
Part VI: Summary of the risk management plan

Summary of risk management plan for Estradiol Besins 1 mg & 2 mg film-coated tablets (Estradiol)

This is a summary of the risk management plan (RMP) for estradiol. The RMP details important risks of Estradiol Besins 1 mg & 2 mg film-coated tablets (Estradiol Besins), how these risks can be minimised, and how more information will be obtained about estradiol's risks and uncertainties (missing information).

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

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

I. The medicine and what it is used for

Estradiol Besins is indicated for:

- Hormone Replacement Therapy (HRT) for oestrogen deficiency symptoms in postmenopausal women. (1mg and 2mg)
- 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. (2mg)

Estradiol Besins is particularly for women who have been hysterectomised and therefore do not require combined oestrogen/progestagen therapy. In women with an intact uterus this medicinal product has to be combined with a suitable progestogen.

The experience treating women older than 65 years is limited.

It contains estradiol as the active substance, and it is given by oral route of administration of 1 and 2 mg film-coated tablets.

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

Important risks of Estradiol Besins, together with measures to minimise such risks and the proposed studies for learning more about estradiol'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*.

II.A List of important risks and missing information

Important risks of Estradiol Besins 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 estradiol. 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	• 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 which are conditions of the marketing authorisation or specific obligation of Estradiol Besins.

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

There are no studies required for Estradiol Besins.