Identifying and managing TRUQAP®▼ (capivasertib)-related cutaneous adverse drug reactions

This resource has been developed and funded by AstraZeneca for UK healthcare professionals.

Information and recommendations provided follow TRUQAP treatment management guidance outlined in the Summary of Product Characteristics (SmPC) and clinical experience provided by an expert dermatologist. This resource is for awareness only and is not intended to replace existing guidance. Consider early consultation with a dermatologist to ensure greater diagnostic accuracy and appropriate management.

TRUQAP is indicated in combination with fulvestrant for the treatment of adult patients with HR-positive, HER2-negative* locally advanced or metastatic breast cancer with ≥1 *PIK3CA/AKT1/PTEN* alterations following recurrence or progression on or after an endocrine based regimen.[1] Please refer to the SmPCs for TRUQAP and fulvestrant for full guidance prior to prescribing.

Prescribing information and adverse event reporting information can be found at the back of this booklet.

TRUQAP-related cutaneous adverse drug reactions (CADRs) in the CAPItello-291 trial†

Patients treated with TRUQAP commonly experienced low-grade events in the CAPItello-291 trial,[1] suggesting the events were generally manageable.

CADRs are listed as one of the special warnings for TRUQAP.[1]

CADRs experiences by patients treated with TRUQAP plus fulvestrant (N=355):[1]

46.5% (n=165) experienced any grade

14.9% (n=53) experienced Grade 3 or 4

Of the patients experiencing TRUQAP-related CADRs (n=165):[1]

12.7% (n=21) required dose reduction

11.5% (n=19) discontinued treatment

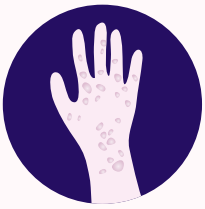
12 days Median time to first occurrence (range 1–377)

Adapted from the TRUQAP SmPC.

Common manifestations of TRUQAP-related rash‡ in patients receiving TRUQAP plus fulvestrant in the CAPItello-291 trial[2]

Erythema (rash) – reddening of the skin[3,4]

Maculo-papular rash – a combination of cutaneous reactions[3,4]



Macules – small red patches (flat)[3,4]

Papules – small red spots (raised)[3,4]

CADRs as defined by the TRUQAP SmPC:[1]

- 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 eruption

Detailed descriptions of these reactions are provided by the Primary Care Dermatology Society and Common Terminology Criteria for Adverse Events (CTCAE)v5.[4,5]

*HER2-negative defined as immunohistochemistry (IHC) 0 or 1+, or IHC 2+/in situ hybridisation (ISH)-negative. †CAPItello-291 is a Phase III, randomised, double-blind trial, investigating TRUQAP plus fulvestrant for the treatment of patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)–negative advanced breast cancer who have experienced relapse or disease progression during or after treatment with an aromatase inhibitor, with or without previous cyclin-dependent kinase 4 and 6 inhibitor (CDK4/6i) therapy.[2] ‡Grouped term: Rash, rash macular, rash maculopapular, rash papular, rash pruritic.[1]

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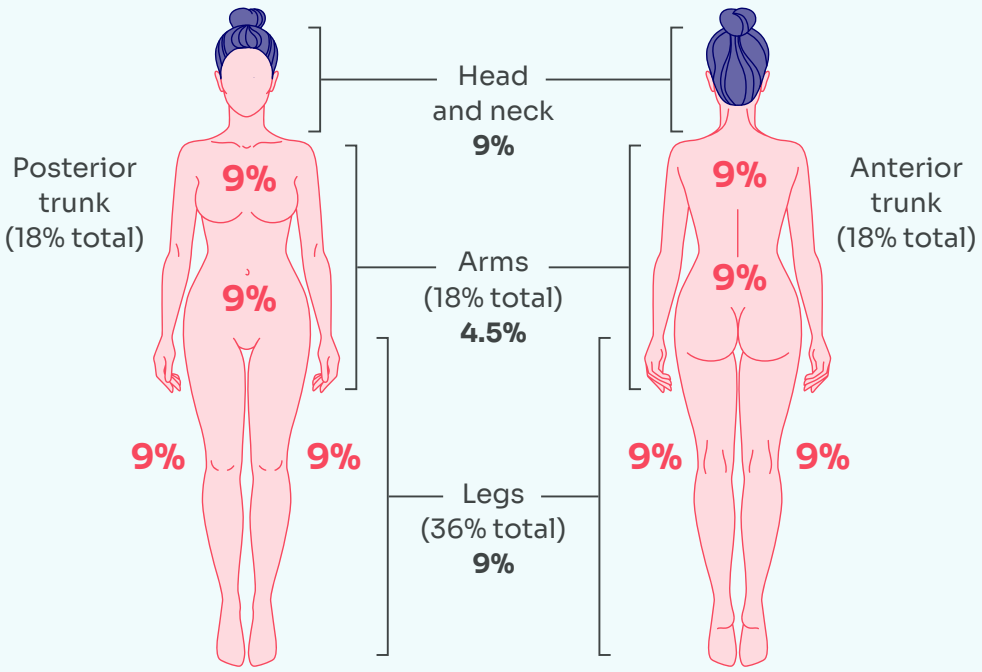
Assessing the severity of cutaneous reactions

