Summary Public Assessment Report

Generics

Lercanidinpihydrochlorid “Sandoz”
Lercanidipine hydrochloride

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Lercanidipinhydrochlorid ”Sandoz”

Lercanidinpine hydrochloride, film-coated tablets 10 mg and 20 mg

This is a summary of the public assessment report (PAR) for Lercanidipinhydrochlorid ”Sandoz”. It explains how Lercanidipinhydrochlorid ”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 Lercanidipinhydrochlorid ”Sandoz”.

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

What is Lercanidipinhydrochlorid ”Sandoz” and what is it used for?
Lercanidipinhydrochlorid ”Sandoz” is a ‘generic medicine’. This means that Lercanidipinhydrochlorid ”Sandoz” is similar to a ‘reference medicine’ already authorised in the European Union (EU) called Zanidip.
Lercanidipinhydrochlorid ”Sandoz” is used to treat high blood pressure also known as hypertension in adults over the age of 18 years

How does Lercanidipinhydrochlorid ”Sandoz” work?
Lercanidipinhydrochlorid ”Sandoz” belongs to a group of medicines called calcium channel blockers.

Lercanidipinhydrochlorid “Sandoz” works by slowing the movement of calcium through the muscle cells that are found in the walls of blood vessels. It does this by blocking 'calcium channels' in these muscle cells. Calcium is needed by muscle cells so that they can contract. Lercanidipinhydrochlorid “Sandoz” reduces the amount of calcium available to muscle cells and so makes them relax.

How is Lercanidipinhydrochlorid ”Sandoz” used?
The pharmaceutical form of Lercanidipinhydrochlorid ”Sandoz” is film-coated tablets and the route of administration is oral.

The recommend dose is one 10 mg film-coated tablet daily at the same time each day, preferably in the morning at least 15 minutes before breakfast, because a high fat meal significantly increases blood levels of the drug. The doctor may advise to increase the dose to one 20 mg film-coated tablet daily, if needed.
The tablets should preferably be swallowed whole with some water.

No adjustment of the daily dose is required in the elderly. However, special care should be exercised in starting treatment.

Special care is needed in starting treatment in patients with liver or kidney problems and an increase in daily dose to 20 mg should be approached with caution.

This medicine should not be used in children under 18 years of age.

Please read section 3 of the package leaflet 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 Lercanidipinhydrochlorid ”Sandoz” have been shown in studies?
Because Lercanidipinhydrochlorid ”Sandoz” is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Zanidip. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.
The company provided data from the published literature on lercanidipine hydrochloride.

What are the possible side effects of Lercanidipinhydrochlorid ”Sandoz”?
Because Lercanidipinhydrochlorid ”Sandoz” 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 Lercanidipinhydrochlorid ”Sandoz” approved?
It was concluded that, in accordance with EU requirements, Lercanidipinhydrochlorid ”Sandoz” has been shown to have comparable quality and to be bioequivalent/be comparable to Zanidip. Therefore, the member states involved in the procedure concluded that, as for Zanidip, 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 Lercanidipinhydrochlorid ”Sandoz”?
A risk management plan has been developed to ensure that Lercanidipinhydrochlorid ”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 Lercanidipinhydrochlorid ”Sandoz”, 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 Lercanidipinhydrochlorid ”Sandoz”
The marketing authorisation for Lercanidipinhydrochlorid ”Sandoz” was granted on 11 March 2015.

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

This summary was last updated in 12-2015.