

## **Part VI: Summary of the risk management plan**

# Summary of risk management plan for ciprofloxacin plus fluocinolone acetonide, ear drops solution

This is a summary of the risk management plan (RMP) for ciprofloxacin plus fluocinolone ear drops solution. The RMP details important risks of the product combination.

Ciprofloxacin plus fluocinolone ear drops solution's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how ciprofloxacin plus fluocinolone ear drops solution should be used.

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

Ciprofloxacin plus fluocinolone ear drops solution in multi dose presentation is authorised for the local treatment of acute diffuse otitis externa of bacterial origin, in the absence of perforations of the tympanic membrane, and Ciprofloxacin plus fluocinolone ear drops solution in single dose presentation is authorised for children aged 6 months to 12 years for acute otitis media in patients with tympanostomy tubes (AOMT) caused by ciprofloxacin susceptible microorganisms (see SmPC for the full indication). Both presentations contain ciprofloxacin and fluocinolone acetonide as the active substances and it is given by auricular (otic) route of administration.

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

The safety profile of ciprofloxacin plus fluocinolone ear drops solution is well characterised and the safety concerns are well known and considered not important for inclusion in the RMP. Therefore, considering that there are no important (identified or potential) risks for the product, this section is not applicable.

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

Important risks are those that need special risk management activities to further investigate or minimise it, so that the medicinal product can be safely administered. 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 the product. 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);

List of important risks and missing information	
Important identified risks	None
Important potential risks	None
Missing information	Use in children younger than 6 months old Pregnancy

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

There are no important risks associated to ciprofloxacin plus fluocinolone ear drops solution, and therefore this section is not applicable.

## ***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 ciprofloxacin plus fluocinolone ear drops solution.

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

There are no studies required for ciprofloxacin plus fluocinolone ear drops solution.