taking a reduced dose, consult product literature. If the CYP3A4 inhibitor is stopped, increase the abemaciclib dose (after 3–5 half lives of the inhibitor) to the dose used before starting the CYP3A4 inhibitor.

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

- **INTERACTIONS** → Appendix 1: abemaciclib
- **SIDE-EFFECTS**
- **Common or very common** Alopecia · anaemia · appetite decreased · decreased leucocytes · diarrhoea · dizziness · embolism and thrombosis · excessive tearing · fatigue · fever · infection · muscle weakness · nausea · neutropenia · skin reactions · taste altered · thrombocytopenia · vomiting
- **CONCEPTION AND CONTRACEPTION** Manufacturer advises highly effective contraception in women of childbearing potential during treatment and for at least 3 weeks after completing treatment. See also *Pregnancy and reproductive function* in Cytotoxic drugs p. 938.
- **PREGNANCY** Manufacturer advises avoid—toxicity in *animal* studies. See also *Pregnancy and reproductive function* in Cytotoxic drugs p. 938.
- **BREAST FEEDING** Manufacturer advises avoid—no information available.
- **HEPATIC IMPAIRMENT** Manufacturer advises caution in severe impairment. Temporary or permanent withdrawal may be needed following increases in aminotransferases—consult product literature.
  Dose adjustments Manufacturer advises dose reduction to 150 mg once daily in severe impairment.
- **RENAL IMPAIRMENT** Manufacturer advises caution in severe impairment—monitor for signs of toxicity.
- **MONITORING REQUIREMENTS** Manufacturer advises monitor full blood count, and alanine and aspartate aminotransferases before starting treatment, every 2 weeks for the first 2 months, monthly for the following 2 months, and as clinically indicated thereafter.
- **NATIONAL FUNDING/ACCESS DECISIONS**

NICE decisions

- **Abemaciclib with an aromatase inhibitor for previously untreated, hormone receptor-positive, HER2-negative, locally advanced or metastatic breast cancer (February 2019)** NICE TA563
  Abemaciclib (*Verzenios*®) with an aromatase inhibitor is recommended, within its marketing authorisation, as an option for treating locally advanced or metastatic, hormone receptor-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer as first endocrine-based therapy in adults. Abemaciclib is recommended only if the manufacturer provides it according to the commercial arrangement.
  www.nice.org.uk/guidance/ta563
- **Abemaciclib with fulvestrant for treating hormone receptor-positive, HER2-negative advanced breast cancer after endocrine therapy (May 2019)** NICE TA579
  Abemaciclib (*Verzenios*®) with fulvestrant is recommended for use within the Cancer Drugs Fund as an option for treating hormone receptor-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer in people who have had endocrine therapy only if:
  - exemestane plus everolimus would be the most appropriate alternative, **and**
  - the conditions in the managed access agreement for abemaciclib with fulvestrant are followed.

  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/ta579

Scottish Medicines Consortium (SMC) decisions

SMC No. SMC2135
The *Scottish Medicines Consortium* has advised (May 2019) that abemaciclib (*Verzenios*®) is accepted for use within NHS Scotland for the treatment of women with hormone receptor-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer in combination with an aromatase inhibitor as initial endocrine-based therapy, or in women who have received prior endocrine therapy. This advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland or a list price that is equivalent or lower.

SMC No. SMC2179
The *Scottish Medicines Consortium* has advised (May 2019) that abemaciclib (*Verzenios*®) is accepted for restricted use within NHS Scotland for the treatment of women with hormone receptor-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer in combination with fulvestrant as initial endocrine-based therapy, or in women who have received prior endocrine therapy. It is restricted to those patients who have progressed on or after (neo) adjuvant endocrine therapy, or progressed during first-line endocrine-based therapy for advanced breast cancer. This advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland or a list price that is equivalent or lower.

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

Tablet

CAUTIONARY AND ADVISORY LABELS 3, 25

- **Verzenios** (Eli Lilly and Company Ltd) ▼
  Abemaciclib 50 mg Verzenios 50mg tablets | 28 tablet PoM £1,475.00 (Hospital only) | 56 tablet PoM £2,950.00 (Hospital only)
  Abemaciclib 100 mg Verzenios 100mg tablets | 28 tablet PoM £1,475.00 (Hospital only) | 56 tablet PoM £2,950.00 (Hospital only)
  Abemaciclib 150 mg Verzenios 150mg tablets | 28 tablet PoM £1,475.00 (Hospital only) | 56 tablet PoM £2,950.00 (Hospital only)

Afatinib

27-Mar-2019

- **DRUG ACTION** Afatinib is a protein kinase inhibitor.

- **INDICATIONS AND DOSE**

Treatment of locally advanced or metastatic non-small cell lung cancer with activating epidermal growth factor receptor (EGFR) mutations, in patients who have not previously been treated with EGFR tyrosine kinase inhibitor

- BY MOUTH
- Adult: 40 mg once daily; increased if tolerated to up to 50 mg once daily, dose increase may be considered after 3 weeks at initial dose; consult product literature for details on dosing and dose adjustment due to side effects

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- **CAUTIONS** Cardiac risk factors · conditions which may affect left ventricular ejection fraction—consider cardiac monitoring, including assessment of left ventricular ejection fraction, at baseline and during treatment · diarrhoea—proactive management recommended (consult product literature) · exposure to sun (protect skin from exposure to sun) · history of keratitis · new pulmonary