

## Summary of risk management plan for Orlistat (Alli®)

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

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

This summary of the RMP for Alli® should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all of 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 Alli®'s RMP.

### I. The medicine and what it is used for

Alli® is authorised in the EU for weight loss in adults who are overweight (body mass index, BMI,  $\geq 28 \text{ kg/m}^2$ ). The product should be used in conjunction with a mildly hypocaloric, low fat diet. (see SmPC for the full indication). It contains Orlistat as the active substance and it is given by mouth.

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

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

Important risks of Alli®, together with measures to minimize such risks and the proposed studies for learning more about Alli®'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 package leaflet and SPC addressed to patients and healthcare professionals;
- important advice on the medicine's packaging;
- the authorized pack size — the amount of medicine in a pack is chosen so as 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 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 Alli® 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 Alli®. 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);

Currently, there are no important, potential risks or missing information that require additional pharmacovigilance activities (beyond routine practices).

## **II.B Summary of important risks**

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

## **II.C Post-authorization development plan**

### **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 Alli®.

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

There are no studies required for Alli®.