

## **Part VI: Summary of the risk management plan**

### **Summary of risk management plan for Broxeltia**

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

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

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

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

Broxeltia is authorised for the treatment of major depressive episodes in adults. It contains vortioxetine as the active substance and it is given by oral route of administration.

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

Important risks of Broxeltia, together with measures to minimise such risks and the proposed studies for learning more about Broxeltia 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 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 Broxeltia is not yet available, it is listed under 'missing information' below.

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

Important risks of Broxeltia 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 Broxeltia. 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).

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<b>List of important risks and missing information</b>	
<b>Important identified risks</b>	<ul style="list-style-type: none"><li>• Serotonin syndrome</li><li>• Hyponatraemia</li></ul>
<b>Important potential risks</b>	<ul style="list-style-type: none"><li>• Precipitation of metabolites in kidney and liver</li><li>• Convulsions / seizure</li><li>• Suicidal ideations and behaviours</li></ul>
<b>Missing information</b>	<ul style="list-style-type: none"><li>• Use during pregnancy and lactation</li><li>• Use in patients with severe renal or hepatic impairment</li><li>• Misuse for illegal purposes</li><li>• Off-label use</li><li>• Off-label paediatric use</li><li>• Use in patients aged <math>\geq 75</math> years</li><li>• Use in patients with co-morbid Alzheimer's disease, Parkinson's disease, multiple sclerosis and stroke</li><li>• Use in patients with a history of mania / hypomania</li></ul>

## **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 Broxeltia.

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

There are no studies required for Broxeltia.