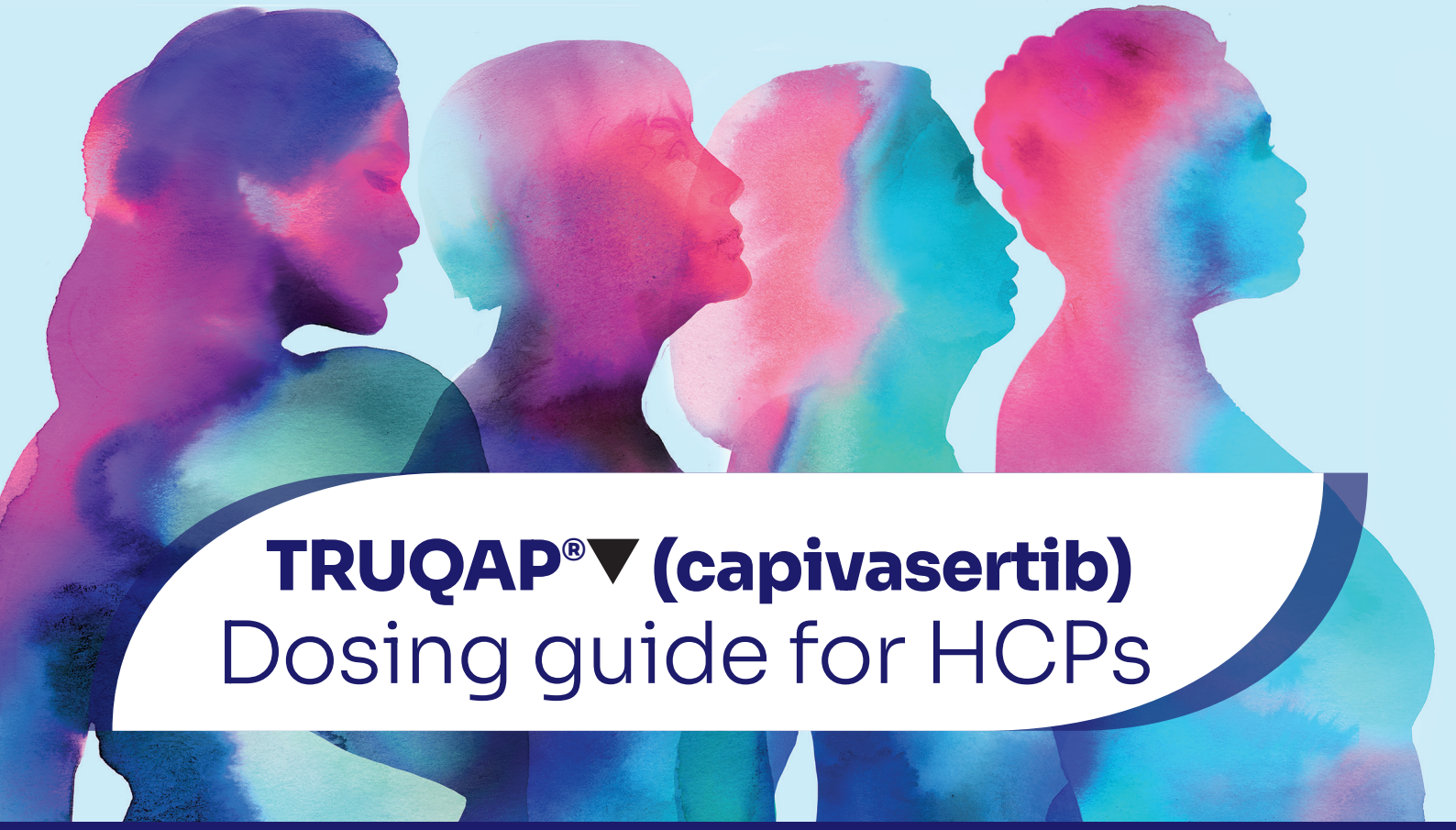
Truqap® capivasertib
160 mg • 200 mg tablets

In combination with fulvestrant for your eligible patients with HR+/HER2– aBC with one or more *PIK3CA/AKT1/PTEN* alterations[1]

For Prescribing Information, click or scan the QR codes on the last page



TRUQAP® (capivasertib) Dosing guide for HCPs

A guide to dosing, modifications and adverse reaction management

An intermittent dosing schedule[1,2]

Please refer to the Summary of Product Characteristics for both TRUQAP and fulvestrant for full guidance prior to prescribing.

Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk or search for MHRA Yellow Card in Google Play or Apple App store. Adverse events should also be reported to AstraZeneca by visiting https://contactazmedical.astrazeneca.com or by calling 0800 783 0033.

INDICATION

TRUQAP is indicated in combination with fulvestrant for the treatment of adult patients with hormone receptor (HR) positive human epidermal growth factor receptor 2 (HER2) negative (defined as IHC 0 or 1+, or IHC 2+/ISH-) 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.[1]

This material has been created and funded by AstraZeneca and is intended for HCPs in the UK only.

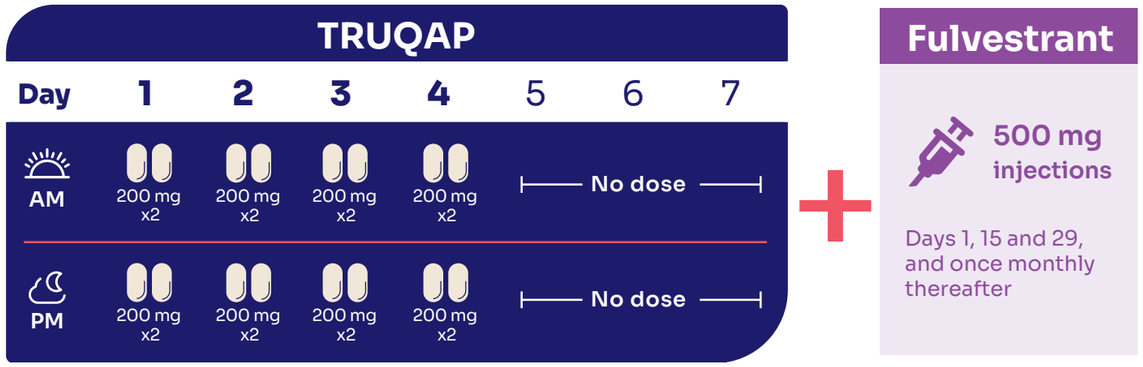
aBC, advanced breast cancer; *AKT1*, serine/threonine protein kinase 1; HER2, human epidermal growth factor receptor 2; HR, hormone receptor; IHC, immunohistochemistry; ISH, *in situ* hybridisation; *PIK3CA*, phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha; *PTEN*, phosphatase and tensin homolog.

GB-68383 | August 2025

TRUQAP dosing

TRUQAP in combination with fulvestrant has an intermittent weekly dosing schedule[1]

The recommended dose is 400 mg twice daily, with doses approximately 12 hours apart, **4 days on and 3 days off**.[1]



Adapted from TRUQAP SmPC.[1]

Please refer to the fulvestrant SmPC for more information.

- In pre- and perimenopausal women, TRUQAP plus fulvestrant should be combined with a luteinising hormone releasing hormone (LHRH) agonist. For men, consider administering a LHRH agonist according to current clinical practice standards[1]

Practical considerations

The recommended dose of TRUQAP is 400 mg taken orally, twice daily, approximately 12 hours apart[1]

TRUQAP can be taken with or without food[1]

500 mg of fulvestrant is administered on days 1, 15 and 29, and once monthly thereafter[1]

TRUQAP should be swallowed whole with water.
Tablets should not be chewed, crushed, dissolved or divided. No tablet should be ingested if it is broken, cracked or otherwise not intact[1]

The dose of TRUQAP should be reduced when concomitantly used with strong or moderate CYP3A4 inhibitors[1]

Patients should limit their grapefruit intake to no more than half a grapefruit, a small glass of grapefruit juice (approximately 125 mL) or 2 teaspoons of orange marmalade daily[2]

CYP3A4, cytochrome P450 family 3 subfamily A member 4.

