AstraZeneca	AZ Swiss Marketing Company

Truqap®

160 mg and 200 mg, film-coated tablets

Summary of the Risk Management Plan (RMP) for Truqap® (Capivasertib)

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Disclaimer:

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 Truqap® 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 Truqap® in Switzerland is the “Arzneimittelinformation / Information sur le médicament” (see www.swissmedicinfo.ch) approved and authorized by Swissmedic. AstraZeneca AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of Truqap®.

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

TRUQAP's Summary of Product Characteristics (SmPC) and its Package Leaflet (PL) give essential information to healthcare professionals and patients on how TRUQAP should be used.

This summary of the RMP for TRUQAP 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 Swiss Public Assessment Report (SwissPAR).

Important new concerns or changes to the current ones will be included in updates of the TRUQAP RMP.

1. THE MEDICINE AND WHAT IT IS USED FOR

TRUQAP is authorised in combination with fulvestrant for the treatment of adult female patients with hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2) negative locally advanced or metastatic breast cancer with one or more PIK3CA/AKT1/PTEN alterations following recurrence or progression on or after an endocrine-based regimen.

It contains capivasertib as the active substance and it is given as two 200 mg tablets taken orally twice daily. The 160 mg tablets can be used to reduce the dose in the event of side effects.

Further information about the evaluation of TRUQAP's benefits can be found in TRUQAP's SwissPAR, including in its plain-language summary, available on the Swissmedic website.

2. RISKS ASSOCIATED WITH THE MEDICINE AND ACTIVITIES TO MINIMISE OR FURTHER CHARACTERISE THE RISKS

Important risks of TRUQAP, together with measures to minimise such risks and the proposed studies for learning more about the risks of TRUQAP, 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 PL 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 (eg, 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 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 TRUQAP is not yet available, it is listed under *missing information* below.

2.1 List of important risks and missing information

Important risks of TRUQAP 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 TRUQAP. 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 (eg, on the long-term use of the medicine).

Table 1 List of Important Risks and Missing Information

Important identified risks	none
Important potential risks	• Complications of hyperglycaemia
Missing Information	• Safety in patients with type 1 and type 2 diabetes (requiring insulin treatment, or HbA1c ≥ 8.0%) • Use in patients with clinically important abnormalities in cardiac rhythm (eg, QT prolongation)

2.2 Summary of important risks

Table 1 Important Potential Risk: Complication of hyperglycaemia

Evidence for linking the risk to the medicine	Rare occurrences of complications due to hyperglycaemia have been reported in the TRUQAP clinical development programme.
Risk factors and risk groups	No specific risk factors for the development of complications of hyperglycaemia in TRUQAP-treated patients have been identified. However, high-risk patients (eg, those with a medical history of type 1 or 2 diabetes, concurrent infections, those receiving concomitant systemic corticosteroids, or other conditions requiring more intensified glycaemia management) may be at greater risk of experiencing hyperglycaemia leading to complications.

Table 1 Important Potential Risk: Complication of hyperglycaemia

Evidence for linking the risk to the medicine	Rare occurrences of complications due to hyperglycaemia have been reported in the TRUQAP clinical development programme.
Risk minimisation measures	**Routine risk minimisation measures:** • SmPC Section ”Warnings and Precautions” • PL Section ”When is caution required when using TRUQAP?” • Prescription-only medicine **Additional risk minimisation measures:** • No additional risk minimisation measures.

Table 2 Missing Information: Safety in patients with type 1 and type 2 diabetes (requiring insulin treatment, or HbA1c ≥ 8.0%)

Risk minimisation measures	**Routine risk minimisation measures:** • SmPC Section ”Warnings and Precautions” • PL Section ”When is caution required when using TRUQAP?” **Additional risk minimisation measures:** • No additional risk minimisation measures.
Additional pharmacovigilance activities	**Additional pharmacovigilance activities:** • A database study of the safety and effectiveness of TRUQAP (capivasertib) + fulvestrant in patients with advanced breast cancer and type 1 or type 2 diabetes

Table 4 Missing Information: Use in patients with clinically important abnormalities in cardiac rhythm (eg, QT prolongation)

Risk minimisation measures	**Routine risk minimisation measures:** • No routine risk minimisation measures. **Additional risk minimisation measures:** • No additional risk minimisation measures.

3. POST-AUTHORISATION DEVELOPMENT PLAN

3.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of capivasertib.

3.2 Other studies in post-authorisation development plan

Other studies in the post authorisation development plan are as follows:

- **A database study of the safety and effectiveness of TRUQAP plus fulvestrant in advanced breast cancer patients with type 1 or type 2 diabetes**
  - *Purpose of the study:* The rationale for this study is to address the lack of efficacy and safety data for patients with insulin-dependent or uncontrolled diabetes (assessed as a baseline HbA1c ≥ 8.0%), given the exclusion of these patients from the pivotal CAPItello-291 study. This gap is particularly relevant as a key safety concern for TRUQAP is complications of hyperglycaemia (such as diabetic ketoacidosis), for which the baseline risk is elevated in diabetic patients.
    The primary objective of this non-interventional post-authorisation study is to assess the effectiveness and safety of TRUQAP + fulvestrant in patients with advanced breast cancer and diabetes (type 1 or type 2; insulin- or non-insulin-dependent) who have received prior endocrine treatment.