TRUQAP® Dosing Guide

A guide to dosing, dose modifications, and adverse reactions

TRUQAP (capivasertib tablets), in combination with fulvestrant, is indicated for the treatment of adult females 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 progression on at least one endocrine-based regimen in the metastatic setting or recurrence on or within 12 months of completing adjuvant therapy.

AKT1=serine/threonine protein kinase 1; *PIK3CA*=phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha; *PTEN*=phosphatase and tensin homolog.

Pr Truqap®
capivasertib
160 mg • 200 mg tablets

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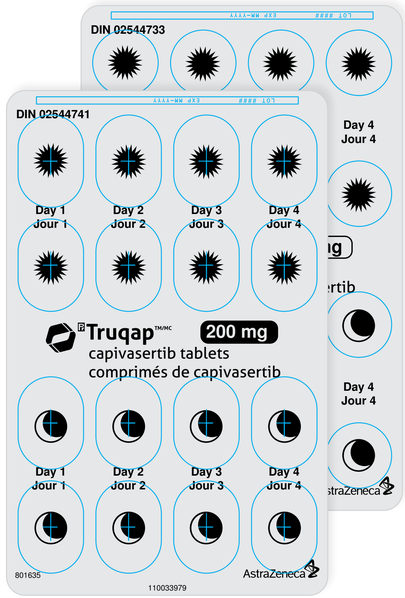
Dosing and administration

The recommended dose of TRUQAP is:

- **400 mg (two 200 mg tablets) taken orally twice daily**, approximately 12 hours apart (total daily dose of 800 mg),
- **for 4 days followed by 3 days off treatment.**

Treatment with TRUQAP should continue until disease progression or unacceptable toxicity occurs.[1]



TRUQAP's 4 days on / 3 days off weekly dosing schedule

TRUQAP							
Day	1	2	3	4	5	6	7
AM	200 mg x2	200 mg x2	200 mg x2	200 mg x2	No Dose		
PM	200 mg x2	200 mg x2	200 mg x2	200 mg x2	No Dose		

+

fulvestrant

Recommended dose of fulvestrant is

500 mg
(2 injections [each injection = 250 mg/5 mL])

on Days 1 and 15† of Cycle 1 and on Day 1 of each cycle thereafter.[1,2]

Morning Dose
Take 2 x 200 mg tablets

Evening Dose
Take 2 x 200 mg tablets

TRUQAP and fulvestrant are both started on the same day (Day 1 Cycle* 1).

Discuss the choice of a start date with your patients.

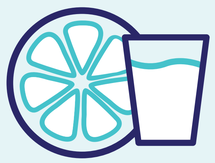
EXAMPLE FOR WEEK 1 CYCLE 1						
MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY	SUNDAY
TRUQAP + fulvestrant	TRUQAP	TRUQAP	TRUQAP			

* Each cycle has a duration of 28 days.
† Day 15 is Week 3 Day 1 of Cycle 1.

Advise your patient on how to take TRUQAP

Swallow whole

Take with or without food



Patients should not drink or eat grapefruit products during treatment with TRUQAP*

Do not crush, chew, dissolve or divide tablets†

Concomitant use of TRUQAP with strong CYP3A4 inducers is not recommended.

In pre-/peri-menopausal women, TRUQAP plus fulvestrant should be combined with a luteinizing hormone-releasing hormone (LHRH) agonist.

Missed dose

If a dose of TRUQAP is missed:

- It can be taken within 4 hours after the time it is usually taken.

After more than 4 hours:

- The dose should be skipped.
- The next dose of TRUQAP should be taken at the usual time.
- There should be at least 8 hours between doses.

If the patient vomits, a replacement dose should not be taken. The next dose of TRUQAP should be taken at the usual time.[1]

Overdose

There is currently no specific treatment in the event of an overdose with TRUQAP. In the event of an overdose, physicians should follow general supportive measures and patients should be treated symptomatically.
In CAPItello-291, a patient with 2 weeks of continuous dosing experienced nausea and vomiting, hyperglycemia, and acute kidney injury.

