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Tidomat 20 mg/ml + 5 mg/ml eye drops, solution Dorzolamide / Timolol Read all of this leaflet carefully before you start using this medicine. - Keep this leaflet. You may need to read it again. - If you have any further questions, ask yourdoctor or pharmacist. - This medicine has been prescribed for you.Do not pass it on to others. It may harmthem, even if their symptoms are the same asyours. - If any of the side effects gets serious, or if younotice any side effects not listed in this leaflet,please tell your doctor or pharmacist. In this leaflet: 1. What Tidomat is and what it is used for 2. Before you use Tidomat 3. How to use Tidomat 4. Possible side effects 5. How to store Tidomat 6. Further information1. WHAT TIDOMAT IS AND WHAT IT IS USEDFOR Tidomat is a combination of two medicines: dorzolamide and timolol. Dorzolamide belongs to a group of medicinescalled carbonic anhydrase inhibitors. Timolol belongs to a group of medicines calledbeta-blockers. Tidomat is prescribed to lower raised pressure within the eye in the treatment of glaucomawhen beta-blocker eye drops used alone are notadequate.2. BEFORE YOU USE TIDOMATDo not use Tidomat if you are allergic (hypersensitive) 2. Tidomat,beta-blockers or any of the ingredients. If you have now or have had in past respiratoryproblems such as asthma, severe chronicobstructive bronchitis (severe lung diseasewhich may cause wheeziness, difficulty inbreathing and/or long-standing cough), if you have severe kidney problems, or a priorhistory of kidney stones, if you have a disturbance in the pH (acid/alkalibalance) of your blood, if you have certain heart problems, includingcertain heart rhythm disturbances producingan abnormally slow heart rate or severe heartfailure. If you think any of these apply to you, do not use Tidomat until you have consulted your doctor.Take special care with Tidomat if you have a history of heart disease you may wish to monitor your pulse rate andother signs of this disease while you are usingTidomat. Tell your doctor if you now have or have had liver problems, if you have muscle weakness or have been diagnosed as having myasthenia gravis. You should also tell your doctor if you now have, or have had in the past, breathing problems,asthma or chronic obstructive pulmonary disease. Prinzmetals angina (chest pains while resting),other heart problems (including disturbances of heart rate such as slow heart beat or severe heartfailure), coronary heart disease (symptoms caninclude chest pain or tightness, breathlessnessor choking), poor blood circulation disease (suchas Raynauds disease or Raynauds syndrome), low blood pressure, diabetes as timolol maymask signs and symptoms of low blood sugar,overactivity of the thyroid gland as timolol maymask signs and symptoms and about any allergiesto a medicine you have taken. If you develop conjunctivitis (redness and irritation of the eye(s)), swelling of the eye or eyelids, skinrash, or itching in and around the eye contact yourdoctor immediately. Such symptoms may be dueto an allergic reaction or may be a side-effect ofTidomat (See Possible Side Effects). Tell your doctor if you develop an eye infection, receive an eye injury, have eye surgery, developother reactions or worsening of symptoms. If you wear soft contact lenses, it is important that your lenses are removed before using youreye drops and not put back into your eyes until15 minutes after using your eye drops as thepreservative benzalkonium chloride may possiblydiscolour the contact lenses. Before you have an operation and anaesthesia (even at the dentist), tell your doctor or dentistthat you are taking Tidomat, as there may be asudden fall in blood-pressure associated with theanaesthetic. Use in children: There is limited experience with Tidomat in infants and children. Use in elderly In studies with Dorzolamide/Timolol eye drops solution, the effects of Dorzolamide/Timolol eyedrops solution were similar in both elderly andyounger patients. Using other medicines 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 any of the following apply to you: You are taking antihypertensive medicines which are used to lower high blood pressureor medicines to treat heart disease such ascalcium channel blockers and B-blockers ordigoxin You are taking quinidine (used to treat heartconditions and some types of malaria) ordigoxin You are using another eyedrop that contains a B-blocker You are taking another carbonic anhydrase inhibitor such as acetazolamide, You are taking this eye medicine by mouth, as eyedrops, or by some other method You