PACKAGE LEAFLET : INFORMATION FOR THE USER

MYDRIASERT 0.28 mg/5.4 mg ophthalmic insert
Tropicamide and phenylephrine hydrochloride

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. WHAT MYDRIASERT IS AND WHAT IT IS USED FOR

MYDRIASERT is an ophthalmic product, which means it is for eye treatment only.

Use of MYDRIASERT is restricted to health professionals.

MYDRIASERT will be put in the inferior eyelid of your eye by the medical staff. It is used to obtain a mydriasis (dilation of the pupil) before a surgical intervention or for diagnostic purposes.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE MYDRIASERT

DO NOT USE MYDRIASERT in the following cases:
- If you are allergic to tropicamide or phenylephrine hydrochloride or any of the other ingredients of this medicine (listed in section 6.1),
- In patients with closed angle glaucoma or at risk of precipitated glaucoma (increase in ocular pressure).
- In children below the age of 12 years.

WARNINGS AND PRECAUTIONS
- Because this medicinal product causes long-lasting visual disturbances, remember to be accompanied when attending the consultation (see possible side effects).
- In the event of discomfort after the insertion of the insert, inform your doctor: a shifting or, more rarely, a loss of the insert is possible.
- If you suffer from severe dry eyes, your doctor may put a drop of saline solution in the eye to reduce the risk of irritation of the eye.
- In case of hypertension (high blood pressure), atherosclerosis (thickening of arterial wall), cardiac disease or hyperthyroidism (increase activity of thyroid gland), prostatic disorders, inform your doctor.

- In certain predisposed persons, mydriatics (products that dilate pupil) may trigger an attack of acute glaucoma (because of sudden increase in pressure in your eye).
- The wearing of soft hydrophilic contact lenses is inadvisable during the treatment.

Children and adolescents
Mydriasert should not be used in children below the age of 12 years as children appear more sensitive to the risk of serious side effects.
Mydriasert is not recommended to be used in children aged 12 to 18 years as adequate clinical experience is missing.

Other medicines and MYDRIASERT
Please tell your doctor if you are using medicines that dilate the pupils (mydriatics) besides Mydriasert, so that your doctor will know the total amount of mydriatics you are exposed to.
Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. Although Mydriasert is locally applied, such information may be important because medicines can influence each other's actions.

Pregnancy and breast-feeding
Adequate data on the use of Mydriasert or its active ingredients in pregnant women are missing. Therefore, Mydriasert should not be used during pregnancy, unless necessary.
Use during breast-feeding is not recommended.

Driving and using machines
Do not drive or use machines because MYDRIASERT may cause troublesome visual disturbances for a few hours (dazzle due to prolonged dilation of the pupil).

Important information about some of the ingredients of MYDRIASERT
Sportsmen should be warned that this medicinal product contains an active ingredient (phenylephrine hydrochloride) which may produce positive results to tests for prohibited substances.

3. HOW TO USE MYDRIASERT

RESTRICTED USE TO HEALTH PROFESSIONALS.

Mydriasert is intended for use in adults. Mydriasert should not be swallowed.
The healthcare professional will place one insert behind the lower eyelid of the concerned eye. The professional will remove the insert within 30 minutes after the pupil is sufficiently dilated, and before the operation or investigation of the eye takes place. The insert should not be left in the eye for more than 2 hours.

If you use more MYDRIASERT than you should
As a single insert will be placed in the eye by the medical or healthcare professional, the risk of using more Mydriasert than recommended is unlikely. However, if the healthcare professional needs to use mydriatic eye drops in addition to Mydriasert, a risk of overdose of the active ingredients of Mydriasert may occur.
Symptoms of overdose of the active ingredients of Mydriasert may include extreme tiredness, sweating, dizziness, a slow heart beat, coma, headache, fast heart beat, dry mouth and skin, unusual drowsiness, flushing and sustained dilation of the pupils.

If you have any further questions on the use of this product, ask your doctor, pharmacist or nurse.

4. POSSIBLE SIDE EFFECTS

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

Common: may affect up to 1 in 10 people:
- stinging,
- blurred vision,
- visual discomfort due to perception of the presence or shifting of the insert.

Uncommon: may affect up to 1 in 100 people:
- tearing,
- irritation,
- dazzle due to the prolonged dilation of the pupil,
- superficial punctuate keratitis (inflammation of cornea).