For management of a suspected drug overdose, contact your regional poison control centre.[1]

* Grapefruit may interact with TRUQAP.
† Patients must not take any tablets that are broken, cracked, or that look damaged.

Assessment

Evaluating your patient before starting TRUQAP

It is important to assess your patients with respect to the following items before deciding to treat with TRUQAP.

Selected warnings and precautions[1]

Diabetes and hyperglycemia

Severe hyperglycemia, including diabetic ketoacidosis, has been observed in patients treated with TRUQAP. Some cases of diabetic ketoacidosis have been reported with a fatal outcome.

Diabetic ketoacidosis can occur at any time during treatment with TRUQAP. In some reported cases, diabetic ketoacidosis developed in less than 10 days.

Patients must be tested for fasting blood glucose (FG) levels and HbA1c prior to treatment with TRUQAP (and blood glucose should be optimized prior to initiation of treatment) and at regular intervals during treatment.

The safety of TRUQAP in patients with Type 1 diabetes, diabetes requiring insulin or those with a HbA1c of ≥8% has not been studied as these patients were excluded from the CAPItello-291 study.

More frequent FG and HbA1c monitoring is required in patients with a medical history of diabetes mellitus, pre-diabetes, or those subjects with risk factors for hyperglycemia such as obesity, HbA1c at or above the upper limit of normal, use of concomitant systemic steroids, intercurrent infections, sepsis or other conditions that may require intensified glycemia management.

- Monitoring of HbA1c, ketones (preferably in blood) and other metabolic parameters (as indicated), in addition to FG, is recommended in these patients.

Counselling on lifestyle changes is recommended for patients with baseline risk factors for hyperglycemia and for those who develop hyperglycemia during treatment with TRUQAP.

Contraception and pregnancy testing

TRUQAP is not recommended during pregnancy and in women of reproductive potential not using contraception.

A pregnancy test should be performed on women of childbearing potential prior to initiating treatment to rule out pregnancy. Consider re-testing throughout treatment.

Patients should be advised to use effective contraception during treatment with TRUQAP and for at least 4 weeks after completion of treatment with TRUQAP.

The following serious adverse reactions were reported in patients treated with TRUQAP: cutaneous adverse reactions including Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), Erythema Multiforme (EM) and palmar-plantar erythrodysesthesia as well as severe diarrhea associated with dehydration and acute kidney injury.

Selected dosing in special populations[1]

Renal and hepatic impairment		
▪ **Mild or moderate renal impairment** (creatinine clearance 30 to 89 mL/min) **or** ▪ **Mild hepatic impairment** (bilirubin ≤ upper limit of normal (ULN) and AST > ULN, or bilirubin >1 ULN to ≤1.5x ULN and any AST value)	▪ **Moderate hepatic impairment**: (bilirubin >1.5x - 3.0x ULN and AST of any value)	▪ **Severe renal impairment** (creatinine clearance 15 to 29 mL/min) **or** ▪ **Severe hepatic impairment** (bilirubin >3.0x ULN and any AST)
No dose adjustment is recommended.	**Administer TRUQAP only if the benefit outweighs the risk and monitor closely for signs of toxicity.** Limited data are available.	**TRUQAP is not recommended for patients, as safety and pharmacokinetics have not been studied in these patients.**

Testing for these conditions can help determine if your patient may require additional monitoring while taking TRUQAP.

AST=aspartate aminotransferase; FG=fasting glucose; HbA1c=hemoglobin A1c; ULN=upper limit of normal.

Monitoring patients treated with TRUQAP

Selected warnings and precautions

Among TRUQAP-treated patients who experienced one of the adverse reactions below, the median time to first event was:

Hyperglycemia

Severe hyperglycemia, including diabetic ketoacidosis has been observed in patients treated with TRUQAP. Some cases of diabetic ketoacidosis have been reported with a fatal outcome.

Recommended schedule for monitoring FG and HbA1c levels†

At screening, before initiating TRUQAP

Test for FG levels and HbA1c. → Optimize the patient's level of blood glucose.