The "Rule of Nines", originally created to assess burns,[6] can also be used to estimate the BSA affected by CADRs.[3]

Adapted from the Minnesota Department of Health. 2024.

Rule of Nines in adults[7]



Severe Cutaneous Adverse Reactions (SCARs)

Patients should be advised of the risk of severe skin reactions and should be monitored for signs and symptoms of CADRs, including rash or dermatitis.[3]

Examples can include:[3]


Generalised redness (>90% body surface area)


Desquamation/ blistering


Mucosal involvement (oral or genital involvement)


Fever


Pustules (pus spots)

Consider consultation with a dermatologist for all grades of skin drug reactions regardless of the severity.[1]

Dermatologist-recommended advice for the management of patients treated with TRUQAP[3]


Instead of soap, use a gentle cleanser to regularly wash skin (i.e. QV Gentle Wash)


Apply emollient regularly


Use a thicker emollient containing urea or paraffin for drier skin


Apply in the direction of hair growth with gentle strokes

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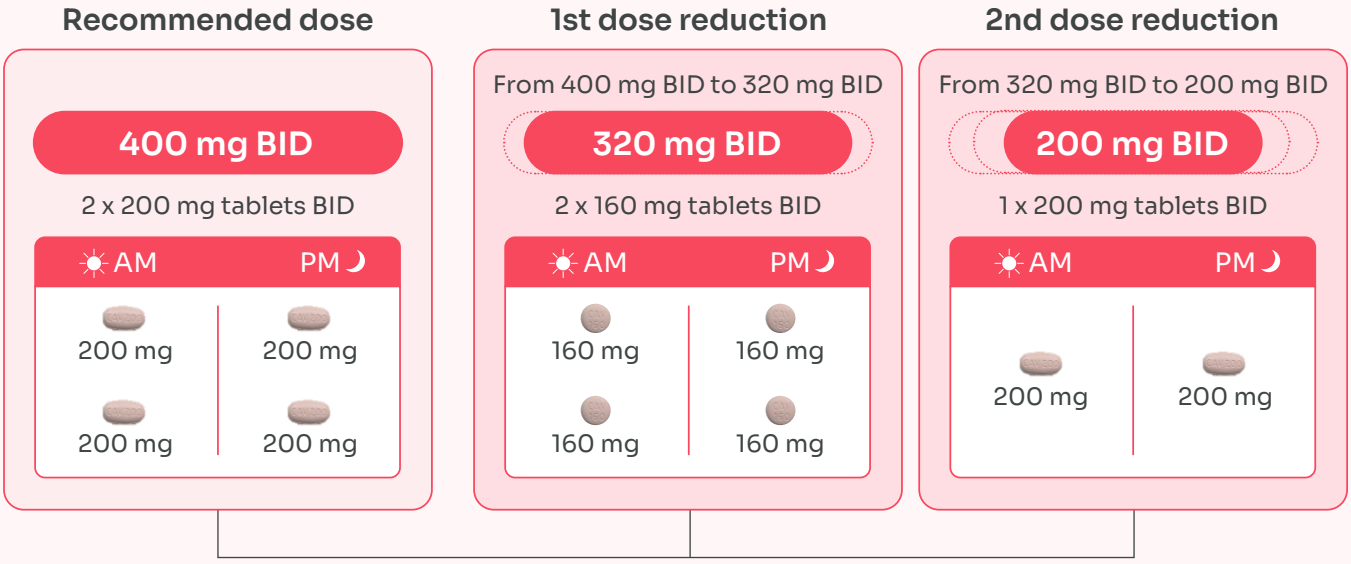
Management strategies for TRUQAP-related CADRs by CTCAE v5 grade

