

Package leaflet: Information for the patient

Carteolol hydrochloride Thea 20 mg/ml, eye drops, solution

carteolol 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 any further questions, 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 Carteolol hydrochloride Thea is and what it is used for
2. What you need to know before you use Carteolol hydrochloride Thea
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1. What Carteolol hydrochloride Thea is and what it is used for

Carteolol hydrochloride Thea contains the active substance carteolol hydrochloride a beta-blocker administered in the eye.

It is used for the treatment of certain types of eye disease involving intraocular hypertension (glaucoma and ocular hypertension).

2. What you need to know before you use Carteolol hydrochloride Thea

Do not use Carteolol hydrochloride Thea

- if you are allergic to carteolol hydrochloride, beta-blockers or any of the other ingredients of this medicine (listed in section 6).
- if you have now or have had in past respiratory problems such as asthma, severe chronic obstructive bronchitis (severe lung disease which may cause wheeziness, difficulty in breathing and/or long-standing cough).
- if you have a slow heart beat, heart failure or disorders of heart rhythm (irregular heart beats).

Warnings and precautions

This medicine is a preservative-free eye drops, solution. Do not allow the tip of the bottle to touch the eye or areas around the eye. It may become contaminated with bacteria that can cause eye infections leading to serious damage of the eye, even loss of vision. To avoid possible contamination of the bottle, keep the tip of the bottle away from contact with any surface.

Talk to your doctor, pharmacist or nurse before using Carteolol hydrochloride Thea.

Do not stop treatment suddenly without your Doctor's advice.

Before you use this medicine, tell your doctor if you have now or have had in the past:

- coronary heart disease (symptoms can include chest pain or tightness, breathlessness or choking), heart failure, low blood pressure,
- disturbances of heart rate such as slow heart beat,
- pheochromocytoma (excess production of a hormone causing severe arterial hypertension) as a close monitoring of arterial blood pressure is required,
- breathing problems, asthma or chronic obstructive pulmonary disease,
- poor blood circulation disease (such as Raynaud's disease or Raynaud's syndrome),
- diabetes as carteolol may mask signs and symptoms of low blood sugar,
- overactivity of the thyroid gland as carteolol may mask signs and symptoms,
- psoriasis (skin rash with white silvery coloured appearance),
- corneal disease,
- muscle weakness caused by myasthenia gravis as signs may get worse with carteolol hydrochloride.

Tell your doctor before you have an operation that you are using Carteolol hydrochloride Thea as carteolol may change effects of some medicines used during anaesthesia.

If you have a history of contact hypersensitivity to silver, you should not use this product as dispensed drops may contain traces of silver from the container.

Children and adolescents

Due to the lack of clinical data, the use is not recommended in children and adolescents.

Elderly, patients with renal impairment and/or liver impairment

Tell your doctor about any renal or liver problems you now have or have suffered from in the past, an adjustment of the dosage regimen is often necessary if you are also using a beta-blocker by oral route.

Other medicines and Carteolol hydrochloride Thea

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Carteolol hydrochloride Thea can affect or be affected by other medicines you are using, including other eye drops for the treatment of glaucoma.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

This is particularly important if you are:

- taking adrenalin (epinephrine) eye drops (risk of enlargement of the pupil of your eye).
- taking medicines to lower blood pressure or to treat heart disease (such as amiodarone, calcium antagonists such as bepridil, diltiazem and verapamil, clonidine and other central antihypertensives, beta-blockers used in cardiac insufficiency, propafenone).
- taking fingolimod (used to treat multiple sclerosis).
- getting anaesthesia.
- taking medicines to treat Alzheimer's disease (anticholinesterases).
- taking quinidine (medicine used to treat heart conditions and some types of malaria).
- taking baclofen (muscle-relaxant medicine).
- taking medicines to treat diabetes including insulin.
- taking medicines to treat mental problems such as antidepressants (tricyclics) or antipsychotics.
- taking medicines that can cause a disturbed or irregular heartbeat such as class Ia and class III antiarrhythmics, bepridil, cisapride, diphenamil, erythromycin IV, vincamine IV, mizolastine, halofantrine, sparfloxacin, pentamidine, moxifloxacin.
- taking non-steroidal anti-inflammatory drugs (NSAIDs), like ibuprofen, diclofenac or celecoxib. NSAIDs are used for the relief of pain, fever or inflammation.