After initiating TRUQAP

Monitor FG at Weeks 1, 2, 4, 6 and 8 after starting TRUQAP and at least once a month thereafter. → HbA1c should be monitored every 3 months.

Additional monitoring/self-monitoring may be required in accordance with the instructions of a healthcare professional, especially within the first 2 weeks of treatment.

In patients with diabetes:

Monitor/self-monitor FG daily for the first 2 weeks of treatment. → Continue to monitor FG as frequently as needed to manage hyperglycemia according to the instructions of a healthcare professional.

Additional HbA1c testing is recommended on Week 4, and then at least every 3 months, in patients with diabetes, pre-diabetes, or hyperglycemia at baseline.

If hyperglycemia develops after initiating treatment with TRUQAP (please see pages 16–17 for recommended dose modifications):

Monitor FG at least twice weekly (on days on and off TRUQAP treatment until FG decreases to baseline levels).

During treatment with an anti-diabetic medication, FG should be monitored at least once a week for 2 months, followed by once every 2 weeks or as clinically indicated.

† It is recommended to test FG pre-dose on Day 3 or 4 of the dosing week.

More frequent FG and HbA1c monitoring is required in patients:[1]

- with medical history of diabetes mellitus,
- pre-diabetes,
- in patients with risk factors for hyperglycemia such as:
  - obesity (BMI >30),
  - elevated FG of > ULN 160 mg/dL (> ULN 8.9 mmol/L),
  - HbA1c at or above the upper limit of normal,
  - use of concomitant systemic steroids or intercurrent infections, or
  - other conditions which may require intensified glycemia management.

Additional recommended monitoring in these patients:[1]

- HbA1c,
- ketones (preferably in blood) and
- other metabolic parameters (as indicated).

Counselling on lifestyle changes is recommended for patients with baseline risk factors for hyperglycemia and for those who develop hyperglycemia during treatment with TRUQAP.

Consider consultation with a healthcare practitioner with expertise in the treatment of hyperglycemia.

Cutaneous adverse reactions and diarrhea

Severe diarrhea associated with dehydration and cutaneous adverse reactions including Erythema Multiforme (EM), palmar-plantar erythrodysesthesia and Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) were reported in patients treated with TRUQAP.

Adverse reactions	Monitoring
Cutaneous	Patients should be monitored for signs and symptoms of cutaneous reactions and based on severity. Early consultation with a dermatologist is recommended.
Diarrhea	Advise patients to start antidiarrheal treatment at the first sign of diarrhea and to increase oral fluids if diarrhea symptoms occur while taking TRUQAP.

Based on the severity of adverse events, TRUQAP dosing may be interrupted, reduced, or permanently discontinued.[1]

BMI=Body Mass Index; FG=fasting glucose; HbA1c=hemoglobin A1c; ULN=upper limit of normal.

Dose modification

Dose modification for adverse reactions

TRUQAP comes in 2 tablet strengths.

200 mg

160 mg

Images of TRUQAP tablets are to scale.

The dose of TRUQAP can be reduced up to 2 times for adverse reaction management

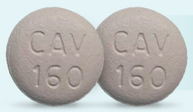
A maximum of 2 dosing reductions are recommended, after which the patient should be discontinued from treatment with TRUQAP.[1]

With all dose reductions, the schedule remains the same:
4 days of treatment followed by 3 days without treatment, every week.

Recommended dose
800 mg

Two 200 mg tablets BID

First dose reduction
640 mg



Two 160 mg tablets BID

Second dose reduction
400 mg

One 200 mg tablet BID

TRUQAP dose should be reduced to 320 mg twice daily (equivalent to a total daily dose of 640 mg) when used concomitantly with strong or moderate CYP3A4 inhibitors.

BID=twice a day; CYP3A4=cytochrome P450 family 3 subfamily A member 4.

Management of adverse drug reactions

Please see later in this guide and the TRUQAP Product Monograph for all recommendations and recommended dose modifications for hyperglycemia, diarrhea, cutaneous and other adverse drug reactions.

Management of adverse drug reactions may require temporary dosing interruption, reduction and/or discontinuation of TRUQAP.

