

DIARRHEA

Best practices for monitoring and management during treatment

PI and Expert-led Guidance

*Per the Prostate Cancer Working Group 4 guidelines.²

mAPMN/S=metastatic androgen pathway modulation-naïve or -sensitive; mHSPC=metastatic hormone-sensitive prostate cancer; PTEN=phosphatase and tensin homolog.

IMPORTANT PRODUCT INFORMATION

Select Safety Information About TRUQAP[®] (capivasertib) tablets

TRUQAP is contraindicated in patients with severe hypersensitivity to TRUQAP or any of its components. Serious adverse reactions include hyperglycemia, including diabetic ketoacidosis and fatal outcomes; diarrhea; and cutaneous adverse reactions. Monitor fasting glucose and hemoglobin A1C levels regularly. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with TRUQAP and for 4 months after the last dose. Among the 503 patients who received TRUQAP in CAPItello-281, the most common ($\geq 20\%$) adverse reactions including laboratory abnormalities were increased fasting glucose (70%), decreased hemoglobin (61%), decreased lymphocytes (58%), cutaneous adverse reactions (53%), diarrhea (53%), decreased potassium (51%), increased creatinine (49%), increased non-fasting glucose (49%), increased alanine aminotransferase (38%), increased triglycerides (37%), increased aspartate aminotransferase (36%), decreased sodium (30%), and fatigue (26%).

Indication and Usage

TRUQAP in combination with abiraterone and prednisone is indicated for the treatment of adult patients with metastatic androgen pathway modulation-naïve or -sensitive (mAPMN/S) prostate cancer that is PTEN-deficient as detected by an FDA-authorized test.

Please see Important Safety Information on pages 10-11 and full Prescribing Information, including Patient Information for TRUQAP.



How to use this brochure

This brochure was designed to inform and educate you on diarrhea associated with TRUQAP + abiraterone/prednisone and how to manage it.

The following PI guidance and expert insights are provided to help with monitoring and managing diarrhea during treatment.



Frequency and severity of diarrhea



Early and consistent monitoring guidance



Dosing



Expert insights for managing diarrhea

Appropriate clinical intervention may help manage diarrhea while on TRUQAP + abiraterone/prednisone^{1,3}

Diarrhea is an on-target effect of PI3K/AKT/PTEN pathway inhibitors such as TRUQAP.³

Diarrhea in patients receiving TRUQAP + abiraterone/prednisone (n=503) in CAPitello-281¹



Median time to first occurrence

12 days

(range: 3-48 days)

Frequency of diarrhea

All grades	Grade 3-4
53%	6.2%

1.2%

Discontinuation rate
of TRUQAP due to diarrhea
of any grade¹

5%

Dose reduction rate
of TRUQAP due to diarrhea
of any grade¹

- **Primary prophylaxis for diarrhea was not permitted in CAPitello-281.**⁴ 64% of the 264 patients who experienced diarrhea were managed with antidiarrheal medication¹
- Monitor patients for signs and symptoms of diarrhea¹
- Withhold, reduce dose, or permanently discontinue TRUQAP based on severity of diarrhea¹



Advise patients to increase oral fluids and start antidiarrheal treatment at the first sign of diarrhea while taking TRUQAP¹

AKT=serine/threonine protein kinase; PI3K=phosphoinositide 3-kinase.

Please see Important Safety Information on pages 10-11 and full [Prescribing Information](#), including [Patient Information](#) for TRUQAP.

 **Truqap[®]**
capivasertib
160 mg • 200 mg tablets

Monitoring guidance and patient understanding may help manage diarrhea during treatment^{1,3}

Inform patients on risk factors and guidance for daily tracking^{1,3}



Before TRUQAP initiation

- Tell patients that diarrhea may occur early—median onset was 12 days (range: 3–48 days)¹
- Assess risk factors + baseline labs³
- Advise taking TRUQAP **with food**—may reduce the incidence of diarrhea^{3*}
- Counsel patients with diarrhea symptoms to start antidiarrheals and increase fluid intake to maintain hydration and electrolyte balance^{3,5}
- Discuss dietary modifications, such as eliminating or avoiding lactose, spicy foods, insoluble fiber, and limiting caffeine and alcohol⁶
- Inform your patients to seek medical attention if they have⁶:
 - Dark urine
 - Dry mouth and skin
 - Moderate to severe abdominal pain
 - Black stools
 - Rapid/irregular heartbeat
 - Fever (100.5 °F or higher)
 - Dizziness
 - Blood in stools

