Summary Public Assessment Report

non-generics

Brimonidintartrat/Timolol “Sandoz”

(Brimonidine tartrate 2 mg/ml + timolol 5 mg/ml)

DK/H/2370/001/DC

16 June 2016

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Brimonidine tartrate 2 mg/ml + timolol 5 mg/ml, eye drops solution

This is a summary of the public assessment report (PAR) for Brimonidintartrat/Timolol ”Sandoz”. It explains how Brimonidintartrat/Timolol ”Sandoz” was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Brimonidintartrat/Timolol ”Sandoz”.

For practical information about using Brimonidintartrat/Timolol ”Sandoz”, patients should read the package leaflet or contact their doctor or pharmacist.

What is Brimonidintartrat/Timolol ”Sandoz” and what is it used for?

Brimonidintartrat/Timolol ”Sandoz” is a ‘hybrid generic medicine’. This means that it is similar to a reference medicine containing the same active substance. Since the active substance combination brimonidine/ timolol acts locally in the eye, and is not absorbed in the body, the levels in blood cannot be measured for direct comparison of Brimonidintartrat/Timolol ”Sandoz” and Combigan eye drops. This is why the term hybrid is used.

The reference medicine for Brimonidintartrat/Timolol ”Sandoz” is Combigan eye drops, solution.

Brimonidintartrat/Timolol ”Sandoz” is used to control glaucoma.

How does Brimonidintartrat/Timolol ”Sandoz” work?

Brimonidintartrat/Timolol ”Sandoz” contains two different medicines (brimonidine and timolol) that both reduce high pressure in the eye. Brimonidintartrat/Timolol ”Sandoz” is prescribed to reduce high pressure in the eye when betablocker eye drops used alone are not enough.

Brimonidintartrat/Timolol ”Sandoz” works by reducing the production of liquid and increasing the amount of liquid that is drained. This reduces the pressure inside the eye whilst still continuing to feed the eye.

How is Brimonidintartrat/Timolol ”Sandoz” used?

The pharmaceutical form of Brimonidintartrat/Timolol ”Sandoz” is eye drops solution and the route of administration is ocular (for use in the eye).

The usual dose in adults is one drop of Brimonidintartrat/Timolol ”Sandoz”, twice a day about 12 hours apart.

Please read section 3 of the PL for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription.

What benefits of Brimonidintartrat/Timolol ”Sandoz” have been shown in studies?

Because Brimonidintartrat/Timolol ”Sandoz” is a hybrid application and is considered to be therapeutically equivalent to the reference product Combigan, their benefits and risks are taken as being the same as those of the reference medicine.

What are the possible side effects from Brimonidintartrat/Timolol ”Sandoz”?

The most common side effects with Brimonidintartrat/Timolol ”Sandoz” (which may affect more than 1 in 10 people) are eye redness or burning.

The most common side effects with Brimonidintartrat/Timolol ”Sandoz” (which may affect up to 1 in 10 people) are:

- Stinging or pain in the eye
- Allergic reaction in the eye or on the skin around the eye,
- Small breaks in the surface of the eye (with or without inflammation)
- Swelling, redness or inflammation of the eyelid
- Irritation, or a feeling of something in the eye
- Itching of the eye and eyelid
- Follicles or white spots on the see through layer which covers the surface of the eye
- Vision disturbance
- Tearing
- Eye dryness
- Sticky eyes

For the full list of all side effects reported with Brimonidintartrat/Timolol ”Sandoz”, see section 4 of the package leaflet.

Brimonidintartrat/Timolol ”Sandoz” should not be used in case of:

- Current or 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).
- Heart problems such as low heart rate, heart failure, heart beat disorders (unless controlled by a pacemaker).
- Concomitant use of monoamine oxidase (MAO) inhibitors or certain other antidepressant drugs.
- Brimonidintartrat/Timolol ”Sandoz” should not be used in children less than 2 years old and should not usually be used in children aged 2 to 17.

For the full list of restrictions, see the package leaflet.

Why is Brimonidintartrat/Timolol ”Sandoz” approved?

The Danish Medicines Agency decided that Brimonidintartrat/Timolol ”Sandoz”’s benefits are greater than its risks and recommended that it be approved for use.

What measures are being taken to ensure the safe and effective use of Brimonidintartrat/Timolol ”Sandoz”?

A risk management plan has been developed to ensure that Brimonidintartrat/Timolol ”Sandoz” is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Brimonidintartrat/Timolol ”Sandoz”, including the appropriate precautions to be ollowed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Brimonidintartrat/Timolol ”Sandoz”

The marketing authorisation for Brimonidintartrat/Timolol ”Sandoz” was granted on 9 April 2015.

The full PAR for Brimonidintartrat/Timolol ”Sandoz” can be found on the website http://mri.medagencies.org/Human/. For more information about treatment with Brimonidintartrat/Timolol ”Sandoz”, read the package leaflet (link) or contact your doctor or pharmacist.

This summary was last updated in 06-2016.