are taking quinidine (used to treat heart conditions and some types of malaria) or selective serotonin reuptakeinhibitors (SSRIs) both of which are used to treat depression or another illness You are taking a parasympathomimeticmedicine which may have been prescribed to help you pass urine. Parasympathomimeticsare also a particular type of medicine whichare sometimes used to help restore normalmovements through the bowel You are taking narcotics such as morphineused to treat moderate to severe pain or if youare taking large doses of aspirin. Although there is no evidence that dorzolamide hydrochlorideinteracts with aspirin, some other medicineswhich are related to dorzolamide hydrochlorideand which are taken by mouth, have beenknown to interact with aspirin You are taking medicines to treat diabetes orhigh blood sugar You are taking epinephrine (adrenaline). You are taking antidepressants known asfluoxetine and paroxetine. Tidomat can affect or be affected by othermedicines you are using, including other eyedrops for the treatment of glaucoma. Pregnancy and breast-feeding Ask your doctor or pharmacist for advice before taking any medicine. Do not use Tidomat if you are pregnant unless your doctor considers it necessary. Tell yourdoctor if you are pregnant or planning to becomepregnant. Do not use Tidomat if you are breast-feedng. Tidomat may get into your milk. Ask your doctorfor advice before taking any medicine duringbreast-feeding. Driving and using machines Tidomat may cause side effects such as blurred vision in some patients. Do not drive or use any tools or machines until the symptoms have cleared. Important information about some of the ingredients of Tidomat Tidomat contains the preservative benzalkonium chloride. Benzalkonium chloride may cause eyeirritation. Benzalkonium chloride is known to discoloursoft contact lenses. Avoid contact with softcontact lenses. Remove contact lenses priorto application and wait until 15 minutes before re-insertion.3. HOW TO USE TIDOMAT Always use Tidomat exactly as your doctor has told you. You should check with your doctor orpharmacist if you are not sure. The appropriate dosage and duration of treatment will be established by your doctor. The usual dose is one drop in the affected eye(s) two times a day, for example in the morning and in the evening. If you use Tidomat with another eye drop, leave at least 10 minutes between putting in Tidomat and the other medicine. Do not change the dosage of the drug without consulting your doctor. If you must stop treatment, contact your doctor immediately. Do not allow the tip of the container to touch your eye or areas around your eye. It maybecome contaminated with bacteria that cancause eye infections leading to serious damageof the eye, even loss of vision. To avoid possiblecontamination of the container, keep the tip of the container away from contact with any surface. In order to secure correct dosage - the dropper tip should not be enlarged. Instructions for use: It is recommended that you wash your hands before putting in your eye drops. It may be easier to apply your eye drops in front of a mirror. 1. Before using the medication for the first time, be sure that the tamper-proof seal on thebottle neck is unbroken. A gap between thebottle and the cap is normal for an unopenedbottle. 2. Take off the cap of the bottle. 3. Tilt your head back and gently pull your lower eyelid down to form a small pocket between your eyelid and your eye. 4. Invert the bottle, and squeeze it until a singledrop is dispensed into the eye as directed byyour doctor. DO NOT TOUCH YOUR EYE OREYELID WITH THE DROPPER TIP. 5. Repeat steps 3 & 4 with the other eye ifinstructed to do so by your doctor. 6. Put the cap back on and close the bottle straightafter you have used it. After using Tidomat, press a finger into the corner of your eye, by the nose for 2 minutes. This helps to stop dorzolamide/timolol getting into the rest of the body.If you use more Tidomat than you should it is important to keep to the dose your doctor has prescribed. If you put too many drops in your eyeor swallow any of the contents of the bottle, youmay feel unwell, for example you may becomeglot-headed, have difficulty breathing, or feel that your heart rate has slowed. If you feel any of theseabove effects you should seek medical attention immediately. If you forget to use Tidomat It is important to use Tidomat as prescribed by your doctor. If you miss a dose, apply it as soon as possible. However, if it is almost time for the next dose, skip the missed dose and go back to your regular dosing schedule. Do not use a double dose to make up for forgotten individual doses. If you stop taking Tidomat If you want to stop using this medicine talk to your doctor first. If you have any further questions on the use of this product, ask your doctor or pharmacist. 