13 Part VI: Summary of the risk management plan for Tibolone, 2.5 mg, Tablet

This is a summary of the risk management plan (RMP) for tibolone, 2.5 mg, tablet. The RMP details important risks of tibolone, tablet, how these risks can be minimized, and how more information will be obtained about tibolone, tablet's risks and uncertainties (missing information).

Tibolone, tablet's summary of product characteristics (SmPCs) and its package leaflet (PLs) give essential information to healthcare professionals (HCPs) and patients on how tibolone, tablet should be used.

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

13.1 Part VI: I. The medicine and what it is used for

Tibolone, tablet is authorized for:

ES/H/0224/001/R/001

- The treatment of estrogen deficiency symptoms in women more than one year after the menopause.

For all women the decision to prescribe tibolone should be based on an assessment of the individual patient’s overall risks and, particularly in the over 60s, should include consideration of the risk of stroke.

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- Treatment of estrogen deficiency symptoms in women postmenopausal more than one year after the menopause
- Prevention of osteoporosis in postmenopausal women at high risk of future fractures who are intolerant of, or contraindicated for, other medicinal products approved for the prevention of osteoporosis.

For all women the decision to prescribe tibolone should be based on an assessment of the individual patient’s overall risks and, particularly in the over 60’s, should include consideration of the risk of stroke.

It contains tibolone as an active substance and is given by oral route in the form of tablet (2.5 mg).

13.2 Part VI: II. Risks associated with the medicine and activities to minimize or further characterize the risks

Important risks of tibolone, tablet together with measures to minimize such risks and the proposed studies for learning more about tibolone tablet’s risks, are outlined below.

Measures to minimize the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the PLs and SmPCs addressed to patients and HCPs;
- Important advice on the medicine’s packaging;

- The authorized 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 minimize its risks.

Together, these measures constitute *routine risk minimization* measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analyzed, so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

13.2.1 Part VI – II.A: List of important risks and missing information

Important risks of tibolone, tablet are risks that need special risk management activities to further investigate or minimize 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 tibolone, tablet. 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).

Table 13-1 List of important risks and missing information

List of important risks and missing information	
Important identified risks	Breast cancer
	Endometrial cancer
	Stroke
Important potential risks	Coronary arterial disease
	Venous thromboembolism (VTE)
	Ovarian cancer
Missing information	None

13.2.2 Part VI – II.B: Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

13.2.3 Part VI – II.C: Post-authorization development plan

13.2.3.1 II.C.1 Studies which are conditions of the marketing authorization

There are no studies which are conditions of the marketing authorization or specific obligation of tibolone, tablet.

13.2.3.2 II.C.2. Other studies in post-authorization development plan

There are no studies required for tibolone, tablet.