NOVARTIS

Regulatory Affairs

Tyverb®

Summary of the EU Safety Risk Management Plan

Active substance(s) (INN or common name):	Lapatinib
Product(s) concerned (brand name(s)):	Tyverb
Document status:	Final
Version number of the RMP Public Summary:	37.0
Date of final sign off of the RMP Public Summary	31.01.2023

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 “Tyverb” 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 “Tyverb” in Switzerland is the “Arzneimittelinformation/ Information sur le médicament” (see www.swissmedic.ch) approved and authorized by Swissmedic. Novartis Pharma Schweiz AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of “Tyverb”.

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This is a summary of the RMP for Tyverb. The RMP details important risks of Tyverb, how these risks can be minimized, and how more information will be obtained about Tyverb risks and uncertainties (missing information).
Tyverb's NPIand its package leaflet give essential information to healthcare professionals and patients on how Tyverb should be used.
This summary of the RMP for Tyverb 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 Tyverb's RMP

I. The medicine and what it is used for
Tyverb contains lapatinib as the active substance and it is used for in the following indications:
Tyverb is indicated for the treatment of adult patients with breast cancer, whose tumours overexpress HER2 (ErbB2);

- In combination with capecitabine for patients with advanced or metastatic disease with progression following prior therapy, which must have included anthracyclines and taxanes and therapy with trastuzumab in the metastatic setting.
- In combination with trastuzumab for patients with hormone receptor-negative metastatic disease that has progressed on prior trastuzumab therapy (ies) in combination with chemotherapy.
- In combination with an aromatase inhibitor for postmenopausal women with hormone receptor positive metastatic disease, not currently intended for chemotherapy.
- Additional details on the approved indications are available in the NPI.

Route of administration, pharmaceutical forms and strengths:

- Tyverb is available as 250 mg film-coated tablets

Additional details are available in the NPI.
Further information about the evaluation of Tyverb’s benefits can be found in Tyverb’s EPAR, including in its plain-language summary, available on the EMA website, under the medicine’s webpage: link to product’s EPAR summary landing pageon the EMA webpage:
https://www.ema.europa.eu/en/medicines/human/EPAR/tyverb..

II. Risks associated with the medicine and activities to minimize or further characterize the risks
Important risks of Tyverb, together with measures to minimize such risks and the proposedstudies for learning more about Tyverb'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 NPI 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 minimize its risks.

Together, these measures constitute routine risk minimization measures.
In addition to these measures, information about adverse reactions is collected continuously andregularly analysed, including PSUR, so that immediate action can be taken as necessary. These measures constitute routine PhV activities.
If important information that may affect the safe use of Tyverb is not yet available, it is listed under ‘missing information’ below.

II.A: List of important risks and missing information

Important risks of Tyverb 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 Tyverb. 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).

Table 13-1 List of important risks and missing information

Important identified risks	None
Important potential risks	None
Missing information	Pregnant or lactating females

II B: Summary of important risks

There are no important identified or potential risks for Tyverb.

Table 13-2 Important missing information: Pregnant or lactating females

Risk minimization measures	**Routine risk minimization measures** Section 4.6 of the SmPC. **Additional risk minimization measures** None

II C: Post-authorization development plan

II.C.1 Studies which are conditions of the marketing authorization

None

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

None