Summary of risk management plan for Doneprion (donepezil hydrochloride) Orion Corporation

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

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

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

I. The medicine and what it is used for

Doneprion is authorised for symptomatic treatment of mild to moderately severe Alzheimer's dementia. (see SmPC for the full indication). It contains donepezil hydrochloride as the active substance and it is given by mouth.

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

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

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 Doneprion.