

1.1. Elements for a Public Summary

1.1.1. Summary of treatment benefits

What is T2488?

- T2488 is a preservative-free eye drop, solution.
- T2488 contains two medicines: dorzolamide and timolol.

What is T2488 used for?

T2488 is prescribed to lower raised pressure in the eye in the treatment of glaucoma when beta-blocker eyedrop medicine used alone is not adequate.

How is T2488 used?

The usual dose is one drop in the affected eye(s) in the morning and in the evening.

How does T2488 work?

When intraocular pressure is raised, it causes damage to the retina (the light-sensitive membrane at the back of the eye) and to the optic nerve that sends signals from the eye to the brain. This can result in serious vision loss and even blindness. By lowering the pressure, T2488 reduces the risk of damage.

- Dorzolamide belongs to a group 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.

How has T2488 been studied?

The combined dorzolamide/timolol preserved formulation has been studied in 1,035 patients in studies, lasting up to 15 months.

T2488 is a ‘generic medicine’. This means that T2488 is similar, with the exact same composition to a ‘reference medicine’ already authorised in the European Union (EU) called Cosopt Preservative-free, which is already marketed for years and was shown to be effective and well tolerated.

What benefit has T2488 shown during the studies?

T2488 was at least as effective as timolol and dorzolamide in reducing intraocular pressure. The treatment with T2488 allows to lower raised pressure in the eye in the treatment of glaucoma when beta-blocker eyedrop medicine used alone is not adequate.

1.1.2. Summary of safety concerns

What is the risk associated with T2488?

Risk	What is known	Preventability
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Respiratory disorders	<ul style="list-style-type: none"> • T2488 should not be used in patients who 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). • T2488 should be used with caution in patients who have now or have had in the past breathing problems, asthma or chronic obstructive pulmonary disease 	<u>Routine</u> Appropriate wording in the patient information:
Cardiac or vascular disorders	<ul style="list-style-type: none"> • T2488 should not be used in patients who have now or had in the past a slow heart beat, heart failure or disorders of heart rhythm (irregular heart beats). • T2488 should be used with caution in patients who 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, poor blood circulation disease (such as Raynaud's disease or Raynaud's syndrome). 	<u>Routine</u> Appropriate wording in the patient information:

What are the other potential risks associated with T2488?

Risk	What is known	Preventability
Allergy and severe skin reactions	<ul style="list-style-type: none"> • T2488 should not be used in patients who are allergic (hypersensitive) to dorzolamide hydrochloride, timolol maleate or any of the other ingredients of 	<u>Routine</u> Appropriate wording in the patient information:

	T2488.	
Kidney stone, kidney disease	<ul style="list-style-type: none"> • T2488 should not be used in patients who have severe kidney disease or problems, or a prior history of kidney stones. • T2488 should not be used in patients who have excess acidity of the blood caused by a build up of chloride in the blood (hyperchloremic acidosis). 	<u>Routine</u> Appropriate wording in the patient information:
Corneal toxicity	<ul style="list-style-type: none"> • Corneal erosion (damage to the front layer of the eyeball) Swelling of the cornea (with symptoms of visual disturbances). Ophthalmic beta-blockers may induce dryness of eyes. Patients with corneal diseases should be treated with caution. 	Routine Appropriate wording in the patient information
Choroidal detachment	<ul style="list-style-type: none"> • Detachment of the layer below the retina that contains blood vessels following from filtration surgery which may cause visual disturbances. 	Routine Appropriate wording in the patient information
Concomitant treatment with systemic beta-blocking agents	<ul style="list-style-type: none"> • T2488 can affect or be affected by other medicines you are using, including other eye drops for the treatment of glaucoma. • This is particularly important in patients taking medicine to lower blood pressure or to treat heart disease (such as calcium channel blockers, beta-blockers or digoxin). 	Routine Appropriate wording in the patient information:
Hypoglycaemia, diabetes	<ul style="list-style-type: none"> • T2488 should be used with caution in patients with diabetes as timolol may mask signs and symptoms of low blood sugar 	Routine Appropriate wording in the patient information:

Missing information

Risk	What is known
Use in children and adolescent	There are no data in children and adolescents. T2820 is not recommended in these patients.
Patients with liver impairment	Tell your doctor about any liver problems you now have or have suffered from in the past. This medicinal product has not been studied in patients with hepatic impairment and should therefore be used with caution in such patients.
Patients with renal impairment	Tell your doctor about any renal problems you now have or have suffered from in the past. This medicinal product has not been studied in patients with renal impairment and should therefore be used with caution in such patients.
Use in pregnant or breast-feeding women	Pregnancy and breast-feeding Do not use JT2488 if you are pregnant unless your doctor considers it necessary. Ask your doctor or pharmacist for advice before taking any medicine. Do not use T2488 if you are breast-feeding. Timolol may get into your milk. Ask your doctor for advice before taking any medicine during breast-feeding.

1.1.3. Summary of risk minimisation measures by safety concern

All medicines have a Summary of Product Characteristics (SmPC) which provides physicians, pharmacists and other health care professionals with details on how to use the medicine, the risks and recommendations for minimising them. An abbreviated version of this in lay language is provided in the form of the package leaflet (PL). The measures in these documents are known as routine risk minimisation measures.

The Summary of Product Characteristics and the Package leaflet for T2488 can be found in the T2488's EPAR page.

T2488 is a 'generic medicine'. This means that T2488 is similar, with the exact same composition to a 'reference medicine' already authorised in the European Union (EU) called Cosopt Preservative-free, which is already marketed for years and was shown to be effective and well tolerated.

Regarding the other potential risks, no additional measures besides routine pharmacovigilance are necessary.

This medicine has no additional risk minimisation measures.

1.1.4. Summary of additional risk minimisation measures by safety concern

No additional risk minimisation measures are deemed necessary.

1.1.5. Planned post authorisation development plan

No additional post authorisation development plan.