Assessing your patients before treatment

If your patient is eligible for TRUQAP, schedule an evaluation to determine whether the treatment is appropriate for them.

Characteristic	Potential treatment impact
Diabetes and hyperglycaemia	▪ Patients with a history of diabetes mellitus may require intensified anti-diabetic treatment and should be closely monitored[1] ▪ The safety and efficacy of TRUQAP in patients with pre-existing diabetes requiring insulin and/or in patients with HbA1c > 8.0% (63.9 mmol/mol) has not been studied[1] ▪ Diabetic ketoacidosis (DKA) can occur at any time during treatment with TRUQAP. In CAPItello-291, DKA developed in <10 days in some reported cases[1] ▪ Consultation with a diabetologist or an HCP experienced in the treatment of hyperglycaemia is recommended for patients with diabetes[1]
Renal and hepatic impairment	▪ TRUQAP is not recommended for patients with severe renal or severe hepatic impairment, as safety and pharmacokinetics have not been studied in these patients[1] ▪ No dose adjustments are required for patients with mild-to-moderate renal impairment or mild hepatic impairment[1] ▪ In patients with moderate hepatic impairment, TRUQAP should be administered only if the benefit outweighs the risk and patients should be monitored closely for adverse effects[1]
Pregnancy, breastfeeding and contraception	▪ TRUQAP should not be taken by patients who are pregnant or breastfeeding and is not recommended in patients of childbearing potential not using contraception[1] ▪ Patients should be advised to use effective contraception during and after completion of treatment with TRUQAP: at least 4 weeks after the last dose for women and 16 weeks after the last dose for men[1]
Receiving bisphosphonates or RANK-ligand inhibitors	▪ Patients with metastatic cancer receiving bisphosphonates or RANK-ligand inhibitors, prior to or during treatment with TRUQAP, should be closely monitored for signs and symptoms of jaw osteonecrosis. It is recommended to advise patients to report any new or worsening oral symptoms promptly[1]

Assessing your patient can help determine if they may be eligible for or require additional monitoring with TRUQAP. Refer to the SmPC for full guidance on special warnings and AEs before prescribing

AE, adverse event; HbA1c, glycated haemoglobin; HCP, healthcare professional; RANK, receptor activator of NF-κB; ULN, upper limit of normal.

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Monitoring patients on TRUQAP

Monitoring patients can help effectively address AEs[1]

Early monitoring can help ensure dose adjustments or changes are made to manage adverse drug reactions (see Dose Management Guidance). The special warnings and precautions listed in the SmPC include hyperglycaemia, diarrhoea and cutaneous adverse drug reactions (CADRS) and co-administration with bisphosphonates or RANK-ligand inhibitors.

All patients must be monitored prior to and during treatment with TRUQAP

Recommended schedule for monitoring hyperglycaemia[1]

At screening, prior to starting TRUQAP

After initiation of TRUQAP

Test for FG levels
Test for HbA1c
Optimise the patient's level of blood glucose

Inform patients about the potential for hyperglycaemia and instruct them to immediately contact their HCP if any symptoms of hyperglycaemia occur

Frequency of FG testing	FG testing schedule during first dosing week	Frequency of HbA1c testing
All patients treated with TRUQAP* **Weeks** **1** **2** **4** **6** **8** **Monthly thereafter**	**Day** 1 2 3 4 5 6 7 **TRUQAP dose** ✓ ✓ ✓ ✓ ← No dose → **FG test** ⊕ (Day 3 or 4) Test FG **pre-dose on day 3 or 4 of dosing week**	Test for HbA1c **every 3 months**
Patients with diabetes treated with TRUQAP **Weeks** **1** **2** **4** **6** **8** + **1** **2** **Daily for first 2 weeks**	**Day** 1 2 3 4 5 6 7 **TRUQAP dose** ✓ ✓ ✓ ✓ ← No dose → **FG test** ⊕ ⊕ ⊕ ⊕ ⊕ ⊕ ⊕ Monitor/self-monitor FG daily **for the first 2 weeks of treatment** After 2 weeks, continue to **monitor FG as frequently as needed** to manage hyperglycaemia according to the instructions of an HCP†	Additional HbA1c test **recommended at week 4‡** Test for HbA1c **every 3 months**