Prescribe antidiarrheals before Day 1—patients should have them at home and be educated on when and how to escalate³



During TRUQAP treatment

- Monitor patients periodically during therapy and have them keep a daily diary tracking³:



Stool characteristics (loose, watery stools) and frequency



Antidiarrheal use



Food and drink intake



Any pattern linked to the dosing cycle

- Review diaries **every 2–3 weeks** for the first 2–3 months³

Advise patients to contact their care team immediately if they experience ≥ 4 loose stools above baseline^{1,3}

*Results from a phase 1, single-center, open-label, randomized, crossover study designed to investigate the effect of food and acid-reducing agents on the pharmacokinetic profile of TRUQAP.⁷

Dietary strategies that may help manage diarrhea³

Choose

- Frequent, small meals
- Buttermilk, skim milk, low-fat milk, plant-based milk, low-fat cheese
- Well-cooked vegetables or fruits without skin or seeds
- Bananas, applesauce, juice without pulp
- Bread, pasta, noodles made with refined white flour, white rice
- Cereals with <2 g of fiber per serving, as indicated on the product's nutritional label
- Tender well-cooked meat, fish, eggs
- Drink 8–10 large glasses of clear liquids/day (eg, water, oral rehydration solutions, broth, decaffeinated coffee or tea)

Limit/Avoid

- Lactose-containing products (eg, whole milk, half-and-half, sour cream)
- Salads
- Raw vegetables and raw fruits (eg, apples, pears, cherries, mangoes, oranges)
- Dry fruits (eg, prunes, raisins)
- High-fiber vegetables (eg, beets, brussels sprouts, broccoli, corn, beans, cabbage, cauliflower, peas)
- Whole wheat and whole grains, brown rice, any bread/cereal with fruits or nuts
- Lentils, lima beans, chickpeas, kidney beans, black beans
- Whole nuts
- Caffeine-containing beverages
- Alcoholic beverages
- High-osmolar supplements (eg, liquid nutritional supplements such as Ensure®, Boost®; electrolyte drinks such as Pedialyte®; protein powders; or fiber supplements)

For additional resources to help your patients during treatment, visit <https://www.truqaphcp.com/prostate-cancer/resources>

TRUQAP recommended dosing and dose modification for adverse reactions (ARs)¹

In combination with abiraterone/prednisone,

TRUQAP dosing schedule¹

Designed to achieve a positive benefit-risk balance

The recommended starting dose of TRUQAP is 400 mg taken orally twice daily, approximately 12 hours apart, 4 consecutive days on, 3 days off, every week

TRUQAP dosing schedule		Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
AM					NO TRUQAP DOSE			NO TRUQAP DOSE
PM					NO TRUQAP DOSE			NO TRUQAP DOSE

Select patients based on an FDA-authorized test for detection of PTEN deficiency.

TRUQAP is taken in combination with other agents



Abiraterone
1000 mg taken orally,
once daily



Prednisone
5 mg, once daily



ADT therapy*

For dosing instructions for combination agents administered with TRUQAP, refer to the respective manufacturers' Prescribing Information.

*Patients with mAPMN/S prostate cancer should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or should have had a bilateral orchiectomy.

Advise male patients with female partners of reproductive potential to use effective contraception during treatment with TRUQAP and for 4 months after the last dose. Based on findings in animal studies, TRUQAP can cause fetal harm.

Advise patients on the following when taking TRUQAP:



Can be taken with or without food



Do not chew, crush, or split tablets prior to swallowing. Do not take tablets that are broken, cracked, or otherwise not intact



Swallow whole with water



Do not consume grapefruit products

In combination with abiraterone/prednisone,

Recommended dosage modification of TRUQAP for ARs¹

No matter the dose, the dosing schedule remains the same: 4 consecutive days on, 3 days off, every week

First dose reduction

320 mg twice daily for 4 consecutive days followed by 3 days off



Two 160-mg tablets BID

Not actual size.

