Part VI: Summary of the risk management plan

Summary of risk management plan for Topiramate 25 mg, 50 mg, 100 mg and 200 mg film-coated tablets (Topiramate)

This is a summary of the risk management plan (RMP) for Topiramate 25 mg, 50 mg, 100 mg and 200 mg film-coated tablets. The RMP details important risks of Topiramate 25 mg, 50 mg, 100 mg and 200 mg film-coated tablets, how these risks can be minimised, and how more information will be obtained about Topiramate 25 mg, 50 mg, 100 mg and 200 mg film-coated tablets risks and uncertainties (missing information).

Topiramate 25 mg, 50 mg, 100 mg and 200 mg film-coated tablet's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Topiramate 25 mg, 50 mg, 100 mg and 200 mg film-coated tablets should be used.

Important new concerns or changes to the current ones will be included in updates of Topiramate 25 mg, 50 mg, 100 mg and 200 mg film-coated tablet's RMP.

I. The medicine and what it is used for

Topiramate 25 mg, 50 mg, 100 mg and 200 mg film-coated tablet is authorised for following indication.

- Monotherapy in adults, adolescents and children over 6 years of age with partial seizures with or without secondary generalised seizures, and primary generalised tonic-clonic seizures.
- Adjunctive therapy in children aged 2 years and above, adolescents and adults with partial onset seizures with or without secondary generalization or primary generalized tonic-clonic seizures and for the treatment of seizures associated with Lennox-Gastaut syndrome.
- Topiramate is indicated in adults for the prophylaxis of migraine headache after careful evaluation of possible alternative treatment options. Topiramate is not intended for acute treatment.

It contains topiramate as the active substance and it is given by oral route.

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

Important risks of Topiramate 25 mg, 50 mg, 100 mg and 200 mg film-coated tablets, together with measures to minimise such risks and the proposed studies for learning more about Topiramate 25 mg, 50 mg, 100 mg and 200 mg film-coated tablet'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 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 Topiramate 25 mg, 50 mg, 100 mg and 200 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 Topiramate 25 mg, 50 mg, 100 mg and 200 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 Topiramate 25 mg, 50 mg, 100 mg and 200 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).

Important identified risks	• Oligohydrosis

	• Mood disturbances and depression • Suicidal ideation and behaviour • Nephrolithiasis • Use in patients with decreased renal function • Use in patients with decreased hepatic function • Acute myopia and secondary angle closure glaucoma • Visual field defects • Metabolic acidosis • Major congenital malformations with use in pregnancy • Hyperammonaemia with or without encephalopathy, with or without concomitant valproic acid • Hypothermia with concomitant valproic acid
Important potential risk	• Low birth weight
Missing information	• Use in neonatal seizures • Use during breastfeeding • Long-term treatment in paediatric patients

II.B Summary of important risks

The safety information in the proposed product information is aligned with topiramate (PT/H/1492/001-003/DC; RMP Version 1.1, date 03-May-2017) safety concerns published by CMDh.

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 Topiramate 25 mg, 50 mg, 100 mg and 200 mg film-coated tablets.

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

There are no studies required for Topiramate 25 mg, 50 mg, 100 mg and 200 mg film-coated tablets.