*Additional FG monitoring/self-monitoring may be required more frequently in the **first 4 weeks** and **especially within the first 2 weeks of treatment**, according to the instructions of an HCP; †All FG monitoring should be performed at the physician's discretion as clinically indicated; ‡Additional HbA1c testing is recommended at week 4 in patients with diabetes, pre-diabetes, or hyperglycaemia at baseline

If hyperglycaemia develops after treatment initiation

- Monitor FG as clinically indicated **(at least twice weekly, i.e. on days on and off TRUQAP)** until FG decreases to baseline levels**
- Consider consultation with an HCP experienced in the treatment of hyperglycaemia
- Based on the severity of hyperglycaemia, TRUQAP dosing may be interrupted, reduced or permanently discontinued
- During treatment with anti-diabetic medication, monitor FG at least **once a week for 2 months, followed by once every 2 weeks or as clinically indicated****

**Recommended to test FG pre-dose at day 3 or 4 of dosing week

AE, adverse event; FG, fasting glucose; HbA1c, glycated haemoglobin; HCP, healthcare professional; RANK, receptor activator of nuclear factor kappa-b.

SmPC guidance

More frequent FG testing is required in patients with:[1]

- Medical history of diabetes mellitus or baseline risk factors for DKA
- FG >ULN 8.9mmol/L (>ULN 160 mg/dL) during treatment without prior history of diabetes mellitus
- Concomitant use of corticosteroids
- Intercurrent infections
- Other conditions that may require intensified glycaemia management to prevent worsening of impaired glucose metabolism and potential complications, **such as DKA**

Additional monitoring of ketones (preferably in blood) and other metabolic parameters (as indicated) is recommended when a patient experiences hyperglycaemia[1]

Monitoring other adverse reactions[1]

Adverse reaction	Recommendations[1]
CADRs	▪ Monitor for signs and symptoms of rash or dermatitis at each visit. Early consultation with a dermatologist is recommended to ensure greater diagnostic accuracy and appropriate management ▪ Based on the severity of rash, dosing may be interrupted, reduced or permanently discontinued
Diarrhoea	▪ Advise patients to start anti-diarrhoeal treatment and to increase oral fluids if diarrhoea symptoms occur while taking TRUQAP ▪ Based on the severity of diarrhoea, TRUQAP dosing may be interrupted, reduced or permanently discontinued

Patients with moderate hepatic impairment during treatment with TRUQAP:[1]

- Patients with moderate hepatic impairment should be monitored closely for adverse effects due to potential increase in capivasertib exposure

Patients receiving biphosphonates and RANK-ligand inhibitors:[1]

- Oral symptoms of osteonecrosis can include changes in dental mobility, pain or swelling, non-healing of mouth sores and discharge
- In patients who develop osteonecrosis of the jaw, standard medical management should be initiated

Please refer to the dose management guidance section to see the full list of terms related to hyperglycemia, diarrhoea and cutaneous adverse drug reactions (CADRs).

CADR, cutaneous adverse drug reaction; DKA, diabetic ketoacidosis; FG, fasting glucose; RANK, receptor activator of NH-kB; ULN, upper limit of normal.

