

AFINITOR®**NICE decisions**

- ▶ **Lenvatinib with everolimus for previously treated advanced renal cell carcinoma (January 2018)** NICE TA498
Lenvatinib plus everolimus is recommended as an option for treating advanced renal cell carcinoma in adults who have had one previous vascular endothelial growth factor (VEGF)-targeted therapy, only if:
 - their Eastern Cooperative Oncology Group (ECOG) performance status score is 0 or 1, **and**
 - the manufacturer provides lenvatinib with the discount agreed in the patient access scheme.
 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/ta498

CERTICAN®**NICE decisions**

- ▶ **Everolimus for preventing organ rejection in liver transplantation (July 2015)** NICE TA348
Everolimus (*Certican*®) is **not** recommended within its marketing authorisation for preventing organ rejection in patients who have undergone a liver transplant. Patients currently receiving everolimus for this indication should have the option to continue treatment until they and their clinician consider it appropriate to stop.
- ▶ **Immunosuppressive therapy for kidney transplant in adults (October 2017)** NICE TA481
Everolimus is **not** recommended as an initial treatment to prevent organ rejection in adults having a kidney transplant. 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/TA481

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

Dispersible tablet

CAUTIONARY AND ADVISORY LABELS 13

- ▶ **Votubia** (Novartis Pharmaceuticals UK Ltd)

Everolimus 2 mg | **Votubia** 2mg dispersible tablets sugar-free | 30 tablet [PoM] £960.00

Everolimus 3 mg | **Votubia** 3mg dispersible tablets sugar-free | 30 tablet [PoM] £1,440.00

Everolimus 5 mg | **Votubia** 5mg dispersible tablets sugar-free | 30 tablet [PoM] £2,250.00

Tablet

CAUTIONARY AND ADVISORY LABELS 25

- ▶ **Everolimus (Non-proprietary)**

Everolimus 2.5 mg | **Everolimus** 2.5mg tablets | 30 tablet [PoM] £1,150.00

Everolimus 5 mg | **Everolimus** 5mg tablets | 30 tablet [PoM] £2,200.00

Everolimus 10 mg | **Everolimus** 10mg tablets | 30 tablet [PoM] £2,920.00

- ▶ **Afinitor** (Novartis Pharmaceuticals UK Ltd)

Everolimus 2.5 mg | **Afinitor** 2.5mg tablets | 30 tablet [PoM] £1,200.00

Everolimus 5 mg | **Afinitor** 5mg tablets | 30 tablet [PoM] £2,250.00

Everolimus 10 mg | **Afinitor** 10mg tablets | 30 tablet [PoM] £2,673.00

- ▶ **Certican** (Novartis Pharmaceuticals UK Ltd)

Everolimus 250 microgram | **Certican** 0.25mg tablets | 60 tablet [PoM] £148.50

Everolimus 750 microgram | **Certican** 0.75mg tablets | 60 tablet [PoM] £445.50

- ▶ **Votubia** (Novartis Pharmaceuticals UK Ltd)

Everolimus 2.5 mg | **Votubia** 2.5mg tablets | 30 tablet [PoM] £1,200.00

Everolimus 5 mg | **Votubia** 5mg tablets | 30 tablet [PoM] £2,250.00

Everolimus 10 mg | **Votubia** 10mg tablets | 30 tablet [PoM] £2,970.00

Gefitinib

04-Dec-2019

- **DRUG ACTION** Gefitinib is a tyrosine kinase inhibitor.

- **INDICATIONS AND DOSE**

Treatment of locally advanced or metastatic non-small cell lung cancer with activating mutations of epidermal growth factor receptor

- ▶ BY MOUTH
- ▶ Adult: 250 mg once daily

IMPORTANT SAFETY INFORMATION

MHRA/CHM ADVICE: EPIDERMAL GROWTH FACTOR RECEPTOR (EGFR) INHIBITORS: SERIOUS CASES OF KERATITIS AND ULCERATIVE KERATITIS (MAY 2012)

Keratitis and ulcerative keratitis have been reported following treatment with epidermal growth factor receptor (EGFR) inhibitors for cancer (cetuximab, erlotinib, gefitinib and panitumumab). In rare cases, this has resulted in corneal perforation and blindness.

Patients undergoing treatment with EGFR inhibitors who present with acute or worsening signs and symptoms suggestive of keratitis should be referred promptly to an ophthalmology specialist. Treatment should be interrupted or discontinued if ulcerative keratitis is diagnosed.

RISKS OF INCORRECT DOSING OF ORAL ANTI-CANCER MEDICINES

See Cytotoxic drugs p. 938.

- **INTERACTIONS** → Appendix 1: gefitinib
 - **SIDE-EFFECTS**
 - ▶ **Common or very common** Alopecia · angioedema · appetite decreased · asthenia · cystitis · dehydration · diarrhoea · dry eye · dry mouth · eye inflammation · fever · haemorrhage · hypersensitivity · interstitial lung disease (discontinue) · nail disorder · nausea · proteinuria · rash pustular · skin reactions · stomatitis · vomiting
 - ▶ **Uncommon** Corneal erosion · gastrointestinal perforation · hepatic disorders · pancreatitis
 - ▶ **Rare or very rare** Cutaneous vasculitis · severe cutaneous adverse reactions (SCARs)
 - **CONCEPTION AND CONTRACEPTION** Contraceptive advice required, see *Pregnancy and reproductive function* in Cytotoxic drugs p. 938.
 - **PREGNANCY** Manufacturer advises avoid unless essential—toxicity in *animal studies*. See also *Pregnancy and reproductive function* in Cytotoxic drugs p. 938.
 - **BREAST FEEDING** Discontinue breast-feeding.
 - **HEPATIC IMPAIRMENT** Manufacturer advises caution in moderate to severe impairment due to cirrhosis—monitor for adverse events (risk of increased drug plasma concentrations).
 - **RENAL IMPAIRMENT** Manufacturer advises caution if creatinine clearance less than 20 mL/minute.
 - **MONITORING REQUIREMENTS**
 - ▶ Monitor for worsening of dyspnoea, cough and fever—discontinue if interstitial lung disease confirmed.
 - ▶ Monitor liver function—consider discontinuing if severe changes in liver function occur.
 - **NATIONAL FUNDING/ACCESS DECISIONS**
- NICE decisions**
- ▶ **Gefitinib for the first-line treatment of locally advanced or metastatic non-small-cell lung cancer (July 2010)** NICE TA192
Gefitinib (*Iressa*®) is recommended as an option for the first-line treatment of locally advanced or metastatic non-small-cell lung cancer if the patient tests positive for the epidermal growth receptor tyrosine kinase (EGFR-TK) mutation **and** the manufacturer provides gefitinib at the fixed price agreed under the patient access scheme.
- www.nice.org.uk/guidance/ta192