

Supplementary Material

Early identification and management of patients with rash on apalutamide – a practical approach

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Supplementary Table 1: Rash management in the Phase 3 clinical trials

Grade	Action
Grade 1	• Continue apalutamide at current dose and initiate the following dermatological treatment:* ○ Topical steroid cream AND ○ Oral antihistamines • Monitor for change in severity*
Grade 2 (or symptomatic grade 1 [†])	• Hold apalutamide for up to 28 days and initiate the following dermatological treatment:* ○ Topical steroid cream AND ○ Oral antihistamines • Monitor for change in severity* • Consider dose reduction by 1 dose level • If rash improves to grade ≤1, re-initiate apalutamide
Grade ≥3 [‡]	• Hold apalutamide for up to 28 days and initiate the following dermatological treatment:* ○ Topical steroid cream AND ○ Oral antihistamines AND • Consider short course of oral corticosteroids • Reassess after 2 weeks: If the rash is the same or has worsened, initiate oral steroids (if not already done) and consider referring the patient to a dermatologist • If not resolved to grade ≤1 after 28 days, consider discontinuation of apalutamide • If rash improves to grade ≤1, re-initiate apalutamide at a one-dose-level reduction[§] (i.e., 180 or 120 mg). If dose reduction results in a dose of <120 mg, discontinue apalutamide

* Obtain bacterial/viral cultures if infection is suspected.

† Patient presents with other rash-related symptoms, such as pruritus, stinging or burning.

‡ If there is blistering or mucosal involvement, stop apalutamide dosing immediately.

§ If a patient previously started oral corticosteroids, continue for at least 1 week after resumption of reduced dose of apalutamide. If the proposed total oral steroid use will exceed 28 days, discontinue apalutamide.