	CTCAE description for maculo-popular rash (example)[5]	SmPC management for all CADRs[1] Adapted from the TRUQAP SmPC.	Dermatologist recommendations per CTCAE grade[3]
Grade 1	Macules/papules covering **<10% BSA** with or without symptoms (e.g. pruritus, burning, tightness)	▪ **No TRUQAP dose adjustment required** ▪ Initiate emollients ▪ Consider oral non-sedating antihistamine treatment as clinically indicated to manage symptoms	**For oral non-sedating antihistamines, consider:** ▪ Cetirizine 10 mg ▪ Loratadine 10 mg ▪ Fexofenadine 180 mg
Grade 2	Macules/papules covering **10–30% BSA** with or without symptoms; limiting instrumental activities of daily life (ADL) or Rash covering **>30% BSA** with or without mild symptoms	▪ **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 by one lower dose level	**For topical steroids, consider:** Clobetasone butyrate (e.g. eumovate cream) Mometasone furoate (e.g. elocon ointment)
Grade 3	Macules/papules covering **>30% BSA** with moderate or severe symptoms; limiting self-care ADL	▪ **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 on 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	**For topical steroids, consider:** E.g. clobetasol propionate - dermovate ointment **For systemic steroids, consider:** ▪ Prednisolone 0.5–1mg/kg/d ▪ If not responsive/severe, we would recommend IV methylprednisolone 1–2mg/kg/d and if stabilised, then convert to oral prednisolone with a slow tapering course
Grade 4	No CTCAE definition	**Permanently discontinue TRUQAP**	

Maculo-papular rash is used as an example. Please refer to the CTCAE for specific descriptions on other CADRs.

Dose reduction guidelines for TRUQAP[1]

Based on severity of treatment-related adverse reactions, TRUQAP may be interrupted, dose reduced or permanently discontinued.



Adapted from the TRUQAP SmPC.
Tablets not to scale.

Click or scan the QR code to access TRUQAP Prescribing information

Click or scan the QR code to access Fulvestrant Prescribing Information

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 the 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.

Abbreviations

ADL, activities of daily life; AKT1, AKT serine/threonine kinase 1; BID, twice daily; BSA, body surface area; CADR, cutaneous adverse drug reaction; CDK4/6i, cyclin-dependent kinase 4/6 inhibitor; CTCAE, Common Terminology Criteria for Adverse Events; HER2, human epidermal growth factor 2; HR, hormone receptor; IHC, immunohistochemistry; ISH, *in situ* hybridisation; NHS, National Health Service; PIK3CA, phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha; PTEN, phosphatase and tensin homolog; SCAR, Severe Cutaneous Adverse Reaction; SmPC, Summary of Product Characteristics.

References

1. TRUQAP (capivasertib) Summary of Product Characteristics. July 2025. Available at: https://www.medicines.org.uk/emc/product/15838/smpc/print (Accessed September 2025); **2.** Rugo HS, et al. ESMO Open. 2024;9:103697 (plus supplementary materials); **3.** Expert Opinion of Dr Silvia Aguilar-Duran; **4.** Primary Care Dermatology Society. Dermatology Dictionary. Available at: https://www.pcds.org.uk/dermatology-dictionary (Accessed September 2025); **5.** Cancer Therapy Evaluation Program. Common Terminology Criteria for Adverse Events (CTCAE) V5. Available at: https://ctep.cancer.gov/protocoldevelopment/electronic_applications/docs/ctcae_v5_quick_reference_5x7.pdf (Accessed September 2025); **6.** National Institute of Health and Care Excellence. Clinical Knowledge Summaries - How should I assess a person with a burn (Jan 2023). Available at: https://cks.nice.org.uk/topics/burns-scalds/diagnosis/assessment/ (Accessed September 2025); **7.** Minnesota Department of Health. Determining Total Body Surface Area. Available at: https://www.health.state.mn.us/communities/ep/surge/burn/tbsa.html (Accessed September 2025).

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