

## **PART VI- Summary of the risk management plan**

### **Summary of risk management plan for Duta Tamsaxiro (dutasteride tamsulosin).**

This is a summary of the risk management plan (RMP) for Duta Tamsaxiro. The RMP details important risks of Duta Tamsaxiro and how more information will be obtained about Duta Tamsaxiro's risks and uncertainties (missing information).

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

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

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

Duta Tamsaxiro is authorised for the treatment of moderate to severe symptoms of benign prostatic hyperplasia (BPH) and for reduction in the risk of acute urinary retention (AUR) and surgery in patients with moderate to severe symptoms of BPH (see SmPC for the full indication).

It contains dutasteride and tamsulosin as active substances 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 Duta Tamsaxiro, together with measures to minimise such 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.

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

Important risks of Duta Tamsaxiro 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 Duta Tamsaxiro. 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).

<b>List of important risks and missing information</b>	
Important identified risks	None
Important potential risks	None
Missing information	None

### ***II.B Summary of important risks***

The safety information in the 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 Duta Tamsaxiro.

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

There are no studies required for Duta Tamsaxiro.