# Summary Public Assessment Report

## Generics

# Atorvastatine Aurobindo 10 mg, 20 mg, 40 mg, and 80 mg, film-coated tablets (atorvastatine)

**NL/H/2982/001-004/DC**

**Date: 16 March 2015**

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Atorvastatine Aurobindo 10 mg, 20 mg, 40 mg, and 80 mg film-coated tablets

Active substance: atorvastatin

This is a summary of the public assessment report (PAR) for Atorvastatine Aurobindo. 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 this medicine.

For practical information about using Atorvastatin Aurobindo tablets, patients should read the package leaflet or contact their doctor or pharmacist.

**What is Atorvastatine Aurobindo and what is it used for?**
Atorvastatine Aurobindo 10 mg, 20 mg, 40 mg, and 80 mg is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Lipitor, also known as Sortis.
This medicine is used to lower elevated cholesterol (hypercholesterolaemia) when a low fat diet and life style changes are not enough.
For patients who are at an increased risk of heart disease, atorvastatin tablet can also be used to reduce such risk.

**How does this medicine work?**
Atorvastatin belongs to a group of medicines known as statins, which are lipid (fat) regulating medicines. Atorvastatin tablet can lower lipids known as cholesterol and triglycerides in the blood. In patients who you are at an increased risk of heart disease, atorvastatin tablets can also be used to reduce such risk even if the cholesterol levels are normal.

**How is this medicine used?**
The medicine can only be obtained with a prescription. When using this medicine, patients should maintain a standard cholesterol lowering diet. In adults the usual starting dose is 10 mg once a day. This may be increased if necessary, as indicated by a doctor until the right amount is reached. The dose will be adapted at intervals of 4 weeks or more. The maximum dose of Atorvastatine Aurobindo tablet is 80 mg once daily for adults.

This medicine should not be given to children below the age of 10. In children aged 10 years or older the usual starting dose is 10 mg once a day. This may be increased if necessary, at intervals of 4 weeks or more. The maximum dose for children is 20 mg once daily.

The medicine should be swallowed whole with a drink of water, and can be taken at any time of day, with or without food. It should preferably be taken at the same time every day.

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 Atorvastatine Aurobindo is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, 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 Atorvastatine Aurobindo 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 atorvastatin tablets, 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 Lipitor. Therefore, the Medicines Evaluation Board of the Netherlands decided that, as for Lipitor, 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 Atorvastatine Aurobindo, 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**

The marketing authorisation for Atorvastatine Aurobindo 10 mg, 20 mg, 40 mg, and 80 mg film-coated tablets for the Netherlands was granted on 6 March 2015.

The full PAR for this medicinal product can be found on http://mri.medagencies.org/Human. For more information about treatment with Atorvastatine Aurobindo film-coated tablets, read the package leaflet (http://mri.medagencies.org/download/NL_H_2982_001_FinalPL.pdf) or contact your doctor or pharmacist.

This summary was last updated in March 2015.