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Complications of hyperglycaemia

Before treatment initiation, patients should be informed about TRUQAP's potential to cause hyperglycaemia and requested to immediately contact their HCP if hyperglycaemia symptoms occur:[1]

- Excessive thirst
- Urinating more often than usual
- Greater amount of urine than usual
- Increased appetite with weight loss

DKA is a life-threatening metabolic complication associated with hyperglycaemia. Several factors can increase the risk of hyperglycaemia and/or DKA:[3–6]

- **Patient factors:** infections, kidney disease, diarrhoea, illness and comorbidities i.e. uncontrolled diabetes
- **Treatment factors:** concomitant medications potentially resulting in hyperglycaemia or insulin resistance, poor adherence to anti-diabetic agents, glucocorticoids and surgery
- **Lifestyle factors:** high BMI, malnutrition, dehydration and alcohol intake

This list is not exhaustive and other considerations may apply.

Counselling on lifestyle changes is recommended for patients with baseline risk factors and those that develop hyperglycaemia during treatment with TRUQAP[1]

Clinical scenarios, signs and symptoms to mitigate and manage DKA[1]

Comorbidities and treatments associated with an increased risk of hyperglycaemia progressing to DKA:	Consider DKA as a differential diagnosis in the event of the following additional non-specific symptoms:
▪ Dehydration/malnourishment ▪ Concurrent chemotherapy/steroids ▪ Sepsis	▪ Nausea, vomiting, abdominal pain ▪ Difficulty breathing ▪ Fruity odour on breath ▪ Confusion, unusual fatigue or sleepiness

If DKA is suspected, immediately interrupt TRUQAP. If DKA is confirmed, permanently discontinue treatment with TRUQAP[1]

BMI, body mass index; DKA, diabetic ketoacidosis; FG, fasting glucose; HCP, healthcare professional; ULN, upper limit of normal

TRUQAP dose management

Dose modification can help your patients manage AEs[1]

Adverse reactions may occur at any time while taking TRUQAP. The majority of adverse reactions have been shown to be grade 1 or 2, which can be managed following the guidance outlined below. If severe, it may be necessary to further modify or discontinue treatment.[1,7]

TRUQAP comes in 2 tablet strengths for dose modifications[1]

200 mg

160 mg

Disclaimer: not to scale.

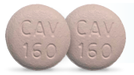
The dose of TRUQAP can be reduced up to twice for AE management[1]

No matter the dose, the treatment regimen remains the same: 4 days of treatment followed by 3 days without treatment, every week.[1]

Recommended dose
400 mg BD

Two 200 mg tablets BD

First dose reduction
320 mg BD



Two 160 mg tablets BD

Second dose reduction
200 mg BD

One 200 mg tablet BD

Adapted from TRUQAP SmPC.[1]
Disclaimer: not to scale.

The dose of TRUQAP should be reduced to 320 mg twice daily, 4 days on, 3 days off when concomitantly used with strong or moderate CYP3A4 inhibitors[1]

AE, adverse event; BD, twice a day; CYP3A4, cytochrome P450 family 3 subfamily A member 4.

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Dose management guidance

Hyperglycaemia[1]

CTCAE grade* & FG values prior to TRUQAP dose	Recommendation
Grade 1 >ULN–8.9 mmol/L or HbA1c >7% or >ULN–160 mg/dL	▪ No dose adjustment required ▪ Consider initiation or intensification of oral anti-diabetic treatment
Grade 2 >8.9–13.9 mmol/L or >160–250 mg/dL	▪ Initiate or intensify oral anti-diabetic treatment ▪ Withhold TRUQAP until FG level decreases to ≤8.9 mmol/L (or ≤160 mg/dL) ▪ If recovery occurs in ≤28 days, resume TRUQAP at the same dose and maintain initiated or intensified anti-diabetic treatment ▪ If improvement to ≤8.9 mmol/L (or ≤160 mg/dL) is reached in more than 28 days, restart at one lower dose level and maintain initiated or intensified anti-diabetic treatment
Grade 3 >13.9–27.8 mmol/L or >250–500 mg/dL	▪ Withhold TRUQAP until FG level decreases to ≤8.9 mmol/L (or ≤160 mg/dL) and consult a diabetologist ▪ Initiate or intensify oral anti-diabetic treatment ▪ Consider additional anti-diabetic medicinal products such as insulin, as clinically indicated. Consider intravenous hydration and provide appropriate clinical management as per local guidelines ▪ If FG decreases to ≤8.9 mmol/L (or ≤160 mg/dL) within 28 days, restart TRUQAP at one lower dose level and maintain initiated or intensified anti-diabetic treatment ▪ If FG does not decrease to ≤8.9 mmol/L (or ≤160 mg/dL) within 28 days following appropriate treatment, permanently discontinue TRUQAP
Grade 4 >27.8 mmol/L or >500 mg/dL	▪ Withhold TRUQAP and consult a diabetologist ▪ Initiate or intensify appropriate anti-diabetic treatment ▪ Consider insulin, as clinically indicated, intravenous hydration and provide appropriate clinical management as per local guidelines ▪ If FG decreases to ≤27.8 mmol/L (or ≤500 mg/dL) within 24 hours, then follow the guidance for the relevant grade ▪ If FG is confirmed at ≥27.8 mmol/L (or ≥500 mg/dL) after 24 hours, permanently discontinue TRUQAP treatment