4. POSSIBLE SIDE EFFECTS Like all medicines, Tidomat can cause side effects, although not everybody gets them. You can usually carry on taking the drops, unless the effects are serious. If you're worried, talk to adctor or pharmacist. Do not stop using Tidomatwithout speaking to your doctor. Like other medicines applied into eyes, dorzolamide/timolol is absorbed into the blood. This may cause similar side effects as seen with intravenous and/or oral as applicable betablocking agents. Incidence of side effects after topical ophthalmic administration is lower thanwhen medicines are, for example, taken by mouth or injected. Listed side effects include reactionsseen within the class of beta-blockers when used for treating eye conditions. If you develop generalized allergic reactions including hives (or itchy rash), localized andgeneralized rash, itchiness, severe sudden life-threatening allergic reaction, swelling beneaththe skin (that can occur in areas such as the faceand limbs, and can obstruct the airway whichmay cause difficulty breathing or swallowing), you should stop Tidomat and talk to your doctorimmediately. The following side effects may be seen with Tidomat: Very Common (affects more than 1 user in 10): Burning and stinging of the eyes, tastealterations. Common (affects 1 to 10 users in 100): Redness in and around the eye(s), watering or itching of the eye(s), swelling and/or irritation in and aroundthe eye(s), feeling of having something in the eye(corneal erosion), decreased corneal sensitivity (not realising of getting something in the eye andnot feeling pain), eye pain, dry eyes, blurred vision, headache, sinusitis (feeling of tension or fullness in the nose), feeling sick, also called nausea, andfatigue. Uncommon (affects 1 to 10 users in 1,000): Dizziness, depression, inflammation of the iris, blurred vision, (in some cases due to withdrawalof medication to treat excessive contraction of the pupil of the eye), slow heart beat, fainting, indigestion, and kidney stones (often marked by a sudden onset of excruciating, cramping pain in the lower back and/or side, groin, or abdomen). Rare (affects 1 to 10 users in 10,000): Systemic lupus erythematosus (an immune disease which may cause an inflammation of internal organs), tingling or numbness of the hands or feet, trouble sleeping, nightmares, memory loss, weakening of the muscles, decreased sex drive, stroke, temporary shortsightedness which may resolve when treatment is stopped, detachment of the layer below the retina thatcontains blood vessels following filtration surgerywhich may cause visual disturbances, drooping of the upper eyelid (making the eye stay half closed), double vision, eyelid crusting, swelling of the cornea (with symptoms of visual disturbances), low pressure in the eye, ringing noises in your ear, low blood pressure, irregular heartbeat, chest pain, palpitations (a quicker and/or irregular heartbeat), heart attack, reduced blood supply to the brain, congestive heart failure (heart disease with shortness of breath and swelling of the feet and legs due to fluid build up), coldness of hands and feet, reduced circulation in your arms and legs, leg cramps and/or leg pain when walking (claudication), shortness of breath, feeling out of breath, runny or stuffed nose, nose bleed, difficulty breathing, cough, throat irritation, dry mouth, diarrhoea, contact dermatitis, hair loss, psoriasis or worsening of psoriasis, Peyronies disease (which may cause a curvature of the penis), muscle weakness/tiredness, allergic type reactions such as rash, hives, itchiness, in rare cases possible swelling of the lips, eyes and mouth, wheezing. Not known (frequency cannot be estimated from the available data): Low blood glucose levels, oedema (fluid build up), severe sudden life-threatening allergic reaction, increases in signs and symptoms of myastheniagravis (muscle disorder), constriction of the airways in the lungs (predominantly in patientswith pre-existing disease), muscle pain not caused by exercise, skin rash with white silvery coloured appearance (psoriasisiform rash), heart failure, abdominal pain, vomiting. