

Part VI: Summary of the risk management plan

Summary of risk management plan for TIBOLONE GEDEON RICHTER (Tibolone 2.5 mg tablets)

This is a summary of the risk management plan (RMP) for TIBOLONE GEDEON RICHTER 2.5 mg tablets. The RMP details important risks of TIBOLONE GEDEON RICHTER 2.5 mg tablets, and how more information will be obtained about TIBOLONE GEDEON RICHTER 2.5 mg tablets's risks and uncertainties (missing information).

TIBOLONE GEDEON RICHTER 2.5 mg tablets summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how TIBOLONE GEDEON RICHTER 2.5 mg tablets should be used.

I. The medicine and what it is used for

TIBOLONE GEDEON RICHTER 2.5 mg (see SmPC for the full indication) is indicated in the treatment of oestrogen deficiency symptoms in postmenopausal women, more than one year after menopause. It contains Tibolone as the active substance and it is given by oral route of administration, as a tablet.

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

Important risks of TIBOLONE GEDEON RICHTER 2.5 mg tablets, together with measures to minimise such 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 TIBOLONE GEDEON RICHTER 2.5 mg tablets 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 TIBOLONE GEDEON RICHTER 2.5 mg tablets. 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);

Summary of safety concerns	
Important identified risks	Endometrial cancer
	Breast cancer
	Stroke
Important potential risks	Ovarian cancer
	Venous thromboembolic events
Missing information	None

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

II.C.1 Studies which are conditions of the marketing authorisation

There are no studies required for TIBOLONE GEDEON RICHTER 2.5 mg tablets.