The dosing reduction recommendations are listed in the Product Monograph.[1]

The safety and tolerability profile of TRUQAP was studied in the phase 3 CAPItello-291 trial.[1]

- **Treatment discontinuation due to adverse reactions occurred in 10.4% of patients.**

Recommendations in managing selected adverse reactions

Recommendations in managing selected adverse reactions: Diarrhea

Diarrhea in patients receiving TRUQAP + fulvestrant

67.3% (n=239)
Experienced any grade

9.3% (n=33)
Experienced Grade 3 or 4

7.9% (n=28)
Required dose reduction

2.0% (n=7)
Discontinued

Median time to first diarrhea event (TRUQAP group): **8 days**[1,3]

Recommended dose modifications for diarrhea*

Severity†	Recommendations	TRUQAP dose
Grade 1	Initiate appropriate anti-diarrheal therapy, maximize supportive care, and monitor as clinically indicated.	▪ **No TRUQAP dose adjustment required.**
Grade 2	Initiate or intensify appropriate anti-diarrheal treatment and monitor as clinically indicated.	▪ **Interrupt TRUQAP dose for up to 28 days until recovery to ≤ Grade 1 and resume TRUQAP dosing at same dose or one lower dose level, as clinically indicated.** ▪ **If Grade 2 diarrhea is persistent or recurring, maintain appropriate medical therapy and restart TRUQAP at one lower dose level, as clinically indicated.**
Grade 3	Initiate or intensify appropriate anti-diarrheal treatment and monitor as clinically indicated.	▪ **Interrupt TRUQAP.** ▪ **If the symptoms improve to ≤ Grade 1 in 28 days, resume TRUQAP at one lower dose level.** ▪ **If the symptoms do not improve to ≤ Grade 1 in 28 days, permanently discontinue TRUQAP.**
Grade 4		▪ **Permanently discontinue TRUQAP.**

CTCAE=Common Terminology Criteria for Adverse Events.
* Diarrhea includes diarrhea and frequent bowel movements.
† Severity grading per CTCAE Version 5.0; severity grading for hyperglycemia per CTCAE Version 4.03.

Recommendations in managing selected adverse reactions: Hyperglycemia†

Hyperglycemia† in patients receiving TRUQAP + fulvestrant

14.4% (n=51)
Experienced any grade

2.3% (n=8)
Experienced Grade 3 or 4

0.6% (n=2)
Required dose reduction

0.6% (n=2)
Discontinued due to hyperglycemia or ketoacidosis

Consider consultation with a healthcare practitioner with expertise in the treatment of hyperglycemia.

Median time to first hyperglycemia event (TRUQAP group): **15 days**[1,3]

Recommended dose modifications for hyperglycemia

Dose modifications and management are based on pre-dose FG and/or HbA1c levels.

