

● **CONCEPTION AND CONTRACEPTION** For women of child-bearing potential, pregnancy must be excluded before initiation of treatment, and monthly during treatment. Women must use two contraceptive methods (including one highly effective method and one barrier method) during treatment and for 24 months after the final dose of vismodegib. Men must use a condom during treatment and for 2 months after the final dose.

● **PREGNANCY Important: teratogenic risk**—may cause severe birth defects and embryo-fetal death.

● **BREAST FEEDING** Avoid during treatment and for 24 months after final dose.

● **RENAL IMPAIRMENT** No information available—manufacturer advises caution in severe impairment.

● **PRESCRIBING AND DISPENSING INFORMATION** Prescribers and pharmacists must comply with prescribing and dispensing restrictions as specified in the manufacturer's Pregnancy Prevention Programme, and ensure that the patient fully acknowledges the programme's pregnancy prevention measures—consult product literature for further information.

● **PATIENT AND CARER ADVICE**

**Conception and contraception** Counselling on pregnancy and contraception advised. Patients must comply with the manufacturer's pregnancy prevention programme.

● **NATIONAL FUNDING/ACCESS DECISIONS**

**NICE decisions**

▶ **Vismodegib for treating basal cell carcinoma (November 2017)** NICE TA489

Vismodegib is not recommended within its marketing authorisation for treating symptomatic metastatic basal cell carcinoma, or locally advanced basal cell carcinoma that is inappropriate for surgery or radiotherapy, in adults.

Patients whose treatment was started within the NHS before this guidance was published should have the option to continue treatment, without change to their funding arrangements, until they and their NHS clinician consider it appropriate to stop.

[www.nice.org.uk/guidance/TA489](http://www.nice.org.uk/guidance/TA489)

● **MEDICINAL FORMS** There can be variation in the licensing of different medicines containing the same drug.

**Capsule**

CAUTIONARY AND ADVISORY LABELS 25

▶ **Erivedge** (Roche Products Ltd)

Vismodegib 150 mg Erivedge 150mg capsules | 28 capsule **PoM** £6,285.00 (Hospital only)

**ANTINEOVASCULARISATION DRUGS >**  
**VASCULAR ENDOTHELIAL GROWTH FACTOR**  
**INHIBITORS**

**Aflibercept**

19-Mar-2020

● **DRUG ACTION** Aflibercept is a recombinant fusion protein that acts as a soluble decoy receptor and binds to vascular endothelial growth factors A and B (VEGF-A, VEGF-B) and placental growth factor (PlGF). Aflibercept inhibits the activation of VEGF receptors and the proliferation of endothelial cells, thereby inhibiting the growth of new vessels that supply tumours with oxygen and nutrients.

● **INDICATIONS AND DOSE**

**In combination with irinotecan, fluorouracil and folinic acid (FOLFIRI) chemotherapy, in metastatic colorectal cancer that is resistant to, or has progressed after, an oxaliplatin-containing regimen**

▶ BY INTRAVENOUS INFUSION

▶ Adult: (consult local protocol)

● **CAUTIONS** Febrile neutropenia · history of cardiovascular disease (may be exacerbated by hypertension) · increased risk of haemorrhage (including fatal events) · increased risk of hypertension · increased risk of thromboembolic events (consult product literature if event occurs) · may impair wound healing—without treatment for at least 4 weeks before elective surgery and for at least 4 weeks after major surgery, or until wound fully healed · neutropenic infection · risk of fistula formation (discontinue if fistula develops) · risk of neutropenia · risk of thrombocytopenia

● **INTERACTIONS** → Appendix 1: aflibercept

● **SIDE-EFFECTS**

▶ **Common or very common** Appetite decreased · asthenic conditions · dehydration · diarrhoea · dysphonia · dyspnoea · embolism and thrombosis · fistula · gastrointestinal discomfort · gastrointestinal disorders · haemorrhage · headache · hypersensitivity · hypertension · increased risk of infection · leucopenia · neutropenia · neutropenic sepsis · oral disorders · oropharyngeal pain · proteinuria · rhinorrhoea · skin reactions · thrombocytopenia · weight decreased

▶ **Uncommon** Healing impaired · heart failure · nephrotic syndrome · osteonecrosis of jaw · posterior reversible encephalopathy syndrome (PRES) · thrombotic microangiopathy

▶ **Frequency not known** Alopecia · anaemia · aneurysm · angina pectoris · artery dissection · cerebrovascular insufficiency · constipation · hyperbilirubinaemia · myocardial infarction · nausea · vomiting · wound complications

● **CONCEPTION AND CONTRACEPTION** Exclude pregnancy before treatment. Effective contraception required during and for at least 6 months after treatment in men and women. Contraceptive advice should be given to men and women before therapy begins (and should cover the duration of contraception required after therapy has ended).

● **PREGNANCY** Manufacturer advises avoid—toxicity in *animal* studies. Considerable caution is necessary if a pregnant woman presents with cancer requiring chemotherapy, and specialist advice should always be sought.

● **BREAST FEEDING** Manufacturer advises avoid—no information available.

● **HEPATIC IMPAIRMENT** Manufacturer advises caution in severe impairment (no information available).

● **RENAL IMPAIRMENT** Caution in severe impairment—no information available.

● **MONITORING REQUIREMENTS**

▶ Monitor blood pressure at initiation and at least fortnightly during treatment (do not initiate treatment if pre-existing hypertension is uncontrolled)—consult product literature if hypertension develops during treatment.

▶ Monitor for signs of gastro-intestinal perforation (discontinue if perforation develops).

▶ Monitor full blood count, including differential count and platelets at baseline and before each treatment cycle.

▶ Monitor for proteinuria before each treatment administration (consult product literature if symptoms develop).

▶ Monitor for signs and symptoms of diarrhoea and dehydration, particularly in elderly—consult product literature if severe diarrhoea occurs.

▶ Monitor for posterior reversible encephalopathy syndrome (presenting as seizures, altered mental status, nausea, vomiting, headache, or visual disturbance).

● **CONTRA-INDICATIONS** Moderate or severe congestive heart failure · uncontrolled hypertension