Second dose reduction

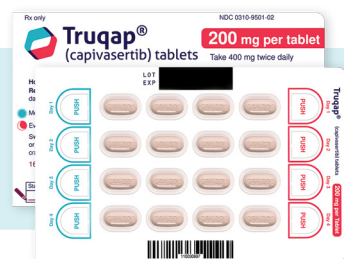
200 mg twice daily for 4 consecutive days followed by 3 days off



One 200-mg tablet BID

Not actual size.

- Permanently discontinue TRUQAP if unable to tolerate the second dose reduction
- **Avoid concomitant use with strong CYP3A inhibitors.** If concomitant use with a strong CYP3A inhibitor cannot be avoided, reduce the dosage of TRUQAP to 320 mg orally twice daily for 4 days followed by 3 days off
- When concomitantly used with a moderate CYP3A inhibitor, reduce the dosage of TRUQAP to 320 mg orally twice daily for 4 days followed by 3 days off
- After discontinuation of a strong or moderate CYP3A inhibitor, resume the TRUQAP dosage (after 3 to 5 half-lives of the inhibitor) that was taken prior to initiating the strong or moderate CYP3A inhibitor
- **Avoid concomitant use of TRUQAP with strong or moderate CYP3A inducers**



Not actual size.

Available in blister packs to help patients track 4 consecutive days on treatment

ADT=androgen deprivation therapy; BID=bis in die (twice daily); CYP3A=cytochrome P450 3A.



If a patient misses a dose within 4 hours of the scheduled time, instruct the patient to take the missed dose. If a patient misses a dose by more than 4 hours of the scheduled time, instruct the patient to skip the dose and take the next dose at its usual scheduled time



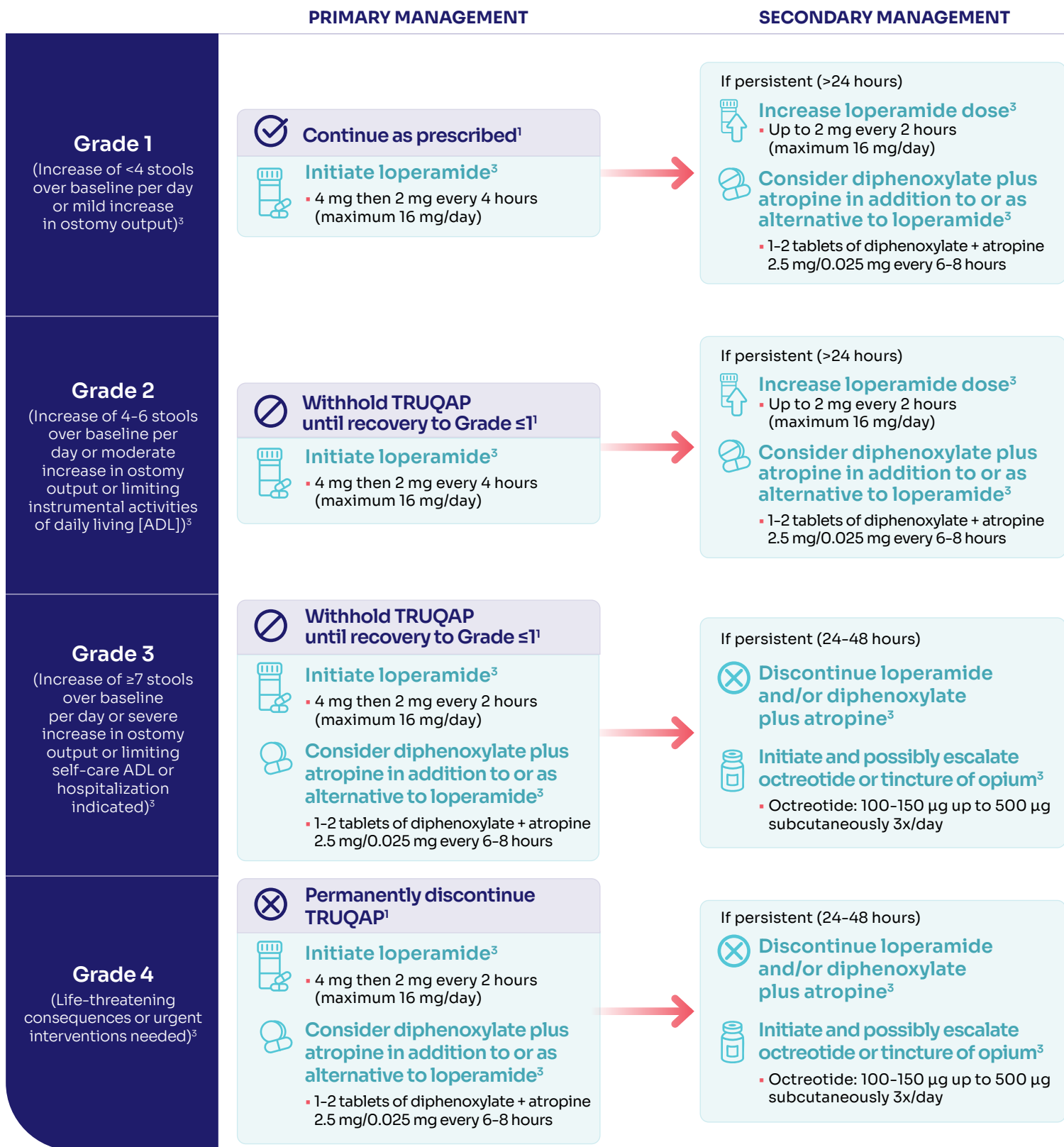
If a patient vomits a dose, instruct the patient not to take an additional dose and to take the next dose at its usual scheduled time

