TRAJENTA (Linagliptin)

Filmtabletten
ZL-Nr.: 61893

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 Trajenta 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 Trajenta in Switzerland is the “Arzneimittelinformation/ Information sur le médicament” (see 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 Trajenta.

PART VI SUMMARY OF THE RISK MANAGEMENT PLAN

SUMMARY OF RISK MANAGEMENT PLAN FOR TRAJENTA AND JENTADUETO (LINAGLIPTIN AND LINAGLIPTIN / METFORMIN)

This is a summary of the Risk Management Plan (RMP) for Trajenta and Jentadueto. There are no important risks or missing information topics for Trajenta or Jentadueto.

The Summaries of Product Characteristics (SmPCs) for Trajenta and Jentadueto and their package leaflets give essential information to healthcare professionals and patients on how Trajenta and Jentadueto should be used.

This summary of the RMP for Trajenta and Jentadueto should be read in the context of all the 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 will be included in updates of the Trajenta and Jentadueto RMP.

I. THE MEDICINE AND WHAT IT IS USED FOR

Trajenta and Jentadueto are authorised for Type 2 diabetes mellitus (see SmPCs for the full indications). Both medicines contain linagliptin as the active substance and in addition, Jentadueto contains metformin. Both Trajenta and Jentadueto are given orally.

Further information about the evaluation of benefits of these medicines can be found in the EPARs for Trajenta and Jentadueto, including plain-language summaries, 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

There are no important risks or missing information topics for Trajenta or Jentadueto.

ABBREVIATIONS

EMA	European Medicines Agency
EPAR	European Public Assessment Report
RMP	Risk Management Plan
SmPC	Summary of Product Characteristics
T2DM	Type 2 diabetes mellitus