

Darolutamide

Indication

Indicated for the treatment of adult men with non-metastatic castration resistant prostate cancer (nmCRPC) who are at high risk of developing metastatic disease

Regimen details

The recommended dose is 600 mg darolutamide (two tablets of 300 mg) taken twice daily, equivalent to a total daily dose of 1200 mg

Cycle frequency

Twice daily to continue

Number of cycles

Until disease progression

Administration

Take orally with food

Investigations – pre first cycle

Investigation	Validity period
PSA	28 days
FBC	28 days
U+E (including creatinine)	28 days
LFT (including AST)	28 days

Investigations –pre subsequent cycles

FBC, U+E (including creatinine), LFT, PSA

Standard limits for administration to go ahead

If blood results not within range, authorisation to administer **must** be given by prescriber/ consultant.

Investigation	Limit
Neutrophil count	$\geq 1.0 \times 10^9/L$
Platelet count	$\geq 100 \times 10^9/L$
Creatinine clearance	≥ 60 mL/min
Bilirubin	$\leq 1.5 \times$ ULN
AST	$< 1.5 \times$ ULN

Dose modifications

To discuss directly with consultant

Adverse effects - for full details consult product literature/ reference texts

- **Serious side effects**

Cardiac side effects (Includes arteriosclerosis coronary artery, coronary artery disease, coronary artery occlusion, coronary artery stenosis, acute coronary syndrome, acute myocardial infarction, angina pectoris, angina unstable, myocardial infarction, myocardial ischaemia)

- **Frequently occurring side effects**

Fatigue

Rash

Pain in extremity

Musculoskeletal pain

Fractures

- **Other side effects**

Neutrophil count decreased

Bilirubin increased

AST increased

Significant drug interactions – for full details consult product literature/ reference texts

Use of strong and moderate CYP3A4 inducers and P-gp inducers (e.g. carbamazepine, phenobarbital, St. John's Wort, phenytoin, and rifampicin) during treatment with darolutamide is not recommended, unless there is no therapeutic alternative.

References

Summary of product characteristics , EMC.

<https://www.medicines.org.uk/emc/product/11324> - accessed 1/7/2020

Fiazzi et al Darolutamide in Nonmetastatic, Castration-Resistant Prostate Cancer. N Engl J Med 2019; 380:1235-1246

THIS PROTOCOL HAS BEEN DIRECTED BY DR PARIKH, CLINICIAN FOR PROSTATE CANCER

RESPONSIBILITY FOR THIS PROTOCOL LIES WITH THE HEAD OF SERVICE

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