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist. 5. HOW TO STORE TIDOMAT Keep out of the reach and sight of children. Do not use Tidomat after the expiry date which is stated on the bottle label and the carton after EXP. The expiry date refers to the last day of thatmonth. This medicinal product does not require any special temperature storage conditions. Tidomat should be used within 28 days after the bottle is first opened. Therefore, you must throw away the bottle 4 weeks after you first opened it even if some solution is left. To help you remember, write down the date that you opened it in the space on the carton and the date that you opened it in the space on the bottle. Do not throw away any medicines used for wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment. 6. FURTHER INFORMATIONWhat Tidomat contains - The active substances are Dorzolamide andTimolol. Each ml contains 20 mg dorzolamide& 22.26 mg of dorzolamide hydrochloride& 5 mg timolol (as 6.83 mg of timololmaleate). - The other ingredients are Mannitol (E421), Hydroxy Ethyl Cellulose, Benzalkonium Chloride(as a preservative), Sodium Citrate (E331), Sodium Hydroxide (E524) for pH adjustment andWater for injection. What Tidomat looks like and contents of the pack Your medicine is in the form of a sterile, clear, slightly viscous, colourless aqueous eye dropsolution. Tidomat is presented in a white opaque medium density polyethylene bottle with a sealed lowdensity polyethylene dropper tip and a highdensity polyethylene cap with tamper proof seal, containing 5 mL of the ophthalmic solution. Pack size: 1,3 or 6 bottles of 5ml each. Not all pack sizes may be marketed. Marketing Authorisation Holder and Manufacturer Marketing Authorisation Holder Pharmathen S.A. 6 Dervenakion str., 153 51 Pallini, Attiki, Greece Manufacturer Pharmathen S.A., 6 Dervenakion str., 153 51 Pallini, Attiki, Greece and Famar S.A., Plant A, 63 Agiou Dimitriou Street, 174 56 Alimos, Greece Distributed by Lupin (Europe) Limited Victoria Court, Bexton Road, Knutsford, Cheshire WA16 0PF United Kingdom This leaflet was last revised in 09/2013. ID#: xxxxxx Back to top Prescription only medicine Log in or Sign up to access My Account functionalities Dorzolamide/Timolol is a combination of two medicines: dorzolamide and timolol. Dorzolamide belongs to a group of medicines called carbonic anhydrase inhibitors. Timolol belongs to a group of medicines called beta-blockers. Other heart problems (including disturbances of heart rate such as slow heart beat or severe heart failure), 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 heartbeat, breathing problems, asthma or chronic obstructive pulmonary disease, poor blood circulation disease (such as Raynauds disease or Raynauds syndrome), diabetes as timolol may mask signs and symptoms of low blood sugar, overactivity of the thyroid gland as timolol may mask signs and symptoms. Tell your doctor before you have an operation that you are using Dorzolamide/Timolol as timolol may change the effects of some medicines used during anaesthesia. Also tell your doctor about any allergies or allergic reactions including hives, swelling of the face, lips, tongue, and/or throat which may cause difficulty in breathing or swallowing. Tell your doctor if you have muscle weakness or have been diagnosed as having myasthenia gravis. If you develop any eye irritation or any new eye problems such as redness of the eye or swelling of the eyelids, contact your doctor immediately. If you suspect that Dorzolamide/Timolol is causing an allergic reaction or hypersensitivity (for example, skin rash, severe skin reaction, or redness and itching of the eye), stop using this medicine and contact your doctor immediately. Tell your doctor if you develop an eye infection, receive an eye injury, have eye surgery, or develop a reaction including weat or worsening of symptoms. When Dorzolamide/Timolol is instilled into the eye it may affect the entire body. If you wear soft contact lenses, you should contact your doctor before using this medicine. There is limited experience with dorzolamide/timolol eye drops, solution in infants and children. In studies with dorzolamide/timolol eye drops, solution the effects of this medicine were similar in both elderly and younger patients. Tell your doctor about any liver problems you have now or have suffered from in the past. Dorzolamide/Timolol 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 using or intend to use medicines to lower blood pressure, heart medicine or medicines to treat diabetes. Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. This is particularly important if you are: re-taking medicines to lower blood pressure or to treat heart disease (such as calcium channel blockers, beta-blockers or digoxin), taking medicines to treat a disturbed or irregular heartbeat such as calcium channel blockers, beta-blockers or digoxin, using another eye drop that contains a beta-blocker, taking another carbonic anhydrase inhibitor such as acetazolamide, taking monoamine oxidase inhibitors (MAOIs) which are used to treat depression, taking a parasympathomimetic medicine which may have been prescribed to help you pass urine. Parasympathomimetics are also a particular type of medicine which is sometimes used to help restore normal movements through the bowel, taking narcotics such as morphine used to treat moderate to severe pain, taking medicines to treat diabetes, taking antidepressants known as fluoxetine and paroxetine taking a sulfa medicine, taking quinidine (used to treat heart conditions and some types of malaria). 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. Pregnancy Do not use Dorzolamide/Timolol if you are pregnant unless your doctor considers it necessary. Breast-Feeding Do not use Dorzolamide/Timolol if you are breast-feeding. Timolol may get into your milk. No studies on the effects on the ability of medicines called carbonic anhydrase inhibitors. Timolol belongs to a group of medicines called beta-blockers. These medicines lower the pressure in the eye in different ways. Dorzolamide/Timolol is prescribed to lower raised pressure in the eye in the treatment of glaucoma when beta-blocker eye drops used alone are not adequate. If you are allergic to dorzolamide, timolol or any of the other ingredients of this medicine (listed in section 6) if you have now or had in the past respiratory problems such as asthma or severe chronic obstructive bronchitis (severe lung disease which may cause wheeziness, difficulty in breathing and/or long-standing cough) if you have a slow heartbeat, heart failure or disorders of heart rhythm (irregular heartbeats) if you have severe kidney disease or problems, or a prior history of kidney stones, if you have excess acidity of the blood caused by a build-up of chloride in the blood (hyperchloramic acidosis), if you are not sure whether you should use this medicine, contact your doctor or pharmacist. Talk to your doctor before using Dorzolamide/Timolol. 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Tell your doctor if you have muscle weakness or have been diagnosed as having myasthenia gravis. If you develop any eye irritation or any new eye problems such as redness of the eye or swelling of the eyelids, contact your doctor immediately. If you suspect that Dorzolamide/Timolol is causing an allergic reaction or hypersensitivity (for example, skin rash, severe skin reaction, or redness and itching of the eye), stop using this medicine and contact your doctor immediately. Tell your doctor if you develop an eye infection, receive an eye injury, have eye surgery, or develop a reaction including weat or worsening of symptoms. When Dorzolamide/Timolol is instilled into the eye it may affect the entire body. If you wear soft contact lenses, you should contact your doctor before using this medicine. There is limited experience with dorzolamide/timolol eye drops, solution in infants and children. In studies with dorzolamide/timolol eye drops, solution the effects of this medicine were similar in both elderly and younger patients. Tell your doctor about any liver problems you have now or have suffered from in the past. Dorzolamide/Timolol 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 using or intend to use medicines to lower blood pressure, heart medicine or medicines to treat diabetes. Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. This is particularly important if you are: re-taking medicines to lower blood pressure or to treat heart disease (such as calcium channel blockers, beta-blockers or digoxin), taking medicines to treat a disturbed or irregular heartbeat such as calcium channel blockers, beta-blockers or digoxin, using another eye drop that contains a beta-blocker, taking another carbonic anhydrase inhibitor such as acetazolamide, taking monoamine oxidase inhibitors (MAOIs) which are used to treat depression, taking a parasympathomimetic medicine which may have been prescribed to help you pass urine. Parasympathomimetics are also a particular type of medicine which is sometimes used to help restore normal movements through the bowel, taking narcotics such as morphine used to treat moderate to severe pain, taking medicines to treat diabetes, taking antidepressants known as fluoxetine and paroxetine taking a sulfa medicine, taking quinidine (used to treat heart conditions and some types of malaria). 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