- taking medicines to treat an enlargement of the prostate gland.
- taking amifostine (medicine used to prevent or decrease damages related to cancer therapy).
- taking dipyridamole (medicine to keep clots from forming after heart valve replacements).
- taking mefloquine (medicine used to treat malaria).
- taking pilocarpine (medicine used to treat dry mouth in some diseases and certain eye disorders).

Pregnancy and breast-feeding

Do not use Carteolol hydrochloride Thea if you are pregnant unless your doctor considers it necessary.

Do not use Carteolol hydrochloride Thea if you are breast-feeding. Carteolol may get into your milk.

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 taking this medicine.

Driving and using machines

You may experience temporary blurred vision after ocular administration of the product. Wait until you have recovered normal vision before driving a vehicle or using any machine. Carteolol hydrochloride Thea may induce also other side effects (dizziness, fatigue) likely to affect your ability to drive or to use machine. If you have any concerns, please consult your doctor.

Carteolol hydrochloride Thea contains phosphates

This medicine contains 0.015 mg phosphates in each drop which is equivalent to 0.51 mg/ml. See section 4.

3. How to use Carteolol hydrochloride Thea

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Dosage

The recommended dose for adults (including the elderly) is one drop in the affected eye, twice a day (morning and evening).

Use in children

There is no experience in children below 18 years. Therefore use of these eye drops in these patients is not recommended

Contact lens wearers

Contact lenses should be removed before instillation of the eye drops and may be reinserted after 15 minutes.

Instruction for use

It is important to comply with the following instructions when using this product:

- ① Before each use wash your hands thoroughly before using the product. Then unscrew the cap and remove it from the bottle tip. Avoid touching your eye or eyelids with the tip of the dropper.
- ② To use, tilt your head back slightly and hold the bottle dropper vertically above your eye. With the index finger of the other hand, pull the lower eyelid down slightly. The created space is called the lower conjunctival sac. Avoid contact of the bottle tip with your fingers or eyes.
To apply a drop in the lower conjunctival sac of the affected eye(s), **press firmly** on the bottle sides
- ③ After using Carteolol hydrochloride Thea, press a finger into the corner of your eye, by the nose for 2 minutes. This helps to stop carteolol getting into the rest of the body.

- ④ Close the tip of the bottle with the cap immediately after use.
- ⑤ Remember to write the date of the first opening of the bottle on the package.

If you use Carteolol hydrochloride Thea with other eye drops

Wait at least 5 minutes between using Carteolol hydrochloride Thea and using other eye drops.

If you use more Carteolol hydrochloride Thea than you should

If you put in too many drops rinse your eyes with a sterile saline eye drops solution

If you accidentally swallow the contents of the bottle, among other effects, you may feel as if you have dizziness, or you may have difficulty in breathing or feel that your pulse rate has slowed down.

Check with your doctor or pharmacist immediately.

If you forget to use Carteolol hydrochloride Thea

Instil the forgotten dose as soon as possible. However, if it is nearly time to take the next dose, simply miss out the forgotten dose.

If in any doubt, consult your doctor or pharmacist for advice.

If you stop using Carteolol hydrochloride Thea

The pressure inside your eye may increase and damage your vision.

Do not stop using this medicine, unless your doctor told you to do so.

4. Possible side effects

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

You can usually carry on taking the drops, unless the effects are serious. If you are worried, talk to a doctor or pharmacist. Do not stop using Carteolol hydrochloride Thea without speaking to your doctor.

