Truqap

Procedural steps taken and scientific information after the authorisation*

*Due to the Agency`s update of its procedure management systems, an additional document, reflecting the historical lifecycle may be available in the 'Assessment history' section. For the complete product lifecycle procedures, you may need to also refer to **EPAR - Procedural steps taken and scientific information after authorisation (archive)**.

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued[2] / amended on	Product Information affected[3]	Summary
Variation type II /	C.I HUMAN AND VETERINARY MEDICINAL	24/07/2025		SmPC and PL	Section 4.4 Special warnings and precautions for

[1] Notifications are issued for type I variations and Article 61(3) notifications (unless part of a group including a type II variation or extension application or a worksharing application). Opinions are issued for all other procedures.
[2] A Commission decision (CD) is issued for procedures that affect the terms of the marketing authorisation (e.g. summary of product characteristics, annex II, labelling, package leaflet). The CD is issued within two months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within one year for other procedures.
[3] SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

EMA/VR/0000272181	PRODUCTS - C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data - Accepted Update of sections 4.4 and 4.8 of the SmPC to amend the current wording pertaining to the adverse drug reaction (ADR) 'hyperglyceamia', update of section 4.8 of the SmPC to add 'Weight Decreased' as a new adverse drug reaction (ADR) with a frequency 'common' as well as to add footnotes in table 8 for the following ADRs: 'Hypokalaemia', 'Diabetic ketoacidosis' and 'Pyrexia', based on the MAH's Core Data Sheet update . The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor formatting changes to the PI as well as to update the list of local representatives in the Package Leaflet.				use Hyperglycaemia The safety and efficacy of TRUQAP in patients with pre existing Type 1 diabetes or Type 2 diabetes requiring insulin and/or in patients with HbA1C > 8.0% (63.9 mmol/mol) has not been studied as these patients were excluded from the phase III clinical study. This study included 21 (5.9%) patients in the TRUQAP plus fulvestrant arm with HbA1C ≥ 6.5%. Hyperglycaemia was more frequently reported in patients with a baseline HbA1C ≥ 6.5% (33.3% of patients) than those with a baseline HbA1C < 6.5% (16.0%). Section 4.8 Undesirable effects Summary of safety profile […] The most common adverse reactions were diarrhoea (72.4%), rash (40.3%), nausea (34.6%), fatigue (32.1%), vomiting (20.6%), stomatitis (17.2%), hyperglycaemia (17.2%), headache (16.9%) and decreased appetite (16.6%). […] Serious adverse reactions were seen in 7.0% of patients receiving TRUQAP plus fulvestrant. Most common serious adverse reactions reported in patients receiving TRUQAP plus fulvestrant included rash (2.3%), diarrhoea (1.7%) and vomiting (1.1%). […] Treatment discontinuation due to adverse reactions occurred in 9.9% of patients. The most common adverse reactions leading to treatment discontinuation were rash (4.5%), diarrhoea (2%) and vomiting (2%). […] Description of selected adverse reactions Hyperglycaemia Hyperglycaemia of any grade occurred in 61 (17.2%) patients and grade 3 or 4 occurred in 8 (2.3%) patients receiving TRUQAP. The median time to first occurrence of

					hyperglycaemia was 15 days (range: 1 to 367). In the study, dose reduction was required in 2 (0.60%) patients and 1 (0.30%) patient discontinued treatment due to hyperglycaemia. In the 61 patients with hyperglycaemia, 29 (47.5%) patients were treated using anti-hyperglycaemic medication (including insulin in 16.4%). See section 4.4. For more information, please refer to the Summary of Product Characteristics.
PSUR/EMA/PSUR/0000248507	Periodic Safety Update EU Single assessment - capivasertib	05/06/2025	n/a		Maintenance