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RISK MANAGEMENT PLAN (RMP) SUMMARY

OBGEMSA (Vibegron)

Filmtabletten

Based on EU-RMP v. 0.5
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DISCLAIMER

The Risk Management Plan (RMP) is a comprehensive document submitted as part of the application dossier for market approval of a medicine. The RMP summary contains information on the medicine's safety profile and explains the measures that are taken in order to further investigate and follow the risks as well as to prevent or minimise them.
The RMP summary of Obgemsa is a concise document and does not claim to be exhaustive.
As the RMP is an international document, the summary might differ from the "Arzneimittelinformation / Information sur le médicament" approved and published in Switzerland, e.g. by mentioning risks occurring in populations or indications not included in the Swiss authorization.
Please note that the reference document which is valid and relevant for the effective and safe use of Obgemsa in Switzerland is the "Arzneimittelinformation/ Information sur le médicament" (see www.swissmedic.ch) approved and authorized by Swissmedic. Pierre Fabre Pharma AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of Obgemsa.

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Summary of risk management plan for Obgemsa (vibegron)

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

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

This summary of the RMP for Obgemsa should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

Important new concerns or changes to the current ones will be included in updates of Obgemsa RMP.

I. The medicine and what it is used for

Obgemsa is authorised for symptomatic treatment of adult patients with overactive bladder (OAB) syndrome (see SmPC for the full indication). It contains vibegron as the active substance and is intended for oral administration.

Further information about the evaluation of Obgemsa benefits can be found in Obgemsa EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage <link to the EPAR summary>.

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

Important risks of Obgemsa, together with measures to minimise such risks and the proposed studies for learning more about Obgemsa 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, 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 Obgemsa are risks that need special risk management activities to further investigate or minimise 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 Obgemsa. 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	Embryo-foetal toxicity
Missing information	None

II.B Summary of important risks

Important identified risk	None
Important potential risk: Embryo-foetal toxicity	
Evidence for linking the risk to the medicine	No adequate and well-controlled clinical studies have been conducted in pregnant women. Data in in rabbits have shown embryo-foetal toxicity at high doses; delayed foetal skeletal ossification and reduced foetal body weights were observed in rabbits at approximately 898-fold clinical exposure (AUC). Although the safety margin for embryo-toxicity in the rabbit based on the NOAEL of 100 mg/kg/day was 285-fold greater than clinical exposure at the recommended daily dose of vibegron, embryo-foetal toxicity is considered as a potential risk in humans because of the 9-times lower potency of vibegron to the β3-AR for rabbits when compared to humans. There is a potential for human embryo-foetal toxicity due to vibegron, hence embryo-foetal toxicity is considered as an important potential risk.
Risk factors and risk groups	Female patients of child-bearing potential and developing foetuses who are exposed to vibegron during gestation.
Risk minimisation measures	Routine risk minimisation measures: - SmPC section 4.6 and section 5.3: - PL section 2 Additional risk minimisation measures: None.
Missing information	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 authorisation or specific obligation of Obgemsa.

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

There are no studies required for Obgemsa.