

**JARDIANCE MET (Empagliflozin Metformin)  
Filmtabletten  
ZL-Nr.: 65570**

*Public Risk Management Plan (RMP) Summary*

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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 Jardiance Met 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 Jardiance Met in Switzerland is the “Arzneimittelinformation/ Information sur le médicament” (see [www.swissmedic.ch](http://www.swissmedic.ch)) approved and authorized by Swissmedic.

Boehringer Ingelheim (Schweiz) GmbH is fully responsible for the accuracy and correctness of the content of the published summary RMP of Jardiance Met.

## **PART VI                    SUMMARY OF THE RISK MANAGEMENT PLAN**

## **SUMMARY OF RISK MANAGEMENT PLAN FOR SYNJARDY (EMPAGLIFLOZIN+METFORMIN)**

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

Synjardy's Summary of Product Characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Synjardy should be used.

This summary of the RMP for Synjardy 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 Synjardy's RMP.

### **I. THE MEDICINE AND WHAT IT IS USED FOR**

Synjardy is authorised the treatment of adults with insufficiently controlled type 2 diabetes mellitus (see SmPC for the full indication). It contains empagliflozin and metformin as the active substances and it is given by oral administration.

Further information about the evaluation of Synjardy's benefits can be found in Synjardy'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 MINIMISE OR FURTHER CHARACTERISE THE RISKS**

Important risks of Synjardy, together with measures to minimise such risks and the proposed studies for learning more about Synjardy'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, including PSUR assessment so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

If important information that may affect the safe use of Synjardy is not yet available, it is listed under ‘missing information’ below.

## **II.A List of important risks and missing information**

Important risks of Synjardy 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 Synjardy. 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**

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Important identified risks	Lactic acidosis <sup>1</sup>
Important potential risks	Urinary tract carcinogenicity <sup>2</sup> Pancreatitis <sup>2</sup>
Missing information	None

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<sup>1</sup> Safety concern derived from the mono compound metformin

<sup>2</sup> Safety concern derived from the mono compound empagliflozin

## **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 Synjardy.

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

#### **PASS 1245-0097**

Purpose of the study: To evaluate the risk of renal and bladder cancer in empagliflozin-treated patients, compared to users of other antidiabetic treatment

## **ABBREVIATIONS**

EMA	European Medicine Agency
EPAR	European Public Assessment Report
PASS	Post-authorisation safety study
PSUR	Periodic Safety Update Report
RMP	Risk Management Plan
SmPC	Summary of Product Characteristics
T2DM	Type 2 diabetes mellitus