ERLEADA® 60 mg and 240mg film-coated tablets
ABBREVIATED PRESCRIBING INFORMATION

ACTIVE INGREDIENT(S): Apalutamide

Please refer to Summary of Product Characteristics (SmPC) before prescribing.

INDICATION(S): Treatment of adult men**:** with non-metastatic castration-resistant prostate cancer (nmCRPC), at high risk of developing metastatic disease; with metastatic hormone-sensitive prostate cancer (mHSPC) in combination with androgen deprivation therapy (ADT).

DOSAGE & ADMINISTRATION: Adults: 240 mg (one 240mg or four 60 mg tablet(s)) single daily dose, swallowed whole with or without food. The tablet should not be crushed or split.
For patients who cannot swallow tablets whole, Erleada can be dispersed in non-fizzy water and mixed with one of the following non-fizzy beverages or soft foods: orange juice, green tea, applesauce, drinkable yogurt, or additional water – refer to SmPC for further details. Erleada can also be administered through a nasogastric feeding tube (NG tube) – refer to SmPC for further details. Continue medical castration with gonadotropin releasing hormone analogue (GnRHa) throughout in patients not surgically castrated. **Elderly:** No dose adjustment. **Renal impairment:** Mild to moderate - no dose adjustment. Severe - not studied; caution advised. If treating, monitor patients for side effects, reduce dose if required. **Hepatic impairment:** Baseline mild or moderate (Child-Pugh Class A and B) - no dose adjustment. Severe (Child-Pugh Class C) - recommended dose is 120 mg (two 60 mg tablets) administered orally once daily.

CONTRAINDICATIONS: Hypersensitivity to active substance or any excipient. Women who are or may become pregnant.

SPECIAL WARNINGS & PRECAUTIONS: Please refer to SmPC for information on the following special warnings and precautions: Seizure; Ischaemic heart disease and ischaemic cerebrovascular disorders; Falls and fractures; Concomitant use with other medicinal products; Recent cardiovascular disease; Androgen deprivation therapy may prolong QT interval; Severe Cutaneous Adverse Reactions (SCARs); Interstitial lung disease (ILD); Excipients.

SIDE EFFECTS: Very common: decreased appetite, hot flush, hypertension, diarrhoea, skin rash, fracture, arthralgia, fatigue, weight decreased, fall. **Common:** neutropenia, hypothyroidism, hypercholesterolaemia, hypertriglyceridaemia, dysgeusia, ischaemic cerebrovascular disorders, ischaemic heart disease, pruritus, alopecia, muscle spasm. **Uncommon**: seizure, restless legs syndrome, lichenoid eruption.
Refer to SmPC for further information on side effects.

LEGAL CATEGORY: Prescription only medicine (POM).

PRESENTATIONS, PACK SIZES, MARKETING AUTHORISATION NUMBER(S):
Blister pack, 112 pack size, EU/1/18/1342/001
Blister pack, 28 pack size, EU/1/18/1342/004

MARKETING AUTHORISATION HOLDER: JANSSEN-CILAG INTERNATIONAL NV, Turnhoutseweg 30, B-2340 Beerse, Belgium.

FURTHER INFORMATION IS AVAILABLE FROM: Janssen Sciences Ireland UC, Barnahely, Ringaskiddy, IRL – Co. Cork P43 FA46

Prescribing information last revised: March 2026

Adverse events should be reported. Healthcare professionals are asked to report any suspected adverse reactions via: HPRA Pharmacovigilance, Website: www.hpra.ie. Adverse events should also be reported to Janssen Sciences Ireland UC, a Johnson & Johnson Company, on 0044 1494 567447 or at dsafety@its.jnj.com.