Adapted from TRUQAP SmPC.[1]

Hyperglycaemia in patients receiving TRUQAP + fulvestrant in the overall population (n=355):

- **17.7%** (n=63/355) experienced any-grade[1]
- **2.5%** (n=9/355) experienced grade 3 or 4[1]
- **3.1%** n=(2/63) required dose reduction[1]
- **1.5%** (n=1/63) discontinued TRUQAP due to hyperglycaemia[1]

Consultation with a diabetologist should be considered when selecting anti-diabetic treatments. A potential for hypoglycaemia with anti-diabetic treatments on non-TRUQAP dosing days should be taken into account. Patients should consider consultation with a dietician to make lifestyle changes that may reduce hyperglycaemia.[1]

If DKA is suspected, immediately interrupt TRUQAP. If DKA is confirmed, permanently discontinue treatment with TRUQAP[1]

*Grading according to NCI CTCAE Version 4.03.[1]
Hyperglycaemia includes hyperglycaemia, blood glucose increased, diabetes mellitus and diabetic metabolic decompensation.[1]
Consideration should also be given to increases in HbA1c.[1]
There is limited experience in patients receiving insulin when being treated with TRUQAP.[1]

Please refer to the SmPC for additional information on the management of AEs.[1]

AE, adverse event; CTCAE, Common Terminology Criteria for Adverse Events; FG, fasting glucose; HbA1c, glycated haemoglobin; NCI, National Cancer Institute; ULN, upper limit of normal.

Diarrhoea[1]

CTCAE grade*	Recommendation
Grade 1	▪ No Truqap dose adjustment required ▪ Initiate appropriate anti-diarrhoeal therapy, maximise supportive care and monitor as clinically indicated
Grade 2	▪ Withhold TRUQAP for up to 28 days until recovery to ≤ grade 1 and resume TRUQAP at same dose or one lower dose level, as clinically indicated ▪ Initiate or intensify anti-diarrhoeal treatment and monitor as clinically indicated ▪ Persistent/recurrent diarrhoea: maintain appropriate medical therapy and restart TRUQAP at one lower dose level, as clinically indicated
Grade 3	▪ Withhold TRUQAP until recovery to ≤ grade 1 ▪ Initiate or intensify appropriate anti-diarrhoeal treatment and monitor as clinically indicated ▪ If recovery occurs in ≤28 days, resume TRUQAP at one lower dose level ▪ If recovery to ≤ grade 1 occurs in >28 days, permanently discontinue TRUQAP
Grade 4	▪ Permanently discontinue TRUQAP

Adapted from TRUQAP SmPC.[1]

Diarrhoea in patients receiving TRUQAP + fulvestrant in the overall population (n=355):

- **72.4%** (n=257/355) experienced any-grade[1]
- **9.3%** (n=33/355) experienced grade 3 or 4[1]
- **10.9%** (n=28/257) required dose reduction[1]
- **2.7%** (n=7/257) discontinued TRUQAP due to diarrhoea[1]

