Vismodegib (intermittent treatment)

Indication

Gorlin syndrome with non-locally advanced, non-metastatic multiple basal cell carcinomas (BCC) (>=6) clinically evident at the point of decision to treat BCCs of which 3 are at least 5mm OR

Non-locally advanced, non-metastatic multiple BCC (>=6) clinically evident at the point of decision to treat BCCs of which 3 are at least 5mm AND are appropriate for surgery i.e. surgically eligible tumours

Regimen details

Vismodegib 150mg orally daily

Must be prescribed in conjunction with the Erivedge Pregnancy Prevention Programme, see below under "Additional comments"

Cycle frequency

Treatment given intermittently – 12 weeks on, 8 weeks off

For women of child-bearing potential (WCBP), maximum supply is limited to 28 days

Number of cycles

Up to 72 weeks

Administration

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

Pre-medication

N/A

Emetogenicity

Minimal

Additional supportive medication

None routinely required

Extravasation

N/A

Investigations – pre first cycle

Investigation	Validity period
FBC	14 days
U+E (including creatinine)	14 days
LFT (including AST)	14 days
Pregnancy test (in WCBP)	7 days

Investigations –pre subsequent cycles

FBC, U+E (including creatinine), LFT (including AST), pregnancy test in WCBP

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	≥ 1.5 x 10^9/L
Platelet count	≥ 100 x 10^9/L
Creatinine clearance	≥ 30 mL/min
Bilirubin	≤ 1.5 x ULN
AST	< 1.5 x ULN

Dose modifications

No specific recommendations for patients with renal or hepatic impairment

Discontinue treatment in the event of severe cutaneous adverse reactions

Adverse effects –

for full details consult product literature/ reference texts

Taste changes
Muscle cramps
Gradual hair loss
Weight loss
Gastrointestinal effects (nausea, vomiting, diarrhoea, constipation)
Fatigue

Severe cutaneous adverse reactions (SCARs) have been reported during post-marketing use:

- Stevens-Johnson Syndrome(SJS)/Toxic Epidermal Necrolysis (TEN)
- Drug reaction with Eosinophilia and Systemic Symptoms (DRESS)
- Acute Generalised Exanthematous Pustulosis (AGEP)

Significant drug interactions

– for full details consult product literature/ reference texts

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

Additional comments

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.

References

Erivedge SPC: https://www.medicines.org.uk/emc/product/1195/smpc

NHS England clinical commissioning policy: https://www.england.nhs.uk/wp-content/uploads/2021/07/1905-policy-Final.pdf

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

RESPONSIBILITY FOR THIS PROTOCOL LIES WITH THE HEAD OF SERVICE

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