Summary Public Assessment Report

Generics

Ezetimibe/Simvastatine SUN Pharma 10 mg/10 mg, 10 mg/20 mg, 10 mg/40 mg tablets

(ezetimibe and simvastatin)

NL/H/3389/001-003/DC

Date: 25 October 2017

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Active substances: ezetimibe and simvastatin

This is a summary of the public assessment report (PAR) for Ezetimibe/Simvastatine SUN Pharma. 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 Ezetimibe/Simvastatine SUN Pharma.

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

What is Ezetimibe/Simvastatine SUN Pharma and what is it used for?
Ezetimibe/Simvastatine SUN Pharma is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Inegy.

This medicine is used in patients with increased levels of cholesterol who cannot control their cholesterol levels by cholesterol lowering diet alone.

Ezetimibe/Simvastatine SUN Pharma is used in addition to a cholesterol-lowering diet in patients who have:

- a raised cholesterol level in the blood (primary hypercholesterolaemia [heterozygous familial and non-familial]) or elevated fat levels in the blood (mixed hyperlipidaemia):
    - that is not well controlled with a statin alone
    - for which the patient has used a statin and ezetimibe as separate tablets
- a hereditary illness (homozygous familial hypercholesterolaemia) that increases the cholesterol level in the blood. The patient may also receive other treatments.
- heart disease; Ezetimibe/Simvastatine SUN Pharma reduces the risk of heart attack, stroke, surgery to increase heart blood flow, or hospitalisation for chest pain.

How does this medicine work?
Ezetimibe/Simvastatine SUN Pharma tablets are used to lower levels of total cholesterol, "bad" cholesterol (LDL cholesterol), and fatty substances called triglycerides in the blood. In addition, ezetimibe/simvastatin tablets raise levels of "good" cholesterol (HDL cholesterol).

LDL cholesterol is often called "bad" cholesterol because it can build up in the walls of the arteries forming plaque. Eventually this plaque build-up can lead to a narrowing of the arteries. This narrowing can slow or block blood flow to vital organs such as the heart and brain. This blocking of blood flow can result in a heart attack or stroke.

HDL cholesterol is often called "good" cholesterol because it helps keep the bad cholesterol from building up in the arteries and protects against heart disease.

Cholesterol is one of several fatty substances found in the bloodstream. Total cholesterol is made up mainly of LDL and HDL cholesterol. Triglycerides are another form of fat in the blood that may increase the risk for heart disease.

Ezetimibe/Simvastatine SUN Pharma tablets reduce cholesterol levels in two ways. The active ingredient ezetimibe reduces the cholesterol absorbed in the digestive tract. The active ingredient simvastatin belonging to the class of "statins" inhibits the production of the cholesterol the body makes by itself. It is important to stay on a cholesterol lowering diet while taking this medicine.

How is this medicine used?
The pharmaceutical form of Ezetimibe/Simvastatine SUN Pharma is tablet and the route of administration is oral. The medicine is taken once a day.
Ezetimibe/Simvastatine SUN Pharma can only be obtained with a prescription.

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 it is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Inegy. 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 Ezetimibe/Simvastatine SUN Pharma 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 Inegy. Therefore, the Medicines Evaluation Board of the Netherlands decided that, as for the reference medicine, 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 Ezetimibe/Simvastatine SUN Pharma, 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 this medicine
In the Netherlands, the marketing authorisation for Ezetimibe/Simvastatine SUN Pharma was granted on 27 July 2016.

The full PAR for this medicine can be found on the website http://mri.cts-mrp.eu/Human/. For more information about treatment with Ezetimibe/Simvastatine SUN Pharma, read the package leaflet (http://mri.cts-mrp.eu/download/NL_H_3389_001_FinalPL.pdf) or contact your doctor or pharmacist.

This summary was last updated in October 2017.