Patients should be advised to start anti-diarrhoeal treatment at the first sign of diarrhoea and increase oral fluids to maintain hydration and electrolyte balance if diarrhoea symptoms occur.[1]

Secondary prophylaxis should be considered in patients with recurrent diarrhoea.[1]

*Grading according to NCI CTCAE Version 5.0. Diarrhoea includes diarrhoea and frequent bowel movements.[1]

AE, adverse event; *AKT1*, serine/threonine protein kinase 1;
NCI CTCAE, National Cancer Institute Common Terminology Criteria for Adverse Events;
PIK3CA, phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha;
PTEN, phosphatase and tensin homolog.

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Dose management guidance (continued)

Rash and other CADRs†[1]

CTCAE grade*	Recommendation
Grade 1	▪ No dose adjustment required. Initiate emollients and consider adding oral non-sedating antihistamine treatment, as clinically indicated, to manage symptoms
Grade 2	▪ Withhold TRUQAP until recovery to ≤ grade 1 ▪ Initiate or intensify topical steroid treatment and consider non-sedating oral antihistamines ▪ If recovery occurs in ≤28 days, resume TRUQAP at the same dose level ▪ If persistent or recurrent, restart TRUQAP at one lower dose level
Grade 3	▪ Withhold TRUQAP until recovery to ≤ grade 1 ▪ Initiate appropriate dermatological treatment with topical steroid of moderate/higher strength, non-sedating oral antihistamines and/or systemic steroids ▪ If recovery occurs in ≤28 days, restart TRUQAP at one lower dose level ▪ If the symptoms do not improve to ≤ grade 1 within 28 days, discontinue TRUQAP ▪ In patients with reoccurrence of intolerable grade 3 rash, permanently discontinue TRUQAP
Grade 4	▪ Permanently discontinue TRUQAP

Adapted from TRUQAP SmPC.[1]

Rash and other CADRs in patients receiving TRUQAP + fulvestrant in the overall population (n=355):

- **46.5%** (n=165/355) experienced any-grade[1]
- **14.9%** (n=53/355) experienced grade 3 or 4[1]
- **12.7%** (n=21/165) required dose reduction[1]
- **11.5%** (n=19/165) discontinued TRUQAP due to rash or other CADRs[1]

Consider a consultation with a dermatologist for all grades of skin reactions, regardless of the severity, for diagnostic accuracy and appropriate management.[1]

In patients with persistent rash and/or previous occurrence of grade 3 rash, secondary prophylaxis may be appropriate by continuing oral antihistamines and/or topical steroids.[1]

*Grading according to CTCAE Version 5.0.
†Cutaneous adverse drug reactions include butterfly rash, dermatitis, dermatitis exfoliative generalised, drug eruption, drug reaction with eosinophilia and systemic symptoms (DRESS), erythema, erythema multiforme, papule, rash, rash erythematous, rash follicular, rash macular, rash maculo-papular, rash papular, rash pruritic, skin reaction, toxic skin eruptions.[1]

Please refer to the SmPC for additional information on the management of AEs.[1]

AE, adverse event; CADR, cuteaneous adverse reaction; CTCAE, Common Terminology Criteria for Adverse Events.

Other toxicities[1]

CTCAE grade*	Recommendation
Grade 1	▪ No TRUQAP dose adjustment required, initiate appropriate medical therapy and monitor as clinically indicated
Grade 2	▪ Withhold TRUQAP until symptoms improve to ≤ grade 1
Grade 3	▪ Withhold TRUQAP until symptoms improve to ≤ grade 1 ▪ If symptoms improve, restart TRUQAP at same dose or one lower dose level as clinically appropriate
Grade 4	▪ Permanently discontinue TRUQAP