Continue treatment until disease progression or unacceptable toxicity occurs.

 **Truqap®**
capiasertib
160 mg • 200 mg tablets

PI-recommended dose modifications and expert insights for managing diarrhea^{1,3}

*The expert insights below are derived from a manuscript developed with funding from AstraZeneca. They represent the authors' clinical opinions and interpretations and are not part of the TRUQAP Prescribing Information. These considerations are for informational purposes only to support the management of diarrhea and are not a substitute for the TRUQAP Prescribing Information recommendations.



BMP=basic metabolic panel; CBC=complete blood count; IV=intravenous.

KEY:

PI-recommended

Expert Insights*

ADDITIONAL HCP CONSIDERATIONS**TRUQAP DOSING AT RECOVERY**

- Consider physical exam, CBC, BMP, and stool cultures for infection (eg, *Clostridium difficile*), as clinically appropriate³

 **Maintain same dose of TRUQAP¹**

- Consider physical exam, CBC, BMP, and stool cultures for infection (eg, *Clostridium difficile*), as clinically appropriate³

 **Maintain same dose of TRUQAP or one lower dose if recovery ≤ 28 days and as clinically indicated¹** **Resume TRUQAP at one lower dose if recovery > 28 days¹** **Reduce TRUQAP by one lower dose if recurrent Grade 2 diarrhea¹**

- Consider hospital admission for IV fluids and antibiotics, as clinically appropriate³
- Perform bloodwork and diagnostic work-up for infectious pathogens (eg, *Clostridium difficile*), as clinically appropriate³

 **Resume TRUQAP at same or one lower dose if recovery ≤ 28 days and as clinically indicated¹** **Permanently discontinue TRUQAP if recovery > 28 days¹**

- Consider hospital admission for IV fluids and antibiotics, as clinically appropriate³
- Perform bloodwork and diagnostic work-up for infectious pathogens (eg, *Clostridium difficile*), as clinically appropriate³

 **Permanently discontinue TRUQAP¹****AT RESOLUTION³**

- Continue dietary modifications; gradually add solid foods
- Discontinue loperamide and/or diphenoxylate plus atropine after a 12-hour diarrhea-free interval. Consider gradual taper for multiple medications
- Consider scheduling loperamide to prevent recurrence; de-escalate as diarrhea improves

Important Safety Information and Indication

IMPORTANT SAFETY INFORMATION ABOUT TRUQAP® (capivasertib) tablets

TRUQAP is contraindicated in patients with severe hypersensitivity to TRUQAP or any of its components.

Hyperglycemia

TRUQAP can cause severe hyperglycemia, including diabetic ketoacidosis and fatal outcomes.

Increased fasting glucose (FG) from baseline occurred in 69% of patients treated with TRUQAP, including 25% of patients with Grade 2 (FG >160 to 250 mg/dL), 12% with Grade 3 (FG >250 to 500 mg/dL), and 1.2% of patients with Grade 4 (FG >500 mg/dL) events. The median time to first occurrence of hyperglycemia was 71 days (range: 1 to 1454). Dose reduction for hyperglycemia was required in 8.7% of patients and permanent discontinuation was required in 2.4% of patients. Diabetic ketoacidosis occurred in 1.2% of patients.

