Part V: Risk minimisation measures (including evaluation of the effectiveness of risk minimisation activities)

Risk Minimisation Plan

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

Part VI: Summary of the risk management plan

Summary of risk management plan for Zonisol 20 mg/ml oral solution (Zonisamide)

This is a summary of the risk management plan (RMP) for Zonisol 20 mg/ml oral suspension. The RMP details important risks of Zonisol 20 mg/ml oral suspension, how these risks can be minimised, and how more information will be obtained about Zonisol 20 mg/ml oral suspension's risks and uncertainties (missing information).

Zonisol 20 mg/ml oral suspension's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Zonisol 20 mg/ml oral suspension should be used.

I. The medicine and what it is used for

Zonisol 20 mg/ml oral suspension is authorised for:

- Monotherapy in the treatment of partial seizures, with or without secondary generalisation, in adults with newly diagnosed epilepsy
- Adjunctive therapy in the treatment of partial seizures, with or without secondary generalisation in adults, adolescents, and children aged 6 years and above
- (see SmPC for the full indication).

It contains Zonisamide as the active substance and it is given by oral suspension.

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

Important risks of Zonisol 20 mg/ml oral suspension, together with measures to minimise such risks and the proposed studies for learning more about Zonisol 20 mg/ml oral suspension'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 addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including PSUR assessment, 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 Zonisol 20 mg/ml oral suspension is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Zonisol 20 mg/ml oral suspension 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 Zonisol 20 mg/ml oral suspension. 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	• Hypersensitivity to sulphonamides • Unexplained rash • Haematologic events • Kidney stones • Heat stroke and dehydration • Pancreatitis and elevated amylase and lipase • Rhabdomyolysis • Weight loss • Metabolic acidosis and its potential for osteopenia • Suicide ideation and behaviour
Important potential risks	• Seizures following sudden withdrawal • Effects on ability to drive and use machines • Use in renal impairment • Hepatic dysfunction in paediatric and adolescent patients • Use in the elderly • Cognitive impairment in paediatric and adolescent patients • Use in pregnancy and breast-feeding
Missing information	• Use in impaired liver function • Use in children below 6 years of age

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 Zonisol 20 mg/ml oral suspension.

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

There are no studies required for Zonisol 20 mg/ml oral suspension.