Like other medicines applied into eyes, carteolol is absorbed into the blood. This may cause similar side effects as seen with “intravenous” and/or “oral” as applicable beta-blocking agents. Incidence of side effects after topical ophthalmic administration is lower than when medicines are, for example, taken by mouth or injected. Listed side effects include reactions seen within the class of beta-blockers when used for treating eye conditions:

- Generalised allergic reactions including swelling beneath the skin (that can occur in areas such as the face and limbs, and can obstruct the airway which may cause difficulty swallowing or breathing), hives (or itchy rash), localised and generalised rash, itchiness, severe sudden life-threatening allergic reaction, disseminated lupus erythematosus (a disease where the immune system produces antibodies that attacks mainly skin and joints).
- Low blood glucose levels.
- Difficulty sleeping (insomnia), depression, nightmares, memory loss.
- Fainting, stroke, reduced blood supply to the brain, increases in signs and symptoms of myasthenia gravis (a disease which may cause excessive muscle weakness), dizziness, unusual sensations (like pins and needles), and headache.
- Signs and symptoms of eye irritation (e.g. burning, stinging, itching, tearing, redness), inflammation of the eyelid, inflammation in the cornea, blurred vision and detachment of the layer below the retina that contains blood vessels following filtration surgery which may cause visual disturbances, decreased corneal sensitivity, dry eyes, corneal erosion (damage to the front layer of the eyeball), drooping of the upper eyelid (making the eye stay half closed), double vision.

- Slow heart rate, chest pain, palpitations, oedema (fluid build up), changes in the rhythm or speed of the heartbeat, congestive heart failure (heart disease with shortness of breath and swelling of the feet and legs due to fluid build up), a type of heart rhythm disorder, heart attack, heart failure.
- Low blood pressure, Raynaud's phenomenon, cold hands and feet, leg cramps and/or leg pain when walking (claudication).
- Constriction of the airways in the lungs (predominantly in patients with pre-existing disease), difficulty breathing, cough.
- Taste disturbances, nausea, indigestion, diarrhoea, dry mouth, abdominal pain, vomiting.
- Hair loss, skin rash with white silvery coloured appearance (psoriasiform rash) or worsening of psoriasis, skin rash.
- Muscle pain not caused by exercise, joint pain, muscle cramps, worsened signs and symptoms of myasthenia gravis.
- Sexual dysfunction, decreased libido, impotence.
- Muscle weakness/tiredness.
- Positive results in antinuclear anti-bodies (positive results in a blood test used to diagnose autoimmune disorder).

If you suffer from severe damage to the clear layer at the front of the eye (the cornea), phosphates may cause in very rare cases cloudy patches on the cornea due to calcium build-up during treatment.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Carteolol hydrochloride Thea

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 carton and the bottle after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

After first opening, the eye drops cannot be kept more than two months. Write down the date of first opening on the carton.

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Carteolol hydrochloride Thea contains

- The active substance is carteolol hydrochloride.
1 ml eye drops solution contains 20 milligrams of carteolol hydrochloride.
- The other ingredients are sodium chloride, disodium phosphate dodecahydrate, sodium dihydrogen phosphate dihydrate, water for injections.

What Carteolol hydrochloride Thea looks like and contents of the pack

Carteolol hydrochloride Thea is a clear, colourless to slightly brown-yellow solution. Each pack contains one multidose bottle. Each 15 ml bottle contains 5 ml of solution (at least 150 drops).

Marketing Authorisation Holder

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Manufacturer

FARMILA-THEA Farmaceutici S.p.A
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This medicinal product is authorised in the Member States of the EEA under the following names:

Germany Carteololhydrochlorid Thea 20 mg/ml Augentropfen, Lösung
Ireland, United Kingdom..... Carteolol hydrochloride Thea
NetherlandsCarteolol hydrochloride Thea 20 mg/ml oogdruppels, oplossing

This leaflet was last revised in {MM/YYYY}.

Detailed information on this medicine is available on the website of {name of MS Agency (link)}