In the study, 41% (204/503) of patients who received TRUQAP had an anti-hyperglycemic medication regimen either initiated or changed, including treatment with insulin in 16% (81/503) of patients.

The safety of TRUQAP has not been established in patients with Type 1 diabetes or Type 2 diabetes that is uncontrolled or requiring insulin at baseline as these patients were excluded from clinical studies. Before initiating treatment with TRUQAP, test fasting glucose levels (FPG or FBG), HbA1C levels, and optimize fasting glucose. After initiating treatment with TRUQAP, monitor or self-monitor FG levels on Day 3 or 4 of the dosing week during weeks 1, 2, 4, 6, and 8; then monthly while on treatment with TRUQAP; and as clinically indicated. Monitor HbA1C levels every 3 months during treatment with TRUQAP and as clinically indicated. Patients with a history of well-controlled Type 2 diabetes mellitus may require intensified anti-hyperglycemic treatment and close monitoring of FG levels.

For patients who experience hyperglycemia during treatment with TRUQAP, monitor FG at least twice weekly, on days on and off TRUQAP, until FG decreases to baseline levels. During treatment with anti-diabetic medications, monitor FG at least once a week for 2 months, followed by once every 2 weeks, or as clinically indicated. Consider consultation with a healthcare practitioner with expertise in the treatment of hyperglycemia and initiation of FG monitoring at home for patients who have risk factors for hyperglycemia or who experience hyperglycemia. Advise patients on the signs and symptoms of hyperglycemia and counsel patients on lifestyle changes.

Withhold TRUQAP immediately when ketoacidosis is suspected. If ketoacidosis is confirmed, permanently discontinue TRUQAP. Withhold TRUQAP in clinical situations known to increase the risk of severe hyperglycemia or ketoacidosis (eg, suspected serious infection or acute illness). Based on the severity of hyperglycemia, withhold, reduce dose, or permanently discontinue TRUQAP.

Diarrhea

TRUQAP can cause severe diarrhea associated with dehydration.

Diarrhea of any grade occurred in 264 (52%) patients. Grade 3 occurred in 31 (6%) patients and Grade 4 occurred in 1 (0.2%) patient. The median time to first occurrence was 12 days (range: 3 to 48). In the study, dose reductions were required in 26 (5%) patients and 6 (1.2%) patients discontinued TRUQAP due to diarrhea. In the 264 patients with diarrhea, anti-diarrheal medication was required in 64% (170/264) of patients to manage diarrhea symptoms.

Monitor patients for signs and symptoms of diarrhea. Advise patients to increase oral fluids and start anti-diarrheal treatment at the first sign of diarrhea while taking TRUQAP. Withhold, reduce dose, or permanently discontinue TRUQAP based on severity.

Cutaneous Adverse Reactions

TRUQAP can cause cutaneous adverse reactions, which can be severe, including erythema multiforme (EM), palmar-plantar erythrodysesthesia (PPE), and drug reaction with eosinophilia and systemic symptoms (DRESS).

Cutaneous adverse reactions occurred in 53% of patients. Grade 3 cutaneous adverse reactions occurred in 84 (17%) patients and Grade 4 occurred in 1 (0.2%) patient. The median time to onset of rash was 13 days (range: 11 to 63 days). In the study, dose reduction was required in 58 (12%) patients and 38 (8%) patients discontinued TRUQAP due to rash. Among the 265 patients with cutaneous adverse reactions, 80% (212/265) required treatment and 91% (242/265) recovered in the study. Of these, 54% (115/212) were treated with topical corticosteroids and 25% (54/212) with systemic corticosteroids.

Monitor patients for signs and symptoms of cutaneous adverse reactions. Early consultation with a dermatologist is recommended. Withhold, reduce dose, or permanently discontinue TRUQAP based on severity.

Embryo–Fetal Toxicity

Based on findings from animals and mechanism of action, TRUQAP can cause fetal harm when administered to a pregnant woman. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with TRUQAP and for 4 months after the last dose.

TRUQAP is used in combination with abiraterone. Refer to the full Prescribing Information of abiraterone for pregnancy and contraception information.