Rare: may affect up to 1 in 1,000 people:
- allergic reactions: inflammation of eyelids (blepharitis), inflammation of the conjunctiva (conjunctivitis).

Very rare: may affect up to 1 in 10,000 people:
- convulsions.

Corneal ulcer (small erosion of the surface of the eye) and corneal oedema (inflammation of the surface of the eye) have been observed when the insert was accidentally left in the eye.

In predisposed subjects, MYDRIASERT may trigger an attack of acute glaucoma (sudden increase in intraocular pressure): in case of abnormal symptoms after administration (redness, pain and visual troubles), take immediate advice from your doctor.

Although unlikely after administration in the eye, the active ingredients contained in MYDRIASERT may cause the following side effects which must be taken into account:
- elevation of blood pressure, tachycardia,
- very rarely, major accidents such as cardiac arrhythmia,
- tremor, pallor, headache, dry mouth.

Additional side effects in children:
Frequency not known (cannot be estimated from the available data):
- Fluid or swelling in the lungs,
- Paleness around the eyes in preterm babies.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.
You can also report side effects directly via the Yellow Card Scheme.
Web site: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5. HOW TO STORE MYDRIASERT

Keep out of the sight and reach of children.
Do not use after the expiry date which is stated on the sachet after 'EXP'.
Do not store above 25°C.
Use immediately after sachet opening.
Do not use MYDRIASERT if you notice deterioration of the sachet closure or of the insert.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What MYDRIASERT contains
- The active substances are tropicamide 0.28 mg and phenylephrine hydrochloride 5.4 mg for one ophthalmic insert.
- The other ingredients are ammonio methacrylate copolymer (type A), polyacrylate dispersion 30%, glycerol dibehenate and ethylcellulose.

What MYDRIASERT looks like and contents of the pack
MYDRIASERT is supplied in a sachet.
MYDRIASERT looks like a white oblong small tablet (4.3 mm x 2.3 mm).
Each pack contains another sachet with disposable sterile forceps used to place MYDRIASERT in the eye.
Packs of 1 insert and 1 forceps, 10 inserts and 10 forceps**,** 20 inserts and 20 forceps, 50 inserts and 50 forceps, or 100 inserts and 100 forceps.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Laboratoires Théa
12, Rue Louis Blériot
63017 CLERMONT-FERRAND Cedex 2 - FRANCE

Manufacturer:
BENAC
27A, avenue Paul Langevin
17180 PERIGNY – FRANCE

or

BENAC
5 rue Albert Turpain
17000 LA ROCHELLE - FRANCE

If you would like any more information, or would like the leaflet in a different format, please contact Medical Information at THEA Pharmaceuticals Ltd, telephone number 0345 521 1290.

This leaflet was last revised in 04/2025.

The following information is intended for medical or healthcare professionals only.
Do not swallow.
Before using the product, check for the integrity of the sachet. In case of deterioration of the sachet's closing, the sterility is no more ensured; in such case, use another insert from an intact packaging.

POSOLOGY
The health professional places one ophthalmic insert in the lower conjunctival sac of the concerned eye, a maximum of 2 hours before surgery or investigative procedure.

Paediatric population

Mydriasert is contraindicated in children aged below 12 years.
There are no data in children aged 12 to 18 years. Mydriasert is not recommended in these patients.

METHOD OF ADMINISTRATION
The sealed edge should be cut along the dotted line, the sachet opened and the insert located. The lower eyelid is pulled down by pinching it between the thumb and index finger **(A)**, and the ophthalmic insert is applied in the lower conjunctival sac, using disposable sterile forceps provided in the packaging that should be discarded immediately after use **(B)**.

INSTRUCTIONS FOR USE
The ophthalmic insert should not be left for more than two hours in the lower conjunctival sac. The practitioner can remove the ophthalmic insert as soon as mydriasis is deemed sufficient for the operation or procedure to be carried out; at the latest, the insert should be removed 30 minutes after sufficient dilation of the pupil is obtained. In the event of discomfort, ensure that the insert has been placed correctly at the base of the lower conjunctival sac.

CAUTION: REMOVAL OF OPHTHALMIC INSERT
Before an operation or procedure, and as soon as the desired mydriasis has been obtained, the ophthalmic insert should be removed from the lower conjunctival sac using either sterile surgical forceps, or a sterile swab or a sterile irrigation or washing solution, by lowering the lower eyelid **(C).**

Do not reuse the insert for the other eye in the same patient, or for another patient.
Discard the insert after use.
(Please also refer to section 3)