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Swiss Summary of the Risk Management Plan (RMP) for Kanjinti® (trastuzumab biosimilar)

RMP Summary: Version 1, January 2020
EU RMP: Version 0.4, January 2018

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 KANJINTI® 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 KAMJINTI® in Switzerland is the "Arzneimittelinformation/ Information sur le médicament" (see www.swissmedic.ch) approved and authorized by Swissmedic.

AMGEN Switzerland AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of KANJINTI®.

The medicine and what it is used for

KANJINTI® is authorized for metastatic breast cancer, early breast cancer and metastatic gastric carcinoma or carcinoma of the gastroesophageal junction.
It contains trastuzumab as the active substance and it is given by intravenous infusion.

Further information about the evaluation of KANJINTI®'s benefits can be found in KANJINTI®'s EPAR, including in its plain-language summary, available on the European Medicines Agency (EMA) website, under the medicine's webpage: https://www.ema.europa.eu/medicines/human/EPAR/KANJINTI.

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

Important risks of KANJINTI®, together with measures to minimize such risks and the proposed studies for learning more about KANJINTI®'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 SmPC 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 to ensure that the medicine is used correctly;
- The medicine's legal status — the way a medicine is supplied to the public (eg, with or without prescription) can help to minimizes its risks.

Together, these measures constitute routine risk minimization measures.

In the case of KANJINTI®, these measures are supplemented with additional risk minimization measures mentioned under relevant risks, below.
In addition to these measures, information about adverse events is collected continuously and regularly analyzed including periodic safety update report (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 KANJINTI® is not yet available, it is listed under 'missing information' below.

Summary of safety concerns

List of important risks and missing information

Important Identified Risk	Cardiac dysfunction
	Administration-related reactions (ARRs)
	Hematotoxicity
	Oligohydramnios
	Pulmonary disorders

Important Potential Risk	Infections Medication errors (eg, reduced efficacy due to SC administration of IV formulation; increased adverse events due to incorrect dose, method, or route of administration)
Missing Information	Treatment of male breast cancer patients Safety of 75 mg/m^2 versus 100 mg/m^2 docetaxel dose

Summary of Risk Minimization Measures

Safety Concern	Routine Risk Minimization Measures	Additional Risk Minimization Measures
Important Identified Risk		
Cardiac dysfunction	Relevant text is provided in the following sections of the KANJINTI® SmPC: • Section Special warnings and precautions for use • Section Undesirable effects • Section Pharmacodynamic properties	None
Administration-related reactions (ARRs)	Relevant text is provided in the following sections of the KANJINTI® SmPC: • Section Posology and method of administration • Section Contraindications • Section Special warnings and precautions for use • Section Effects on ability to drive and use machines • Section Undesirable effects	None
Hematotoxicity	Relevant text is provided in the following sections of the KANJINTI® SmPC: • Section Undesirable effects	None
Oligohydramnios	Relevant text is provided in the following sections of the KANJINTI® SmPC: • Section Fertility, pregnancy and lactation • Section Undesirable effects	None
Pulmonary disorder	Relevant text is provided in the following sections of the KANJINTI® SmPC: • Section Contraindications • Section Special warnings and precautions for use • Section Undesirable effects	None

Safety Concern	Routine Risk Minimization Measures	Additional Risk Minimization Measures
Important Potential Risk		
Infections	Relevant text is provided in the following sections of the KANJINTI® SmPC: • Section Undesirable effects	None
Medication errors (eg, reduced efficacy due to SC administration of IV formulation; increased adverse events due to incorrect dose, method, or route of administration)	Relevant text is provided in the following sections of the KANJINTI® SmPC: • Section Posology and method of administration	None
Missing Information		
Treatment of male breast cancer patients	Relevant text is provided in the following sections of the KANJINTI® SmPC: • Section Interaction with other medicinal products and other forms of interaction • Section Preclinical safety data	None
Safety of 75 mg/m2 versus 100 mg/m2 docetaxel dose	None	None

Post-authorisation development plan

Studies which are a condition of the marketing authorisation

There are no studies which are conditions of the marketing authorization or specific obligation of KANJINTI®.

This summary was generated in January 2020