
PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for Tachifene® (paracetamol and ibuprofen all formulations)

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

Tachifene's SmPCs and its package leaflets give essential information to healthcare professionals and patients on how Tachifene should be used.

I. The medicine and what it is used for

Tachifene is authorised for the short-term management of mild-to-moderate acute pain and the reduction of fever (see SmPC for the full indication). It contains paracetamol and ibuprofen as active substances and it is given by oral route.

II. Risk associated with the medicine and activities to minimize or further characterize the risks

Important risks of Tachifene, together with measures to minimise such risks and the proposed studies for learning more about Tachifene's risks, are outlined below.

Measures to minimise the risks identified for medicinal products are:

- 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, including PSUR assessment so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

II.A List of important risks and missing information

Important risks of Tachifene are risks that need special risk management activities to further investigate or minimise the risk, 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 Tachifene. 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	Safety during the first 6 months of pregnancy and breastfeeding

II.B Summary of important risks

Missing information: Safety during the first 6 months of pregnancy and breast-feeding	
Risk minimisation measures	<u>Routine risk minimization measures:</u> <ul style="list-style-type: none"> SmPC section 4.6. PL section 2. <u>Additional risk minimization measures:</u> None
Additional pharmacovigilance activities	<u>Additional pharmacovigilance activities:</u> None

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 authorization or specific obligation of Tachifene.

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

There are no studies required for Tachifene.