Package leaflet: Information for the user

Xabrixa 10 mg/ml + 2 mg/ml eye drops, suspension
brinzolamide/brimonidine tartrate

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, optometrist (optician) or pharmacist.
- 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, optometrist (optician) or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Xabrixa is and what it is used for
2. What you need to know before you use Xabrixa
3. How to use Xabrixa
4. Possible side effects
5. How to store Xabrixa
6. Contents of the pack and other information

1. What Xabrixa is and what it is used for

Xabrixa contains two active substances, brinzolamide and brimonidine tartrate. Brinzolamide belongs to a group of medicines called carbonic anhydrase inhibitors and brimonidine tartrate belongs to a group of medicines called alpha-2 adrenergic receptor agonists. Both substances work together to reduce pressure within the eye.

Xabrixa is used to lower pressure in the eyes in adult patients (aged 18 years and over) who have eye conditions known as glaucoma or ocular hypertension and whose high pressure in the eyes cannot be controlled effectively by one medicine alone.

2. What you need to know before you use Xabrixa

Do not use Xabrixa
- if you are allergic to brinzolamide or brimonidine tartrate or any of the other ingredients of this medicine (listed in section 6)
- if you are allergic to sulphonamides (examples include medicines used to treat diabetes and infections and also diuretics (water tablets))
- if you are taking a monoamine oxidase (MAO) inhibitors (examples include medicines to treat depression or Parkinson's disease) or certain antidepressants. You must inform your doctor if you are taking any antidepressant medicines
- if you have severe kidney problems
- if you have too much acidity in your blood (a condition called hyperchloraemic acidosis)
- in babies and infants aged less than 2 years.

Warnings and precautions
Talk to your doctor, optometrist (optician) or pharmacist before using Xabrixa if you have now or have had in the past:
- liver problems
- a type of high pressure in the eyes called narrow-angle glaucoma
- dry eyes or cornea problems
- coronary heart disease (symptoms can include chest pain or tightness, breathlessness or choking), heart failure, high or low blood pressure
- depression
- disturbed or poor blood circulation (such as Raynaud's disease, Raynaud's syndrome or cerebral insufficiency).
- if you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after using Xabrixa or other related medicines.

Take special care with Xabrixa :
Serious skin reactions including Stevens-Johnson syndrome and toxic epidermal necrolysis have been reported in association with brinzolamide treatment. Stop using Xabrixa and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

If you wear soft contact lenses, do not use the drops with your lenses in.

Children and adolescents
Xabrixa is not intended for use by children and adolescents aged below 18 years because it has not been studied in this age group. It is particularly important that the medicine is not used in children under the age of 2 years (see section 'Do not use Xabrixa ' above) because it is unlikely to be safe.

Other medicines and Xabrixa
Tell your doctor, optometrist (optician) or pharmacist if you are using, have recently used, or might use any other medicines.

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

Tell your doctor if you are taking or intend to take any of the following medicines:
- medicines to lower blood pressure
- heart medicines including digoxin (used to treat heart conditions)
- other medicines for glaucoma that also treat altitude sickness known as acetazolamide, methazolamide and dorzolamide
- medicines that can affect the metabolism, such as chlorpromazine, methylphenidate and reserpine
- antiviral, antiretroviral (used to treat Human Immunodeficiency Virus (HIV)) or antibiotic medicines
- antiyeast or antifungal medicines
- monoamine oxidase (MAO) inhibitors, or antidepressants including amitriptyline, nortriptyline, clomipramine, mianserin, venlafaxine and duloxetine
- anaesthetics
- sedatives, opiates, or barbiturates.

You should also tell your doctor if the dose of any of your current medicines is changed.

Xabrixa with alcohol
If you regularly consume alcohol, ask your doctor, optometrist (optician) or pharmacist for advice before taking this medicine. Xabrixa can be affected by alcohol.

Pregnancy and breast-feeding
If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor, optometrist (optician) or pharmacist for advice before taking this medicine. Women who may become pregnant are advised to use effective contraception during Xabrixa treatment. The use of Xabrixa is not recommended during pregnancy. Do not use Xabrixa unless clearly indicated by your doctor.

If you are breast-feeding, Xabrixa may pass into your milk. The use of Xabrixa is not recommended during breast-feeding.

Driving and using machines
You may find that your vision is blurred or abnormal for a time just after using Xabrixa .Xabrixa may also cause dizziness, drowsiness or tiredness in some patients.

Do not drive or use machines until the symptoms are cleared.

3. How to use Xabrixa

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

Only use Xabrixa for your eyes. Do not swallow or inject.

