

Part VI: Summary of the risk management plan

A separate RMP Part VI is provided below.

Summary of risk management plan for Hydroxyzine Bluefish (Hydroxyzine hydrochloride)

This is a summary of the risk management plan (RMP) for Hydroxyzine Bluefish. The RMP details important risks of Hydroxyzine Bluefish, which can be minimized through routine pharmacovigilance activities.

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

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

I. The medicine and what it is used for

Hydroxyzine Bluefish 10 mg is authorised for the indications symptomatic treatment of anxiety in adults and symptomatic treatment of pruritus associated with urticaria. Hydroxyzine Bluefish 25 mg is authorised for the indications symptomatic treatment of anxiety in adults and symptomatic treatment of pruritus associated with urticaria in adults, **adolescents and children (≥5-11 years)** (see SmPC for the full indication). It contains hydroxyzine hydrochloride as the active substance and it is given orally as film coated tablets.

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

Important risks of Hydroxyzine Bluefish, together with measures to minimise such risks about Hydroxyzine Bluefish'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

Important risks of Hydroxyzine Bluefish 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 Hydroxyzine Bluefish. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this