Summary Public Assessment Report

Generics

Bisoprolol Xantis 2.5 mg
Bisoprolol Xantis 5 mg
Bisoprolol Xantis 10 mg

Bisoprolol fumarate

SK/H/0183/001-003/DC

Date: June 2018

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Generics

Bisoprolol Xantis 2.5 mg

Bisoprolol Xantis 5 mg

Bisoprolol Xantis 10 mg

Bisoprolol fumarate
Tablets
2.5 mg, 5 mg and 10 mg

This is a summary of the public assessment report (PAR) for Bisoprolol Xantis. It explains how Bisoprolol Xantis 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 Bisoprolol Xantis.

For practical information about using Bisoprolol Xantis, patients should read the package leaflet or contact their doctor or pharmacist.

What is Bisoprolol Xantis and what is it used for?

Bisoprolol Xantis is a 'generic medicine'. This means that Bisoprolol Xantis is similar to a 'reference medicine' already authorised in the European Union (EU) called Concor COR 2.5 mg, Concor 5 mg and Concor 10 mg.

Bisoprolol Xantis is used in combination with other medicines (ACE inhibitors, diuretics and heart glycosides) to treat stable heart failure. Heart failure occurs when the heart muscle is weak and unable to pump enough blood to supply the body´s needs.

Bisoprolol Xantis is also used to treat high blood pressure (hypertension) and angina pectoris (chest pain caused by blockage in the arteries that supply the heart muscle).

How does Bisoprolol Xantis work?

The active substance of Bisoprolol Xantis is bisoprolol. Bisoprolol belongs to a group of medicines called beta-blockers. These medicines work by affecting the body´s response to some nerve impulses, especially in the heart. As a result, bisoprolol slows down the heart rate and makes the heart more efficient at pumping blood around the body.

How is Bisoprolol Xantis used?

The pharmaceutical form of Bisoprolol Xantis is tablet and the route of administration is oral.

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

<u>Increased blood pressure/angina pectoris</u>
The recommended starting dose of Bisoprolol Xantis in the treatment of increased blood pressure/angina pectoris is 5 mg.

Recommended daily dose is 10 mg. Maximum daily dose is 20 mg. Treatment with Bisoprolol Xantis is usually long-term.
Patients with severe kidney disease should not exceed 10 mg of bisoprolol daily.

Heart failure (decreased ability of heart to work as a pump)
Treatment of heart failure with Bisoprolol Xantis requires regular medical monitoring. It is necessary especially at the start or treatment and during titration of dosage. Treatment with bisoprolol must be started at a low dose and increased gradually. It should be normally be done in the following way:

- 1.25 mg bisoprolol once daily for 1 week
- 2.5 mg bisoprolol once daily for 1 week
- 3.75 mg bisoprolol once daily for 1 week
- 5 mg bisoprolol once daily for 4 weeks
- 7.5 mg bisoprolol once daily for 4 weeks
- 10 mg bisoprolol once daily for maintenance (ongoing) therapy.

The maximum recommended daily dose is 10 mg of bisoprolol. In some patients a maintenance dose lower than 10 mg of bisoprolol may be sufficient.

The tablet can be divided into equal doses.
Bisoprolol Xantis is taken in the morning, with or without food with some water. Do not crush or chew tablets.

The medicine can only be obtained with a prescription.

What benefits of Bisoprolol Xantis have been shown in studies?
Because Bisoprolol Xantis is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Concor. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects of Bisoprolol Xantis?

Because Bisoprolol Xantis is a generic medicine and is bioequivalent to the reference medicine, its benefits and possible side effects are taken as being the same as the reference medicine.
For the full list of restrictions, see the package leaflet.

Why is Bisoprolol Xantis approved?

It was concluded that, in accordance with EU requirements, Bisoprolol Xantis has been shown to have comparable quality and to be bioequivalent/be comparable to Concor. Therefore, the State Institute for Drug Control decided that, as for Concor, the benefits are greater than its risk and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Bisoprolol Xantis?

A risk management plan has been developed to ensure that Bisoprolol Xantis 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 Bisoprolol Xantis, including the appropriate precautions to be followed 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 Bisoprolol Xantis

The marketing authorisation for Bisoprolol Xantis was granted on 14 June 2018.

The full PAR for Bisoprolol Xantis can be found on the ŠÚKL website. For more information about treatment with Bisoprolol Xantis, read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 06-2018.