- **CONCEPTION AND CONTRACEPTION** Effective contraception required during for at least 6 months after treatment.
- **PREGNANCY** Manufacturer advises avoid unless potential benefit outweighs risk. See also *Pregnancy and reproductive function* in Cytotoxic drugs p. 938.
- **BREAST FEEDING** Avoid—no information available.
- **HEPATIC IMPAIRMENT** Manufacturer advises caution in moderate to severe impairment (risk of increased exposure)—monitor ECG monthly during the first 3 months of treatment, followed by at least every 3 months thereafter (if QTc interval is prolonged, consult product literature).
- **RENAL IMPAIRMENT** Manufacturer advises caution in severe impairment.
- **MONITORING REQUIREMENTS**
  - Monitor ECG and electrolytes before treatment, after one month and following dose adjustment (treatment not recommended if QT interval greater than 500 milliseconds at baseline).
  - Monitor liver function before treatment and periodically thereafter.
  - Monitor for uveitis, iritis and retinal vein occlusion.
  - Monitor for cutaneous and non-cutaneous squamous cell carcinoma and new primary melanoma before, during and for up to 6 months after treatment—consult product literature.
- **DIRECTIONS FOR ADMINISTRATION** Food may affect absorption (take at the same time with respect to food).
- **PATIENT AND CARER ADVICE** Counselling advised (administration).
  Drug rash with eosinophilia and systemic symptoms (DRESS syndrome) Patients should be advised to stop taking vemurafenib and consult their doctor immediately if skin rash develops.
- **NATIONAL FUNDING/ACCESS DECISIONS**

**NICE decisions**

- **Vemurafenib for treating locally advanced or metastatic BRAF V600 mutation-positive malignant melanoma (updated January 2015)** NICE TA269
  Vemurafenib (*Zelboraf*®) is recommended as an option for the treatment of BRAF V600 mutation-positive unresectable or metastatic melanoma only if the manufacturer provides vemurafenib with the discount agreed in the patient access scheme.
  www.nice.org.uk/guidance/ta269

**Scottish Medicines Consortium (SMC) decisions**

The *Scottish Medicines Consortium* has advised (December 2013) that vemurafenib (*Zelboraf*®) is accepted for restricted use within NHS Scotland as monotherapy for the first-line treatment of BRAF V600 mutation-positive unresectable or metastatic melanoma.

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

**Tablet**

CAUTIONARY AND ADVISORY LABELS 25

- **Zelboraf** (Roche Products Ltd)
  **Vemurafenib 240 mg** Zelboraf 240mg tablets | 56 tablet PoM £1,750.00 (Hospital only)

## ANTINEOPLASTIC DRUGS › OTHER

# Niraparib

10-Aug-2018

- **DRUG ACTION** Niraparib is an inhibitor of PARP enzymes which are involved in DNA repair. PARP inhibition results in disruption of cellular homoeostasis and cell death.

- **INDICATIONS AND DOSE**

**Ovarian cancer (initiated by a specialist) | Fallopian tube cancer (initiated by a specialist) | Peritoneal cancer (initiated by a specialist)**

- BY MOUTH
- Adult: 300 mg once daily, consider initial dose of 200 mg in patients with body-weight less than 58 kg, for dose adjustments due to side-effects—consult product literature

**IMPORTANT SAFETY INFORMATION**

RISKS OF INCORRECT DOSING OF ORAL ANTI-CANCER MEDICINES
See Cytotoxic drugs p. 938.

- **CAUTIONS** Pre-existing hypertension (control before treatment initiation)
- **SIDE-EFFECTS**
  - **Common or very common** Anaemia · anxiety · appetite decreased · arthralgia · asthenia · back pain · conjunctivitis · constipation · cough · depression · diarrhoea · dizziness · dry mouth · dyspnoea · epistaxis · gastrointestinal discomfort · headache · hypertension · hypokalaemia · increased risk of infection · insomnia · leucopenia · mucositis · myalgia · nausea · neutropenia · palpitations · peripheral oedema · photosensitivity reaction · rash · stomatitis · tachycardia · taste altered · thrombocytopenia · vomiting · weight decreased
  - **Uncommon** Pancytopenia
  - **Frequency not known** Acute myeloid leukaemia (discontinue permanently) · myelodysplastic syndrome (discontinue permanently)
- **CONCEPTION AND CONTRACEPTION** Manufacturer advises effective contraception in women of childbearing potential during treatment and for 1 month after receiving the last dose.
- **PREGNANCY** Manufacturer advises avoid—limited information available.
- **BREAST FEEDING** Manufacturer advises avoid during treatment and for 1 month after last dose—no information available.
- **HEPATIC IMPAIRMENT** Manufacturer advises caution in severe impairment (no information available).
- **RENAL IMPAIRMENT** Manufacturer advises caution in severe impairment—no information available.
- **MONITORING REQUIREMENTS**
  - Manufacturer advises monitor full blood count weekly for the first month of treatment, then monthly for the next 10 months and periodically thereafter.
  - Manufacturer advises monitor blood pressure monthly for the first year of treatment and periodically thereafter.
- **PATIENT AND CARER ADVICE**
  **Driving and skilled tasks** Manufacturer advises patients and their carers should be counselled on the effects on driving and skilled tasks—increased risk of dizziness and fatigue.
- **NATIONAL FUNDING/ACCESS DECISIONS**

**NICE decisions**

- **Niraparib for maintenance treatment of relapsed, platinum-sensitive ovarian, fallopian tube and peritoneal cancer (July 2018)** NICE TA528
  Niraparib (*Zejula*®) is recommended for use within the Cancer Drugs Fund as an option for treating relapsed, platinum-sensitive high-grade serous epithelial ovarian,