

Chemotherapy Protocol

PROSTATE

ENZALUTAMIDE

Regimen

- Prostate-Enzalutamide

Indication

- Enzalutamide is recommended within its marketing authorisation as an option for treating metastatic hormone-relapsed prostate cancer in adults whose disease has progressed during or after docetaxel-containing chemotherapy, only if the manufacturer provides enzalutamide with the agreed NHS discount.
- Enzalutamide is recommended in people who have no or mild symptoms after androgen deprivation therapy has failed, and before chemotherapy is indicated
- The use of enzalutamide for treating metastatic hormone-relapsed prostate cancer previously treated with abiraterone is not covered by NICE guidance.
- Performance status 0, 1, 2

Toxicity

Drug	Adverse Effect
Enzalutamide	Fatigue, musculoskeletal pain, arthralgia, hot flush, peripheral oedema, insomnia, respiratory infections, hypertension, headaches, seizures, confusion, restless leg syndrome

The adverse effects listed are not exhaustive. Please refer to the relevant Summary of Product Characteristics for full details.

Monitoring

- FBC, U&Es, LFTs, PSA every four weeks for the first 12 weeks then every 8-12 weeks thereafter
- Blood pressure and fluid retention should be monitored before treatment and every 4 weeks for the first 12 weeks then every 8-12 weeks thereafter.

Dose Modifications

The dose modifications listed are for liver and renal function and drug specific toxicities only. Dose adjustments may be necessary for other toxicities as well.

Hepatic Impairment

No dose adjustment is necessary for patients with mild hepatic impairment (Child-Pugh Class A). Caution is advised in patients with moderate hepatic impairment (Child-Pugh Class B). Enzalutamide is not recommended in patients with severe hepatic impairment (Child-Pugh Class C).

Renal impairment

No dose adjustment is necessary for patients with mild or moderate renal impairment. Caution is advised in patients with severe renal impairment or end-stage renal disease.

Other

If a patient experiences a NCI-CTC grade 3 or above toxicity or an intolerable adverse reaction, dosing should be withheld for one week or until symptoms improve to at least NCI-CTC grade 2, then resumed at the same or a reduced dose (120 mg or 80 mg) if warranted.

Regimen

28 day cycle until disease progression (12 cycles will be set in Aria)

Drug	Dose	Days	Administration
Enzalutamide	160mg	1-28 inclusive	Oral

Dose Information

- Enzalutamide is available as 40mg capsules or 40mg and 80mg film coated tablets. The products are interchangeable.
- The tablets will be the default in ARIA

Administration Information

- If a patient misses taking a dose of enzalutamide at the usual time, the prescribed dose should be taken as close as possible to the usual time. If a patient misses a dose for a whole day, treatment should be resumed the following day with the usual daily dose.
- Enzalutamide capsules should be swallowed whole.
- Enzalutamide tablets should be swallowed whole.

Additional Therapy

- Gastric protection with a proton pump inhibitor or a H₂ antagonist may be considered in patients considered at high risk of GI ulceration or bleed.

Additional Information

- Enzalutamide treatment should be supervised by a consultant oncologist.
- Always check for drug interactions. Enzalutamide is known to interact with many medications. It is a potent CYP3A4 inducer.

Coding

- Procurement – X74.1
- Delivery – X73.1

References

1. Scher HI, Fizazi K, Saad F et al. Increased survival with enzalutamide in prostate cancer after chemotherapy. N Engl J Med 2012; 367 (13): 1187-1197.
2. National Institute of Health and Clinical Excellence (2016). Enzalutamide for treating hormone-relapsed prostate cancer before chemotherapy is indicated. TA377.
3. National Institute of Health and Clinical Excellence (2014). Enzalutamide for metastatic hormone-relapsed prostate previously treated with a docetaxel containing chemotherapy. TA316.

REGIMEN SUMMARY

Enzalutamide

Day 1

Take Home Medicines

1. Enzalutamide 160mg once a day oral
Administration Instructions
Oral SACT.

Enzalutamide is available as 40mg capsules or 40mg and 80mg film coated tablets. These are interchangeable formulations. The ARIA regimen has been set as tablets to reduce the number of tablets people have to take. You can dispense either tablets or capsules depending on stock availability, patient preference or cost.

DOCUMENT CONTROL

Version	Date	Amendment	Written By	Approved By
1.2	Aug 2019	Information on tablets added. References updated Adverse effects updated Monitoring updated	Dr Deborah Wright Pharmacist	Rebecca Wills Pharmacist
1.1	May 2015	Disclaimer updated Administration instructions added	Donna Kimber Pharmacy Technician	Rebecca Wills Pharmacist
1	Oct 2014	None	Dr Deborah Wright Pharmacist	Dr Matthew Wheeler Consultant Medical Oncologist

This chemotherapy protocol has been developed as part of the chemotherapy electronic prescribing project. This was and remains a collaborative project that originated from the former CSCCN. These documents have been approved on behalf of the following Trusts;

Hampshire Hospitals NHS Foundation Trust
 NHS Isle of Wight
 Portsmouth Hospitals NHS Trust
 Salisbury Hospitals NHS Foundation Trust
 University Hospital Southampton NHS Foundation Trust
 Western Sussex Hospitals NHS Foundation Trust

All actions have been taken to ensure these protocols are correct. However, no responsibility can be taken for errors which occur as a result of following these guidelines.