Part VI: Summary of the risk management plan

Summary of risk management plan for Sumatriptan 6 mg/0.5 ml Solution for Injection

This is a summary of the risk management plan (RMP) for Sumatriptan 6 mg/0.5 ml Solution for Injection. The RMP details important risks of Sumatriptan 6 mg/0.5 ml Solution for Injection; how these risks can be minimised and how more information will be obtained about its risks and uncertainties (missing information).

Sumatriptan 6 mg/0.5 ml Solution for Injection summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Sumatriptan 6 mg/0.5 ml Solution for Injection should be used.

Important new concerns or changes to the current ones will be included in updates of Sumatriptan 6 mg/0.5 ml Solution for Injection's RMP.

I. The medicine and what it is used for

Sumatriptan 6 mg/0.5 ml Solution for Injection is authorised for the acute relief of migraine attacks, with or without aura, and for the acute treatment of cluster headache. Sumatriptan 6 mg/0.5 ml Solution for Injection should only be used where there is a clear diagnosis of migraine or cluster headache.

It contains Sumatriptan succinate as the active substance and it is given by subcutaneous route.

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

Important risks of Sumatriptan 6 mg/0.5 ml Solution for Injection, together with measures to minimise such risks for learning more about of Sumatriptan 6 mg/0.5 ml Solution for Injection’s 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 Pack contains two pre-filled syringes with an auto-injector, in a plastic tray within a carton
- The medicine’s legal status — Prescription only medicine.

Together, these measures constitute routine risk minimisation measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

If important information that may affect the safe use of Sumatriptan 6 mg/0.5 ml Solution for Injection is not yet available, it is listed under ‘missing information’ below.

II.A List of important risks and missing information

Important risks of Sumatriptan 6 mg/0.5 ml Solution for Injection 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 Sumatriptan 6 mg/0.5 ml Solution for Injection.

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);

Safety concerns	
Important identified risk(s)	1. Myocardial ischaemia/ infarction
	2. Cerebrovascular events
	3. Hypersensitivity
	4. Serotonin syndrome with concomitant use with SSRIs or SNRIs or MAO inhibitors
	5. Seizures
	6. Use in patients with severe hepatic insufficiency
	7. Concomitant use with ergot-containing compounds
	8. Medication overuse headache
	9. Hypertension
Important potential risk(s)	1. Use in patients with basilar or hemiplegic migraine
	2. Ischaemic colitis
Missing information	1. Use in paediatric population
	2. Use in elderly patients (over 65 years)

II.B Summary of important risks

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