Summary of the risk management plan

Summary of risk management plan for Atorvastatin Laboratorios Liconsa 10 mg, 20 mg, 40 mg and 80 mg film-coated tablets and Atorvastatin Chemo 10 mg, 20 mg, 40 mg and 80 mg film-coated tablets. [2]

This is a summary of the risk management plan (RMP) for Atorvastatin Laboratorios Liconsa 10 mg, 20 mg, 40 mg and 80 mg film-coated tablets and Atorvastatin Chemo 10 mg, 20 mg, 40 mg and 80 mg film-coated tablets.

The RMP details important risks of Atorvastatin Laboratorios Liconsa 10 mg, 20 mg, 40 mg and 80 mg film-coated tablets and Atorvastatin Chemo 10 mg, 20 mg, 40 mg and 80 mg film-coated tablets, how these risks can be minimised, and how more information will be obtained about Atorvastatin Laboratorios Liconsa 10 mg, 20 mg, 40 mg and 80 mg film-coated tablets and Atorvastatin Chemo 10 mg, 20 mg, 40 mg and 80 mg film-coated tablets risks and uncertainties (missing information).

Atorvastatin Laboratorios Liconsa 10 mg, 20 mg, 40 mg and 80 mg film-coated tablets and Atorvastatin Chemo 10 mg, 20 mg, 40 mg and 80 mg film-coated tablets summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Atorvastatin Laboratorios Liconsa 10 mg, 20 mg, 40 mg and 80 mg film-coated tablets and Atorvastatin Chemo 10 mg, 20 mg, 40 mg and 80 mg film-coated tablets should be used.

I. The medicine and what it is used for

Atorvastatin Laboratorios Liconsa **10 mg, 20 mg, 40 mg and 80 mg film-coated tablets** and **Atorvastatin Chemo 10 mg, 20 mg, 40 mg and 80 mg film-coated tablets** are authorised for the treatment of hypercholesterolaemia and prevention of cardiovascular disease (see SmPC for the full indication). It contains atorvastatin as the active substance, and it is given by oral route.

[2] Name of the product in the RMS

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

Important risks of Atorvastatin Laboratorios Liconsa 10 mg, 20 mg, 40 mg and 80 mg film-coated tablets and Atorvastatin Chemo 10 mg, 20 mg, 40 mg and 80 mg film-coated tablets together with measures to minimise such 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.

If important information that may affect the safe use of Atorvastatin Laboratorios Liconsa 10 mg, 20 mg, 40 mg and 80 mg film-coated tablets and Atorvastatin Chemo 10 mg, 20 mg, 40 mg and 80 mg film-coated tablets is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Atorvastatin Laboratorios Liconsa 10 mg, 20 mg, 40 mg and 80 mg film-coated tablets and Atorvastatin Chemo 10 mg, 20 mg, 40 mg and 80 mg 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 administered. 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 Laboratorios Liconsa 10 mg, 20 mg, 40 mg and 80 mg film-coated tablets and Atorvastatin Chemo 10 mg, 20 mg, 40 mg and 80 mg 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).

Table 3. Summary of Safety Concerns

Important Identified Risks	-Hepatic failure -Skeletal muscle effects, rhabdomyolysis and rhabdomyolysis-related events -Hyperglycaemia, which may require diabetes care in patients - Steven-Johnson syndrome and toxic epidermal necrolysis - Interstitial lung disease - Concomitant use of coumarin anticoagulants / warfarin
Important Potential Risks	- Haemorrhagic stroke - Autoimmune events
Missing Information	- Use in paediatric patients < 10 years old

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 Film Coated Tablets (10mg, 20mg, 40mg & 80mg).

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

There are no studies required for Atorvastatin Film Coated Tablets (10mg, 20mg, 40mg & 80mg).