# Part VI: Summary of the risk management plan

# Summary of risk management plan for *Maritop* (topiramate)

This is a summary of the risk management plan (RMP) for *Maritop*. The RMP details important risks of *Maritop*, how these risks can be minimised, and how more information will be obtained about *Maritop*'s risks and uncertainties (missing information).

*Maritop*'s summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how *Maritop* should be used.

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

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

*Maritop* is authorised for

- 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.
- In adults for the prophylaxis of migraine headache after careful evaluation of possible alternative treatment options. Topiramate is not intended for acute treatment.

(see SmPC for the full indication).

It contains topiramate as the active substance and is given via oral route of administration.

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

Important risks of *Maritop*, together with measures to minimise such risks and the proposed studies for learning more about *Maritop*'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.

In the case of *Maritop*, these measures are supplemented with *additional risk minimisation measures* mentioned under relevant important risks, below.

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

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

Important risks of *Maritop* 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 *Maritop*. 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);

| List of important risks and missing information | |
|---|---|
| Important identified risks | Major congenital malformations |
| Important potential risks | Neurodevelopmental disorders |
| Missing information | None |

## *II.B Summary of important risks*

| Major congenital malformations | |
|---|---|
| Risk minimisation measures | Routine risk minimisation measures:<br><br>*SmPC section 4.2*<br>*SmPC section 4.3*<br>*SmPC section 4.4*<br>*SmPC section 4.6*<br>*SmPC section 4.8*<br><br>*PL section 2*<br><br>Additional risk minimisation measures:<br><br>A) Pregnancy Prevention Programme<br>• Healthcare professional guide including risk awareness form<br>• Patient guide<br>• Patient card<br>*B)* DHPC |
| Additional pharmacovigilance activities | Additional pharmacovigilance activities:<br><br>A) Drug Utilisation Study (EUPAS1000000494)<br>B) Survey |

| Major congenital malformations | |
|---|---|
| | See section II.C of this summary for an overview of the post-authorisation development plan. |

| Neurodevelopmental disorders | |
|---|---|
| Risk minimisation measures | Routine risk minimisation measures:<br><br>*SmPC section 4.2*<br>*SmPC section 4.3*<br>*SmPC section 4.4*<br>*SmPC section 4.6*<br><br>*PL section 2*<br><br>Additional risk minimisation measures:<br><br>A) Pregnancy Prevention Programme<br>• Healthcare professional guide including risk awareness form<br>• Patient guide<br>• Patient card<br>*B)* DHPC |
| Additional pharmacovigilance activities | Additional pharmacovigilance activities:<br><br>A) Drug Utilisation Study (EUPAS1000000494)<br>B) Survey<br><br>See section II.C of this summary for an overview of the post-authorisation development plan. |

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

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

The following studies are conditions of the marketing authorisation:

Drug Utilisation Study (EUPAS1000000494)
Purpose of the study: To evaluate the effectiveness of implemented risk minimisation measures and to characterise the prescribing patterns for topiramate in the target populations for pregnancy prevention.

Survey
Purpose of the study: To assess the knowledge of healthcare professionals and patients with regard to the risks of topiramate use during pregnancy and the measures to prevent pregnancies together with the receipt/use of the educational materials.
The survey consists of two parts, among:

1) Healthcare professionals: The survey part among healthcare professionals also includes the behaviour with regard to the risks of topiramate and the measures to prevent pregnancies also include the receipt and use of the distributed DHPC.
2) Patients

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

There are no studies required for *Maritop*.