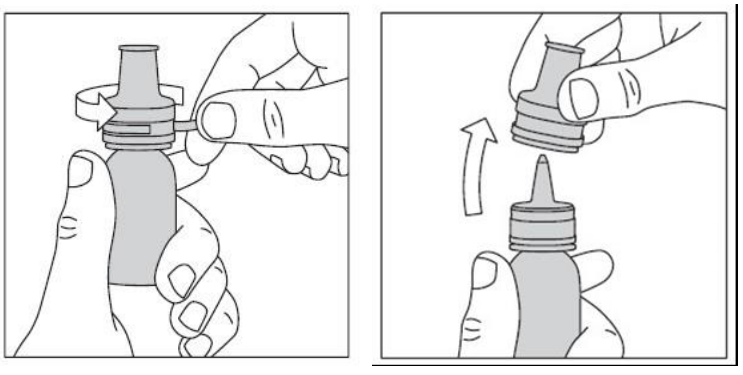
The recommended dose is one drop in the affected eye or eyes two times a day. Use at the same time each day.

How to use

Wash your hands before you start.

Get the bottle and a mirror.
Do not use this medicine if you notice that the tamper-proof seal on the bottleneck is broken before you first use it.

Shake well before every use.
Tear off the tamper evident ring.
Pull off the over cap.



Do not touch the dropper with your fingers when opening or closing the bottle. It could infect the drops.

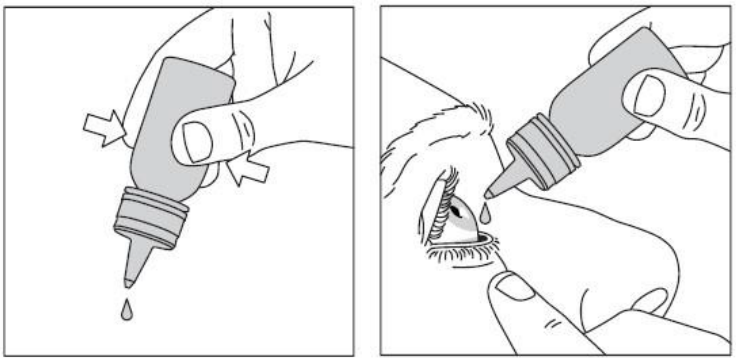
When using the bottle for the very first time, before delivering a drop to the eye, you should shake the bottle and squeeze it slowly to deliver one drop to discard.

Hold the bottle, pointing down, between your thumb and fingers.Tilt your head back.

Pull down your lower eyelid with a clean finger, until there is a ‘pocket’ between the eyelid and your eye. The drop will go in here.

Squeeze the bottle gently in the middle and let a drop fall into your eye. Please note that there might be a few seconds delay between squeezing and the drop coming out. Do not squeeze too hard.

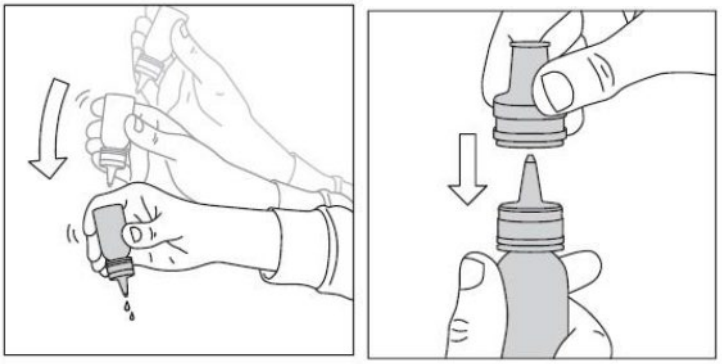
Do not touch your eye or eyelid, surrounding areas or other surfaces with the dropper. It could infect the drops.



Close your eye and apply gentle pressure to the corner of the eye next to the nose with a finger for at least 2 minutes to reduce the amount of medicine getting into the rest of the body.

If you use drops in both eyes, repeat the steps for your other eye. It is not necessary to close and shake the bottle before you apply the drop in your other eye.

After each use and prior to closing the bottle, shake off any residual drop on the tip by moving the bottle up and down quickly without touching the dropper tip.



Close the bottle with the cap firmly immediately after use.

If you are using other eye drops as well as Xabrixa , wait at least five minutes between using Xabrixa and the other drops.

If a drop misses your eye, try again.

If you use more Xabrixa than you should
Rinse your eye with warm water. Do not put in any more drops until it is time for your next regular dose.

Adults who accidentally swallowed medicines containing brimonidine experienced a decreased heart rate, decreased blood pressure which may be followed by increased blood pressure, heart failure, difficulty breathing and effects in the nervous system. Should this happen, contact your doctor immediately.

Serious side effects have been reported in children who accidentally swallowed medicines containing brimonidine. Signs included sleepiness, floppiness, low body temperature, paleness and breathing difficulties. Should this happen, contact your doctor immediately.

