Summary Public Assessment Report

Generics

Cinglan 30 mg, 60 mg and 90 mg film-coated tablets

(cinacalcet)

NL/H/4211/001-003/MR

Date: 6 November 2018

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Active substance: cinacalcet

This is a summary of the public assessment report (PAR) for Cinglan. It explains how this medicine 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 Cinglan.

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

What is Cinglan and what is it used for?
Cinglan film-coated tablets are 'generic medicine'. This means that they are similar to a 'reference medicine' already authorised in the European Union (EU) called Mimpara 30 mg, 60 mg and 90 mg film-coated tablets.

This medicine is used:

- To treat secondary hyperparathyroidism in patients with serious kidney disease who need dialysis to clear their blood of waste products. "Secondary" means that the hyperparathyroidism is caused by another condition, e.g., kidney disease.
- To reduce high levels of calcium in the blood (hypercalcaemia) in patients with parathyroid cancer.
- To reduce high levels of calcium in the blood (hypercalcaemia) in patients with primary hyperparathyroidism who still have high calcium levels after removal of the parathyroid gland or when removal of the gland is not possible. "Primary" means that the hyperparathyroidism is not caused by any other condition.

How does this medicine work?
The active substance in cinacalcet, is a calcimimetic agent. This means that it mimics the action of calcium in the body. Cinacalcet works by increasing the sensitivity of the calcium-sensing receptors on the parathyroid glands that regulate PTH secretion. By increasing the sensitivity of these receptors, cinacalcet leads to a reduction in the production of PTH by the parathyroid glands. The reduction in PTH levels also leads to a decrease in blood calcium levels.

How is this medicine used?
The pharmaceutical form of Cinglan is a film-coated tablet and the route of administration is oral. The medicine can only be obtained with a prescription. The film-coated tablet must be taken orally, with or shortly after food.

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

How has this medicine been studied?
Because Cinglan is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Mimpara. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects of this medicine?
Because Cinglan 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 all side effects reported with this medicine, see section 4 of the package leaflet.

Why is this medicine approved?
It was concluded that, in accordance with EU requirements, this medicine has been shown to have comparable quality and to be bioequivalent to the reference medicine. Therefore, the Medicines Evaluation Board of the Netherlands decided that, as for reference medicine called Mimpara, 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 this medicine?
A risk management plan has been developed to ensure that this medicine 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 Cinglan, 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.

Other information about this medicine
In the Netherlands, the marketing authorisation for Cinglan 30 mg, 60 mg and 90 mg film-coated tablets was granted on 20 July 2017.

The full PAR for this medicine can be found on the website http://mri.medagencies.org/Human. For more information about treatment with Cinglan, read the package leaflet (https://mri.cts-mrp.eu/Human/Downloads/NL_H_4211_001_FinalPL.pdf) or contact your doctor or pharmacist.

This summary was last updated in November 2018.