STATE INSTITUTE FOR DRUG CONTROL
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Summary Public Assessment Report

Generics

Moxonidine Saneca 0.2 mg, Moxonidine Saneca 0.3 mg, Moxonidine Saneca 0.4 mg
moxonidine

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Generics

Moxonidine Saneca 0.2 mg; Moxonidine Saneca 0.3 mg; Moxonidine Saneca 0.4 mg.

Moxonidine, film-coated tablets, 0.2 mg; 0.3 mg; 0.4 mg.

This is a summary of the public assessment report (PAR) for Moxonidine Saneca 0.2 mg; Moxonidine Saneca 0.3 mg; Moxonidine Saneca 0.4 mg (hereinafter Moxonidine Saneca).
It explains how Moxonidine Saneca 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 Moxonidine Saneca.

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

What is Moxonidine Saneca and what is it used for?

Moxonidine Saneca is a 'generic medicine'. This means that Moxonidine Saneca is similar to a 'reference medicine' already authorised in the European Union (EU) called Cynt® 0.2/0.3/0.4.
Moxonidine Saneca is used to treat increased blood pressure.

Moxonidine Saneca belongs to the group of medicines called antihypertensives – medicines used to treat increased blood pressure.
The site of action of moxonidine, active substance of Moxonidine Saneca is central nervous system. It works by relaxing and widening the vessels which helps to reduce blood pressure.

Moxonidine Saneca is not intended for children and adolescents under 18 years because the efficacy and safety have not yet been established.

How does Moxonidine Saneca work?
In various animal models moxonidine has been shown to be a potent antihypertensive. Available experimental data indicate that the site of action of the antihypertensive effect of moxonidine is the central nervous system (CNS).

How is Moxonidine Saneca used?
The pharmaceutical form of Moxonidine Saneca is film-coated tablet and the route of administration is oral use.

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

Swallow the whole tablet with plenty of water.
It is recommended to take Moxonidine Saneca everyday at the same time.

The recommended dose is 0.2 mg of moxonidine. In case the dose is not adequate, your doctor will adjust the dose up to 0.4 mg of moxonidine after at least three weeks of therapy.
If the effect is still not adequate, your doctor will adjust your daily dose up to 0.6 mg moxonidine after further three weeks. If your doctor prescribes you 0.6 mg dose, use it divided into two separate doses (in the morning and in the evening).
Maximum single dose is 0.4 mg of moxonidine.
If you have problems with kidneys, your doctor may reduce your dose.

Dosage can be tailored according to individual needs. Exact dosage is determined by your doctor.

The medicine can only be obtained with a prescription.

What benefits of Moxonidine Saneca have been shown in studies?
Because Moxonidine Saneca is a generic medicine, studies in patients have been limited to tests to determine that it is equivalent to the reference medicine, Cynt® 0.2/0.3/0.4. Applicant sought for BCS-based biowaiver. BCS-based biowaiver approach is meant to reduce bioequivalence studies in human. Bioequivalence studies in human may be exempted if an assumption of equivalence in human performance can be justified by satisfactory *in vitro* data (e.g. dissolution profiles). The dissolution profiles of developed products are rapidly dissolving (more than 85% of moxonidine is dissolved within 15 minutes) and are comparable with dissolution profiles of reference products Cynt® 0.2 /0.3/0.4 through the physiological pH range.

What are the possible side effects of Moxonidine Saneca?

Because Moxonidine Saneca 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 Moxonidine Saneca approved?

It was concluded that, in accordance with EU requirements, Moxonidine Saneca has been shown to have comparable quality and to be comparable to Cynt® 0.2/0.3/0.4. Therefore, the State Institute for Drug Control decided that, as for reference medicine called Cynt® 0.2/0.3/0.4, 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 Moxonidine Saneca?

A risk management plan has been developed to ensure that Moxonidine Saneca 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 Moxonidine Saneca, 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 Moxonidine Saneca

The marketing authorisation for Moxonidine Saneca was granted on 11.12.2017.

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

This summary was last updated in 12/2017.