

## **Part VI: Summary of the risk management plan**

### **Summary of risk management plan for Atorvastatin film-coated tablets 10mg, 20mg, 30mg, 40mg, 80mg**

This is a summary of the risk management plan (RMP) for Atorvastatin film-coated tablets. The RMP details important risks of Atorvastatin film-coated tablets and how more information will be obtained about Atorvastatin film-coated tablets risks and uncertainties (missing information).

Atorvastatin film-coated tablets summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Atorvastatin film-coated tablets should be used.

#### **I. The medicine and what it is used for**

Atorvastatin film-coated tablets is authorised for hypercholesterolaemia and prevention of cardiovascular disease (see SmPC for the full indication).

It contains atorvastatin as the active substance and it is given by mouth as tablets.

Important new concerns or changes to the current ones will be included in updates of 's RMP.

#### **II. Risks associated with the medicine and activities to minimise or further characterise the risks**

Important risks of Atorvastatin film-coated tablets together with measures to minimise such risks and the proposed studies for learning more about Atorvastatin film-coated tablets risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine's legal status — the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.

## **II.A List of important risks and missing information**

Important risks of Atorvastatin film-coated tablets are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Atorvastatin film-coated tablets. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine);

<b>List of important risks and missing information</b>	
Important identified risks	<ul style="list-style-type: none"><li>• Skeletal muscle effects (including Immune-mediated necrotizing myopathy), rhabdomyolysis and rhabdomyolysis-related events</li><li>• Hepatic failure</li></ul>
Important potential risks	<ul style="list-style-type: none"><li>• Haemorrhagic stroke in patients with prior haemorrhagic stroke or lacunar infarct</li></ul>
Missing information	<ul style="list-style-type: none"><li>• None</li></ul>

## **II.B Summary of important risks**

The safety information in the proposed Product Information is aligned to the reference medicinal product.

## **II.C Post-authorisation development plan**

### **II.C.1 Studies which are conditions of the marketing authorisation**

There are no studies which are conditions of the marketing authorisation or specific obligation of Atorvastatin.

### **II.C.2 Other studies in post-authorisation development plan**

There are no studies required for Atorvastatin.