If Xabrixa has been accidentally swallowed then you should contact your doctor immediately.

If you forget to use Xabrixa
Continue with the next dose as planned. Do not use a double dose to make up for a forgotten dose. Do not use more than one drop in the affected eye(s) two times a day.

If you stop using Xabrixa
Do not stop using Xabrixa without first speaking to your doctor. If you stop using Xabrixa the pressure in your eye will not be controlled, which could lead to loss of sight.

If you have any further questions on the use of this medicine, ask your doctor, optometrist (optician) or pharmacist.

4. Possible side effects

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

If you experience any of the following side effects, please stop using this medicine and seek immediate medical attention as these could be signs of a reaction to the medicine. The frequency of an allergic reaction to the medicine is not known (frequency cannot be estimated from the available data).
- Severe skin reactions, including rash or redness or itching on your body or eyes
- Trouble breathing
- Chest pain, irregular heart beat

Contact your doctor immediately if you develop extreme tiredness or dizziness.

The following side effects have been observed with Xabrixa and other medicines containing brinzolamide or brimonidine alone.

Stop using Xabrixa and seek medical attention immediately if you notice any of the followingsymptoms:
- reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis).

Common (may affect up to 1 in 10 people)
- Effects in the eye: allergic conjunctivitis (eye allergy), eye surface inflammation, eye pain, eye discomfort, blurred or abnormal vision, eye redness
- General side effects: drowsiness, dizziness, bad taste in mouth, dry mouth

Uncommon (may affect up to 1 in 100 people)
- Effects in the eye: eye surface damage with loss of cells, inflammation of the eyelid, deposits on the eye surface, sensitivity to light, swelling of the eye (affecting the cornea or eyelid), dry eye, eye discharge, watery eye, eyelid redness, abnormal or decreased sensation in eye, tired eye, reduced vision, double vision, product particles in eyes.
- General side effects: decreased blood pressure, chest pain, irregular heartbeat, slow or fast heart rate, palpitations, difficulty sleeping (insomnia), nightmares, depression, generalized weakness, headache, dizziness, nervousness, irritability, general feeling of being unwell, memory loss, shortness of breath, asthma, nose bleeds, cold symptoms, dry nose or throat, sore throat, throat irritation, cough, runny nose, stuffy nose, sneezing, sinus infection, chest congestion, ringing in ear, indigestion, intestinal gas or stomach ache, nausea, diarrhoea, vomiting, abnormal sensation in mouth, increased allergic symptoms on skin, rash, abnormal skin sensation, hair loss, generalized itching, increased blood chlorine levels, or decreased red blood cell count as seen ina blood test, pain, back pain, muscle pain or spasm, kidney pain such as lower back pain, decreased libido, male sexual difficulty.

Very rare (may affect up to 1 in 10 000 people)
- Effects in the eye: decreased pupil size
- General side effects: fainting, increased blood pressure

Not known (frequency cannot be estimated from the available data)
- Effects in the eye: decreased growth of eyelashes
- General side effects: tremor, decreased sensation, loss of taste, abnormal liver function values as seen in a blood test, swelling of the face, joint pain, frequent urination, chest pain, swelling of the extremities, reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes, which can be preceded by fever and flu-like symptoms. These serious skin rashes can be potentially life- threatening (Stevens-Johnson syndrome, toxic epidermal necrolysis).

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 Yellow Card Scheme at: 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 Xabrixa

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

Store in the original bottle.

This medicine does not require any special storage conditions.

Throw away the bottle 8 weeks after first opening to prevent infections and use a new bottle. Write down the date of opening on the carton in the space provided.

Do not throw away any medicines via waste water or household waste. Ask your optometrist (optician) or 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 Xabrixa contains
- The active substances are brinzolamide and brimonidine tartrate. One ml of suspension contains 10 mg of brinzolamide and 2 mg of brimonidine tartrate equivalent to 1.3 mg brimonidine.
- The other ingredients are carbomer 974P, disodium edetate, mannitol, sodium chloride, tyloxapol, hydrochloric acid and/or sodium hydroxide (for pH adjustment) and purified water.

Tiny amounts of hydrochloric acid and/or sodium hydroxide are added to keep acidity levels (pH levels) normal.

What Xabrixa looks like and contents of the pack
Xabrixa eye drops, suspension, is a liquid (white-to-off-white suspension) supplied in a pack containing one or three 10 ml plastic bottles with a cap.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Viatris Products Limited,
Station Close, Potters Bar, EN6 1TL, United Kingdom.

Manufacturer
Lusomedicamenta Sociedade Técnica Farmacêutica, S.A.,
Rua Norberto de Oliveira, no 1/5, Póvoa de Santo Adrião, 2620-111, Portugal.

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