Chemotherapy Protocol

DRUG REGIMEN
Vismodegib

Indication for use
Locally advanced or metastatic basal cell carcinoma

Regimen
Vismodegib 160mg orally daily

Take continuously until disease progression or unacceptable toxicity (dispense every 28 days)

Investigation prior to initiating treatment
FBC, U&Es, LFTs, pregnancy test in women of childbearing potential (WCBP)
Patients must agree to comply with the Erivedge Pregnancy Prevention Programme (see below)

Cautions/Contraindications
Vismodegib capsules contain lactose monohydrate. Patients with galactose intolerance, primary hypolactasia or glucose-galactose malabsorption should not take vismodegib
Patients should not take St John's wort with vismodegib

Investigations and consultations prior to each cycle
FBC, U&Es, LFTs, pregnancy test in WCBP

Acceptable levels for treatment to proceed (if outside these levels defer one week or contact consultant)
Neutrophils > 1.5, platelets > 100

Side Effects
Muscle spasms, alopecia, taste disturbances, weight loss, fatigue, nausea, vomiting, loss of appetite, diarrhoea, constipation, infertility
Amenorrhea in WCBP, raised hepatic enzymes, hyponatremia, loss of taste, dyspepsia, abdominal pain, pruritis, rash, arthralgia and myalgia were also reported

Dose Modification Criteria
No specific information regarding dosing in renal or hepatic failure
Interrupt dose in the event of toxicity

Specific Information on Administration
Vismodegib capsules should be swallowed whole with water, with or without food
Do not crush or open the capsules

Drug Interactions
Clinically significant drug interactions are not expected. Concomitant administration with strong CYP inducers (e.g. rifampicin, carbamazepine) may reduce vismodegib exposure. Concomitant administration with St John's wort is not permitted

Vismodegib may reduce the effectiveness of the contraceptive pill

Caution should be exercised when using vismodegib in combination with any statin

Erivedge Pregnancy Prevention Programme

The patient must be provided with the Erivedge Pregnancy Prevention Programme Brochure and the Erivedge Verification of Counselling Form must be completed and signed prior to starting treatment with vismodegib.

Women of childbearing potential (WCBP) must comply with the Erivedge Pregnancy Prevention Programme. Initial prescription and dispensing should occur within 7 days of a negative pregnancy test. A pregnancy test must be conducted monthly prior to each cycle thereafter. WCBP must not become pregnant during treatment and for 24 months after the final dose.2 methods of recommended contraception must be used (one highly effective method and a barrier method).

Male patients must use the recommended protection - condom (with spermicide, if available) even after a vasectomy, whilst on treatment and for 2 months after the final dose.

THIS PROTOCOL HAS BEEN DIRECTED BY DR BOARD, CLINICIAN FOR SKIN CANCER

RESPONSIBILITY FOR THIS PROTOCOL LIES WITH THE HEAD OF SERVICE

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