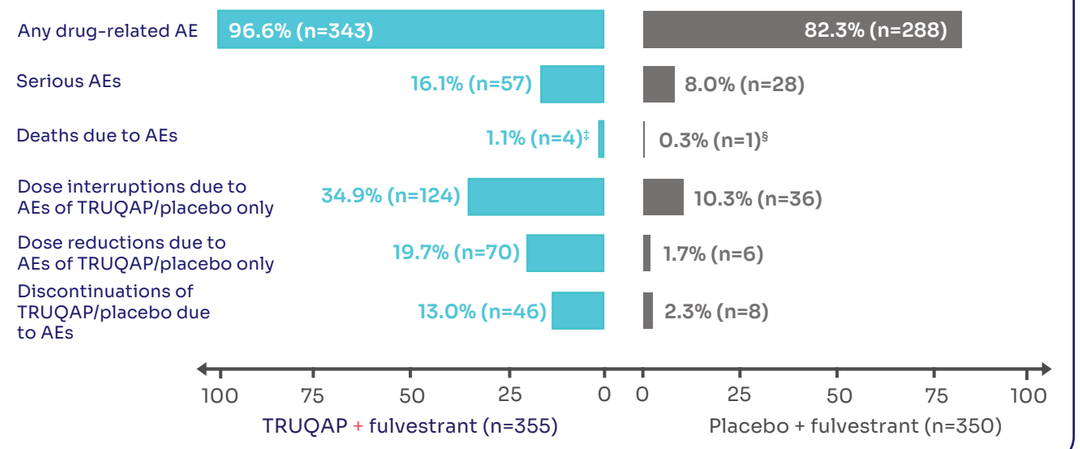
*Grading according to CTCAE Version 5.0.[1]
Adapted from TRUQAP SmPC.[1]

Safety profile

The safety profile of TRUQAP + fulvestrant was demonstrated in the CAPItello-291 trial[7,8]

AEs were a prespecified key secondary endpoint of the CAPItello-291 trial[7]

Proportion of patients experiencing AEs with TRUQAP + fulvestrant vs placebo + fulvestrant (safety population)[7,8†]



Adapted from Turner NC, et al. 2023.[7,8]
Data cut-off date: 15 August 2022.[7]

†The safety population included all the patients who received at least one dose of capivasertib, fulvestrant or placebo. The listed events were reported as a single term (or for rash, as a group term) in at least 10% of the patients for any grade in the capivasertib–fulvestrant group. AEs are reported regardless of the relationship to capivasertib, fulvestrant or placebo.[7]
‡From acute myocardial infarction, cerebral haemorrhage, aspiration pneumonia and sepsis, in one patient each.[7]
§From coronavirus disease 2019.[7]

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AE, adverse event; CTCAE, Common Terminology Criteria for Adverse Events.

TRUQAP offers targeted treatment with an intermittent dosing schedule[1]

See front cover for TRUQAP indication

Intermittent weekly schedule[1,2]

- **4 days on | 3 days off** + fulvestrant

2 tablet strengths if dose modifications required[1]

- **200 mg | 160 mg**

Click or scan QR code for TRUQAP prescribing information

Click or scan QR code for fulvestrant prescribing information

References: 1. TRUQAP (capivasertib). Summary of Product Characteristics. **2.** Turner NC, et al. N Engl J Med 2023;388:2058–70. Protocol. **3.** Shahid RK, et al. Cancers. 2021;13:5735. **4.** Lizzo JM, et al. Adult Diabetic Ketoacidosis. [Updated 2023 Jul 10]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan. Available at: https://www.ncbi.nlm.nih.gov/books/NBK560723/. Accessed August 2025. **5.** Umpierrez GE, et al. Diabetes Care. 2024;47:1257–75. **6.** Umpierrez GE. Endocrinology. Springer, Cham. 2018. Available at: https://doi.org/10.1007/978-3-319-44433-8_21. Accessed August 2025. **7.** Turner NC, et al. N Engl J Med 2023;388:2058–70. **8.** Turner NC, et al. N Engl J Med 2023;388:2058–70. Supplementary appendix.

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