Severity‡	Recommendations	TRUQAP dose
Grade 1 > ULN–160 mg/dL or > ULN–8.9 mmol/L or HbA1c >7%	Consider initiation or intensification of oral anti-diabetic treatment.	▪ **No TRUQAP dose adjustment required.**
Grade 2 >160–250 mg/dL or >8.9–13.9 mmol/L	Initiate or intensify oral anti-diabetic treatment without dose adjustment of TRUQAP.	▪ **If FG does not decrease to ≤160 mg/dL (or ≤8.9 mmol/L) with treatment, interrupt TRUQAP for up to 28 days until FG level decreases to ≤160 mg/dL (or ≤8.9 mmol/L).** ▪ **If improvement to ≤160 mg/dL (or ≤8.9 mmol/L) is reached within 28 days, restart TRUQAP at the same dose level and maintain initiated or intensified anti-diabetic treatment.** ▪ **If improvement to ≤160 mg/dL (or ≤8.9 mmol/L) is reached after 28 days, restart TRUQAP at one lower dose level and maintain initiated or intensified anti-diabetic treatment.**
Grade 3 >250–500 mg/dL or >13.9–27.8 mmol/L	Withhold TRUQAP and consult a healthcare professional experienced in the treatment of hyperglycemia. Initiate or intensify oral anti-diabetic treatment. Consider additional anti-diabetic medicinal products such as insulin, as clinically indicated.	▪ **If FG decreases to ≤160 mg/dL (or ≤8.9 mmol/L) within 28 days, restart TRUQAP at one lower dose level and maintain initiated or intensified anti-diabetic treatment.** ▪ **If FG does not decrease to ≤160 mg/dL (or ≤8.9 mmol/L) within 28 days following appropriate treatment, permanently discontinue TRUQAP.** ▪ **If symptoms of diabetic ketoacidosis are observed, withhold TRUQAP immediately. If diabetic ketoacidosis is confirmed, permanently discontinue TRUQAP.**
Grade 4 >500 mg/dL or >27.8 mmol/L or life-threatening sequelae of hyperglycemia	Withhold TRUQAP and consult a healthcare professional experienced in the treatment of hyperglycemia. Initiate or intensify oral anti-diabetic treatment. Consider insulin, intravenous hydration and provide appropriate clinical management as per local guidelines.	▪ **If FG decreases to ≤500 mg/dL (or ≤27.8 mmol/L) within 24 hours, then follow the guidance in the table for the relevant grade.** ▪ **If FG is confirmed at >500 mg/dL (or >27.8 mmol/L) after 24 hours, permanently discontinue TRUQAP treatment.** ▪ **For life-threatening sequelae of hyperglycemia, permanently discontinue TRUQAP.** ▪ **If symptoms of diabetic ketoacidosis are observed, withhold TRUQAP immediately. If diabetic ketoacidosis is confirmed, permanently discontinue TRUQAP.**

CTCAE=Common Terminology Criteria for Adverse Events; FG=fasting glucose; HbA1c=hemoglobin A1c; MedDRA=Medical Dictionary for Regulatory Activities; PT=MedDRA Preferred Term; ULN=upper limit of normal.
† Hyperglycemia includes PTs of hyperglycemia and blood glucose increased.
‡ Severity grading per CTCAE Version 5.0; severity grading for hyperglycemia per CTCAE Version 4.03.

Recommendations in managing selected adverse reactions: Cutaneous

Cutaneous adverse reactions in patients receiving TRUQAP + fulvestrant

46.5% (n=165)
Experienced any grade

16.9% (n=60)
Experienced Grade 3 or 4

6.5% (n=23)
Required dose reduction

6.5% (n=23)
Discontinued due to cutaneous reactions

Median time to first rash event (TRUQAP group): **12 days**[1,3]

Recommended dose modifications for cutaneous adverse reactions

Severity†	Recommendations	TRUQAP dose
Grade 1	Initiate emollients and consider adding an oral non-sedating antihistamine treatment as clinically indicated to manage symptoms.	▪ **No TRUQAP dose adjustment required.**
Grade 2	Initiate or intensify topical steroid treatment and consider non-sedating oral antihistamines.	▪ **If no improvement with treatment, interrupt TRUQAP.** ▪ **Resume at the same dose level once the rash becomes clinically tolerable.**
Grade 3	Initiate appropriate dermatological treatment with topical steroid of moderate/higher strength, non-sedating oral antihistamines and/or systemic steroids.	▪ **Interrupt TRUQAP.** ▪ **If symptoms improve within 28 days to ≤ Grade 1, restart TRUQAP at one lower dose level.** ▪ **If the symptoms do not improve to ≤ Grade 1 in 28 days, discontinue TRUQAP.**
		▪ **In patients with reoccurrence of ≥ Grade 3 rash, permanently discontinue TRUQAP.**
Grade 4		▪ **Permanently discontinue TRUQAP.**

CTCAE=Common Terminology Criteria for Adverse Events.
† Severity grading per CTCAE Version 5.0; severity grading for hyperglycemia per CTCAE Version 4.03.