ADVERSE REACTIONS

Among the 503 patients who received TRUQAP in CAPItello-281, the most common ($\geq 20\%$) adverse reactions including laboratory abnormalities were increased fasting glucose (70%), decreased hemoglobin (61%), decreased lymphocytes (58%), cutaneous adverse reactions (53%), diarrhea (53%), decreased potassium (51%), increased creatinine (49%), increased non-fasting glucose (49%), increased alanine aminotransferase (38%), increased triglycerides (37%), increased aspartate aminotransferase (36%), decreased sodium (30%), and fatigue (26%).

In the 503 patients treated with TRUQAP + abiraterone and prednisone, dose reductions due to adverse reactions were reported in 32% of patients. Permanent TRUQAP discontinuation due to an adverse reaction occurred in 20% of patients. Dose interruptions of TRUQAP occurred in 65% of patients.

DRUG INTERACTIONS

Strong CYP3A Inhibitors: Avoid concomitant use with a strong CYP3A inhibitor. If concomitant use cannot be avoided, reduce the dose of TRUQAP and monitor patients for adverse reactions.

Moderate CYP3A Inhibitors: When concomitantly used with a moderate CYP3A inhibitor, reduce the dose of TRUQAP and monitor patients for adverse reactions.

Strong or Moderate CYP3A Inducers: Avoid concomitant use of TRUQAP with strong or moderate CYP3A inducers.

INDICATION AND USAGE

TRUQAP in combination with abiraterone and prednisone is indicated for the treatment of adult patients with metastatic androgen pathway modulation-naïve or -sensitive (mAPMN/S) prostate cancer that is PTEN-deficient as detected by an FDA-authorized test.



Please see full **Prescribing Information**, including **Patient Information** for TRUQAP or scan here.

You may report side effects related to AstraZeneca products [here](#).

References: **1.** TRUQAP® (capivasertib) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2026. **2.** Armstrong AJ, Morris MJ, Abida W, et al. Trial design and objectives for patients with prostate cancer: recommendations from the Prostate Cancer Working Group 4. *J Clin Oncol*. 2026;44(13):1249-1265. doi:10.1200/JCO-25-02834 **3.** Iyengar NM, O'Shaughnessy JA, Moore HN, et al. Optimizing clinical monitoring and management guidelines for capivasertib in HR-positive/HER2-negative advanced breast cancer: expert opinion. *NPJ Breast Cancer*. 2025;12(1):16. doi:10.1038/s41523-025-00864-2 **4.** Data on file. REF-345381. AstraZeneca Pharmaceuticals LP. **5.** Benson AB 3rd, Ajani JA, Catalano RB, et al. Recommended guidelines for the treatment of cancer treatment-induced diarrhea. *J Clin Oncol*. 2004;22(14):2918-2926. doi:10.1200/JCO.2004.04.132 **6.** ChemoCare. Diarrhea and chemotherapy. Accessed August 5, 2026. <https://chemocare.com/sideeffect/diarrhea> **7.** Miller C, Sommovilla R, Murphy D, Morris T, Khatun M, Cullberg M. The effect of food and acid-reducing agents on the pharmacokinetic profile of capivasertib: Results from a randomized, crossover study. *Br J Clin Pharmacol*. 2023;89(11):3330-3339. doi:10.1111/bcp.15831

DIARRHEA

PI recommendations and expert insights may help manage diarrhea with TRUQAP + abiraterone/prednisone^{1,3}

▶ TRUQAP discontinuation due to ARs occurred in 20% of patients¹



Diarrhea was **mostly Grade 1-2**



1.2% discontinued TRUQAP due to diarrhea

▶ Monitor patients for signs and symptoms¹



Ask patients to **keep a stool diary**³



Assess risk factors and baseline labs³

▶ Consider additional medications and advise patients of strategies¹



Increase oral fluids and start **antidiarrheal treatment** at first sign of diarrhea¹



Counsel on **dietary modifications**³



Learn more about managing diarrhea in patients treated with TRUQAP + abiraterone/prednisone.
Download the [Dosing and AR Management Handbook](#)

Recommendations for diarrhea management are from organizations outside of AstraZeneca and should be considered along with the complete Prescribing Information and physicians' own clinical experience.

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Please see Important Safety Information on pages 10-11 and full Prescribing Information, including Patient Information for TRUQAP.



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