Summary Public Assessment Report

Generics

Gliclazid “Sigillata”
Gliclazide

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Gliclazid ”Sigillata”

Gliclazide, modified-release tablets 30 mg and 60 mg

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

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

What is Gliclazid ”Sigillata” and what is it used for?
Gliclazid ”Sigillata” is a ‘generic medicine’. This means that Gliclazid ”Sigillata” is similar to a ‘reference medicine’ already authorised in the European Union (EU) called Diamicron.
Gliclazid ”Sigillata” is used in a certain form of diabetes (type 2 diabetes mellitus) in adults, when diet, exercise and weight loss alone do not have an adequate effect on keeping blood sugar at the correct level.

How does Gliclazid ”Sigillata” work?
Gliclazid ”Sigillata” is a medicine that reduces blood sugar levels (oral anti-diabetic medicine belonging to the sulphonylurea group).

How is Gliclazid ”Sigillata” used?
The pharmaceutical form of Gliclazid ”Sigillata” is modified-release tablets and the route of administration is oral (through the mouth).

The recommended starting dose is 30 mg. The usual dose is 30 mg-120 mg in a single intake at breakfast time.

Tablets or half tablets should be swallowed in one piece and should not be chewed or crushed. Tablets should be taken with a glass of water at breakfast time (and preferably at the same time each day). It is recommended to always eat a meal after taking the tablets.

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 Gliclazid ”Sigillata” have been shown in studies?
Because Gliclazid ”Sigillata” is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Diamicron. 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 gliclazide.

What are the possible side effects of Gliclazid ”Sigillata”?
Because Gliclazid ”Sigillata” 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 Gliclazid ”Sigillata” approved?
It was concluded that, in accordance with EU requirements, Gliclazid ”Sigillata” has been shown to have comparable quality and to be bioequivalent/be comparable to Diamicron. Therefore, the member states involved in the procedure concluded that, as for Diamicron, 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 Gliclazid ”Sigillata”?
A risk management plan has been developed to ensure that Gliclazid ”Sigillata” 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 Gliclazid ”Sigillata”, 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 Gliclazid ”Sigillata”
The marketing authorisation for Gliclazid ”Sigillata” was granted on 4 August 2015.

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

This summary was last updated in 08-2016.