Recommendations in managing selected adverse reactions: Other adverse reactions

Recommended dose modifications for other adverse reactions

Severity†	Recommendations	TRUQAP dose
Grade 1	Initiate appropriate medical therapy and monitor as clinically indicated.	▪ **No TRUQAP dose adjustment required.**
Grade 2		▪ **Interrupt TRUQAP until symptoms improve to ≤ Grade 1.**
Grade 3	If symptoms improve, restart TRUQAP at same dose or one lower dose level, as clinically appropriate.	▪ **Interrupt TRUQAP until symptoms improve to ≤ Grade 1.**
Grade 4		▪ **Permanently discontinue TRUQAP.**

CTCAE=Common Terminology Criteria for Adverse Events.
† Severity grading per CTCAE Version 5.0; severity grading for hyperglycemia per CTCAE Version 4.03.

Safety profile: Safety population CAPItello-291 trial

Adverse drug reactions* occurring in ≥10% (All Grades) of patients

Please consult the TRUQAP Product Monograph for a full listing of adverse drug reactions.

System Organ Class (SOC)	TRUQAP + fulvestrant n=355		Placebo + fulvestrant n=350	
Adverse reactions	All Grades n (%)	Grade 3-4 (%)	All Grades (%)	Grade 3-4 (%)
Gastrointestinal disorders				
Diarrhea[a]	239 (67.3)	33 (9.3)	46 (13.1)	0
Nausea	97 (27.3)	2 (0.6)	37 (10.6)	2 (0.6)
Vomiting	56 (15.8)	5 (1.4)	9 (2.6)	2 (0.6)
Stomatitis[b]	58 (16.3)	6 (1.7)	11 (3.1)	0
General disorders and administration site conditions				
Fatigue[c]	78 (22.0)	5 (1.4)	47 (13.4)	0
Skin and subcutaneous tissue disorders				
Cutaneous adverse reactions[d]	165 (46.5)	60 (16.9)	38 (10.9)	1 (0.3)
Metabolism and nutrition disorders				
Hyperglycemia[e]	51 (14.4)	8 (2.3)	7 (2.0)	1 (0.3)
Decreased appetite	38 (10.7)	1 (0.3)	8 (2.3)	1 (0.3)

Adapted from the TRUQAP Product Monograph[1]

MedDRA=Medical Dictionary for Regulatory Activities; PT=MedDRA Preferred Term.
*Adverse drug reaction frequencies are those considered to be causally related to treatment based on assessment by the investigator.
[a]Diarrhea includes PTs of diarrhea and frequent bowel movements.
[b]Stomatitis includes PTs of stomatitis, aphthous ulcer, lip ulceration, mouth ulceration and mucosal inflammation.
[c]Fatigue includes PTs of fatigue, malaise and asthenia.
[d]Cutaneous adverse reaction includes the PTs of dermatitis allergic, acne, butterfly rash, dermatitis, drug reaction with eosinophilia and systemic symptoms, dry skin, eczema, erythema multiforme, papule, pruritus, rash, rash erythematous, rash follicular, rash macular, rash maculo-papular, rash papular, rash pruritic, skin discoloration, skin fissures, skin hyperpigmentation, skin reaction, skin ulcer, urticaria, rash pustular, purpura, erythema, drug eruption, dermatitis exfoliative generalized.
[e]Hyperglycemia includes PTs of hyperglycemia, blood glucose increased, type 2 diabetes mellitus and diabetes mellitus.

Serious adverse reactions occurred in 6.2% of patients receiving TRUQAP + fulvestrant[1]

Serious adverse reactions reported in ≥1% of patients	
Adverse reaction	**TRUQAP + fulvestrant n (%)**
Cutaneous reactions	12 (3.4%)
Diarrhea	6 (1.7%)

Rates of dose reduction/discontinuations due to adverse reactions with TRUQAP + fulvestrant

Dose reductions

18.6%

TRUQAP + fulvestrant

Most frequent (≥2%) adverse reactions leading to dose reductions:

- Diarrhea (7.9%)
- Cutaneous adverse reactions (6.5%)

Low discontinuation rate reported

10.4%

of **TRUQAP + fulvestrant** patients discontinued due to adverse reactions

Most frequent (≥2%) adverse reactions leading to discontinuation:

- Cutaneous adverse reactions (6.5%)
- Diarrhea (2%)
- Vomiting (2%)

Important safety information

Clinical use:

No pediatric data are available to Health Canada; therefore, Health Canada has not authorized an indication for pediatric use.

