

Summary of risk management plan for Dutasteride/Tamsulosin Orion 0.5 mg/0.4 mg hard capsules (dutasteride/tamsulosin hydrochloride) Orion Corporation

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The RMP details important risks of Dutasteride/Tamsulosin Orion, how these risks can be minimized, and how more information will be obtained about Dutasteride/Tamsulosin Orion's risks and uncertainties (missing information).

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

Important new concerns or changes to the current ones will be included in updates of Dutasteride/Tamsulosin Orion's RMP.

I. The medicine and what it is used for

Dutasteride/Tamsulosin Orion is authorised for treatment of moderate to severe symptoms of benign prostatic hyperplasia (BPH), and 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 hydrochloride as the active substances and it is given by mouth.

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

Important risks of Dutasteride/Tamsulosin Orion, together with measures to minimise such risks and the proposed studies for learning more about Dutasteride/Tamsulosin Orion'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 so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

II.A List of important risks and missing information

This product has no safety concerns requiring additional pharmacovigilance actions or additional risk minimisation activities.

Safety concerns are adequately addressed in the product information.

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

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

There are no studies required for Dutasteride/Tamsulosin Orion.