnancy and breast feeding period
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

No data are available on possible risks. It should therefore not be used during pregnancy and breastfeeding. Systemic side effects, e.g. B. on the cardiovascular system, cannot be ruled out. Particular risks must be taken into account in the case of pregnancy-related illnesses (pregnancy toxicosis).

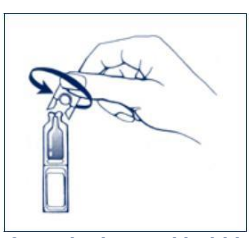
Ability to drive and use machines
Even when used as directed, this medicinal product can change visual performance and the ability to react to such an extent that the ability to actively participate in road traffic, operate machines or work without a secure footing is impaired.
The effects of this medicine can last up to 24 hours.

3. How is cyclolate EDO® apply?

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
Unless otherwise prescribed, the following dosages are recommended for the individual indications (compare areas of application):

For use on the eye.
To determine refraction: Children and adults: instill 1 drop into the conjunctival sac; possibly repeat the application if the effect is not sufficient after 15-30 minutes. In patients with darkly pigmented eyes, 2 drops are generally required.
Iritis, iridocyclitis, keratitis: Instill 1 drop into the conjunctival sac every 6 to 8 hours while maintaining other usual therapies.
Choroiditis: 1 drop instilled into the conjunctival sac at 6 to 8 hourly intervals, combined with specific therapy.
Lens adhesions: instill 1 drop into the conjunctival sac; if necessary, instill pilocarpine or a combination of pilocarpine and eserine 6 hours later. Repeat every 24 hours if necessary.

Proper handling of single-dose optioles



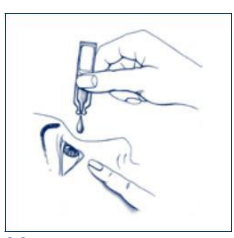


Fig. 1 Separate one-dose Ophtiole from the bar and hold by the label side.
Fig. 2 Unscrew the cap.
Fig. 3 For instillation, hold the one-dose Ophtiole vertically over the eye.
In this way you ensure targeted dripping.

Note: In order to reduce the absorption of the active substance cyclopentolate into the bloodstream, you should close the tear duct of the eye to be treated with finger pressure during the application of the eye drops and 2-3 minutes afterwards.

Note: If you also use other eye drops/eye ointments, there should be an interval of at least 15 minutes between them and Zyklolat EDO® always be applied last.

Please follow the instructions for use, as Zyklolat EDO® otherwise it cannot work properly.

If you take a larger amount of Zyklolat EDO® applied than you should

Typical symptoms of overdose or poisoning are dryness of the skin and mucous membranes, increased heart rate (tachycardia), dilated pupils (mydriasis), central excitation, motor restlessness, spasms, and with large doses coma and respiratory paralysis. Cyclopentolate hydrochloride should be discontinued immediately if symptoms of intoxication appear. After swallowing the solution containing the active substance, gastric lavage may have to be carried out and additional medicinal charcoal must be given to bind the residues of the active substance. If it is necessary to antagonize the side effects, the intravenous injection of physostigmine 1-2 mg is suitable, which can be repeated at hourly intervals if necessary. For convulsions, diazepam 10-20 mg should be injected intravenously. Other sedatives are less suitable because of the anticholinergic side effects. Depending on the condition (e.g. increase in body temperature (hyperthermia)), accompanying measures should be taken to stabilize and safeguard vital (vital) functions. A blood wash (hemodialysis) does not appear to be necessary as a rule.

If you stop using Zyklolat EDO® have forgotten
Do not apply twice if you forget the previous application.

If you stop using Zyklolat EDO® interrupt
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. What side effects are possible?

Like all medicines, this medicine can cause side effects, although not everybody gets them.

possible side effects

Occasionally: may affect up to 1 in 100 people
- skin rash (contact allergy)

Not known: Frequency cannot be estimated from the available data
- **In individual cases, signs of CNS toxicity such as disorientation, impaired balance, dysarthria (speech disorders), hallucinations, psychotic reactions, drowsiness and nausea are possible. In these cases, the doctor must be consulted immediately.**
- **Ataxia (impaired coordination of movements), central nervous disorders (seizures) can occur, especially in children**
- **Eye stinging, disturbances in distance adjustment of the eyes, a seizure trigger in angle-closure glaucoma**
- **Necrotizing enterocolitis (in premature babies)**
- **an increase in intraocular pressure, especially in people who are prepared accordingly**

Systemic side effects such as dry mouth, reddening and dryness of the skin, increased temperature, urinary blockage and accelerated pulse cannot be ruled out.

The side effects mentioned are more likely to occur in children, especially small children, and in the elderly.

Monitoring of the intraocular pressure is required, especially in the case of multiple use.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This also applies to side effects that are not listed in this leaflet. You can also directly dem side effects

Federal Institute for Drugs and Medical Devices Dept.
Pharmacovigilance
Kurt-Georg-Kiesinger Allee 3
53175 Bonn
site: http://www.bfarm.de

to sue.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How is cyclolate EDO® to keep?

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and carton. until" or "usable until" no longer use the specified expiry date. The expiry date refers to the last day of that month.

Cyclolate EDO® (One-dose optioles) do not contain any preservatives and must therefore not be stored after opening. The residue remaining in the Ophtiole after application should be discarded.

Store at 2 - 8 °C.

6. Contents of the pack and other information

What cyclolate EDO® contains

- **The active substance is cyclopentolate hydrochloride.**
  1 ml solution contains 10.0 mg cyclopentolate hydrochloride.
- **The other ingredients are:**
  potassium chloride; hydrochloric acid 3.6% (for pH adjustment); water for injections.

Like cyclolate EDO® looks and contents of the pack
Cyclolate EDO® is a clear, colorless solution.
Cyclolate EDO® is available in packs containing 20 single-dose, transparent, colorless polyethylene (LDPE) containers, each containing 0.5 ml of solution.

Pharmaceutical entrepreneur and manufacturer
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This leaflet was last revised in November 2018.

Prescription only

Approval no. 6253221.00.00

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dr Gerhard Mann chem.-pharm. Fabrik GmbH is a Bausch & Lomb Incorporated company.

EDO® = Esingledosis container