## Part VI: Summary of the risk management plan

# Summary of risk management plan for Histec film-coated tablets (cetirizine)

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

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

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

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

Histec is authorised for the relief of nasal and ocular symptoms associated with seasonal and perennial allergic rhinitis and treatment of symptoms of chronic idiopathic urticaria (see SmPC for the full indication). It contains cetirizine 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 Histec, together with measures to minimise such risks and the proposed studies for learning more about Histec'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*.

If important information that may affect the safe use of Histec is not yet available, it is listed under ‘missing information’ below.

## 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.

## 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

There are no studies required for Histec.