Safety analyses suggest a higher incidence of severe adverse reactions in those >65 years of age compared to younger patients.

Contraindications:

TRUQAP is contraindicated in patients who are hypersensitive to capivasertib or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container.

Most serious warnings and precautions:

Cutaneous adverse reactions including Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), Erythema Multiforme (EM) and palmar-plantar erythrodysesthesia. Patients should be monitored for signs and symptoms of cutaneous reactions and based on severity, TRUQAP dosing may be interrupted, reduced, or permanently discontinued. Early consultation with a dermatologist is recommended.

Hyperglycemia, including diabetic ketoacidosis. Some cases have been fatal. Patients must be tested for fasting blood glucose (FG) levels and HbA1c prior to treatment with TRUQAP and at regular intervals during treatment. Blood glucose should be optimized prior to initiation of treatment. Before initiating treatment with TRUQAP, patients should be informed about the potential of TRUQAP to cause hyperglycemia, and to contact their healthcare professional immediately if hyperglycemia symptoms occur. Consider consultation with a healthcare practitioner with expertise in the treatment of hyperglycemia. Based on the severity of hyperglycemia, TRUQAP dosing may be interrupted, reduced, or permanently discontinued.

Severe diarrhea associated with dehydration and acute kidney injury. Advise patients to start antidiarrheal treatment at the first sign of diarrhea and to increase oral fluids if diarrhea symptoms occur while taking TRUQAP. Based on the severity of diarrhea, TRUQAP may be interrupted, reduced, or permanently discontinued.

Other relevant warnings and precautions:

- Caution when driving or operating machinery
- Testing for fasting blood glucose (FG) levels and HbA1c
- Monitoring of ketones and other metabolic parameters
- Use effective contraception during treatment and for at least 4 weeks after completion of treatment with TRUQAP
- Rule out pregnancy before treatment and avoid becoming pregnant
- Do not breastfeed
- Teratogenic risk

For more information:

Please consult the TRUQAP Product Monograph at **truqap-en.azpm.ca** for important information relating to adverse reactions, drug interactions, and dosing information which have not been discussed in this piece.

The Product Monograph is also available by calling 1-800-668-6000.

References:
1. TRUQAP Product Monograph. AstraZeneca Canada Inc. October 29, 2025. **2.** Data on file. **3.** Rugo HS, *et al*. Capivasertib and fulvestrant for patients with hormone receptor-positive advanced breast cancer: characterization, time course, and management of frequent adverse events from the phase III CAPItello-291 study. *ESMO Open* 2024;9(9):103697.

TRUQAP's 4 days on / 3 days off weekly dosing schedule

TRUQAP and fulvestrant are both started on the same day (Day 1 Cycle* 1).

Discuss the choice of a start date with your patients.

TRUQAP + fulvestrant dosing

The recommended dose of TRUQAP is:

- **400 mg (two 200 mg tablets) taken orally twice daily**, approximately 12 hours apart (total daily dose of 800 mg),
- **for 4 days followed by 3 days off treatment.**[1]

TRUQAP

Day	1	2	3	4	5	6	7
AM	200 mg x2	200 mg x2	200 mg x2	200 mg x2	No Dose		
PM	200 mg x2	200 mg x2	200 mg x2	200 mg x2	No Dose		

+

fulvestrant

Recommended dose of fulvestrant is

500 mg
(2 injections [each injection = 250 mg/5 mL])

on Days 1 and 15† of Cycle 1 and on Day 1 of each cycle thereafter.[1,2]

Access resources and support materials at

TRUQAP.ca

Receive updates from AZ

SIGN UP

* Each cycle has a duration of 28 days.
† Day 15 is Week 3 Day 1 of Cycle 1.

CA-10432E

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REVIEWED BY PAAB

Pr Truqap® capivasertib
160 mg • 200 mg tablets