

Chronic lymphocytic leukaemia in patients who have received at least one prior therapy [in combination with rituximab] (specialist use only)

- ▶ BY MOUTH
- ▶ Adult: (consult product literature)

IMPORTANT SAFETY INFORMATION

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

- **CAUTIONS** Ensure adequate hydration
- **INTERACTIONS** → Appendix 1: venetoclax
- **SIDE-EFFECTS**
- ▶ **Common or very common** Anaemia · constipation · diarrhoea · electrolyte imbalance · fatigue · hyperuricaemia · increased risk of infection · lymphopenia · nausea · neutropenia · tumour lysis syndrome · vomiting
- **CONCEPTION AND CONTRACEPTION** Manufacturer advises ensure effective, non-hormonal contraception during and for 30 days after treatment in women of child-bearing potential. 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 moderate impairment (increased risk of toxicity); avoid in severe impairment (no information available).
- **RENAL IMPAIRMENT** Manufacturer advises close monitoring (increased risk of tumour lysis syndrome); use only if potential benefit outweighs risk in severe impairment—no information available.
- **MONITORING REQUIREMENTS** Manufacturer advises monitor renal function before starting treatment.
- **PATIENT AND CARER ADVICE**
- Hydration Manufacturer advises patients should drink 1.5–2 L of water daily, starting 2 days before and throughout the dose-titration phase; intravenous fluids should be administered for those who cannot maintain an adequate level of oral hydration with consideration of overall risk of tumour lysis syndrome.
- Vomiting Manufacturer advises that if vomiting occurs following dose administration, no additional doses should be taken on that day and the next dose should be taken at the normal time.
- Missed doses Manufacturer advises that if a dose is more than 8 hours late, the missed dose should not be taken and the next dose should be taken at the normal time.
- **NATIONAL FUNDING/ACCESS DECISIONS**
- **NICE decisions**
- ▶ **Venetoclax** for treating chronic lymphocytic leukaemia (November 2017) NICE TA487
Venetoclax is recommended for use within the Cancer Drugs Fund, within its authorisation, as an option for treating chronic lymphocytic leukaemia in adults:
 - with a 17p deletion or TP53 mutation and when a B-cell receptor pathway inhibitor is unsuitable, or whose disease has progressed after a B-cell receptor pathway inhibitor **or**
 - without a 17p deletion or TP53 mutation, and whose disease has progressed after both chemoimmunotherapy and a B-cell receptor pathway inhibitor, **and**
 - only if the conditions in the managed access agreement 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/TA487

- ▶ **Venetoclax with rituximab for previously treated chronic lymphocytic leukaemia (February 2019) NICE TA561**
Venetoclax (*Venlyxto*®) with rituximab is recommended, within its marketing authorisation, as an option for treating chronic lymphocytic leukaemia in adults who have had at least 1 previous therapy. It is recommended only if the manufacturer provides it according to the commercial arrangement.
www.nice.org.uk/guidance/ta561

Scottish Medicines Consortium (SMC) decisions

SMC No. 1249/17

The *Scottish Medicines Consortium* has advised (August 2017) that venetoclax (*Venlyxto*®) is accepted for use within NHS Scotland as monotherapy for the treatment of chronic lymphocytic leukaemia:

- in the presence of 17p deletion or TP53 mutation in patients who are unsuitable for or have failed a B-cell receptor pathway inhibitor; **or**
- in the absence of 17p deletion or TP53 mutation in patients who have failed both chemoimmunotherapy and a B-cell receptor pathway inhibitor.

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. SMC2166

The *Scottish Medicines Consortium* has advised (August 2019) that venetoclax (*Venlyxto*®), in combination with rituximab, is accepted for use within NHS Scotland for the treatment of adults with chronic lymphocytic leukaemia who have received at least one prior 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.

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

Tablet

CAUTIONARY AND ADVISORY LABELS 21, 25

- ▶ **Venlyxto** (AbbVie Ltd) ▼

Venetoclax 10 mg Venlyxto 10mg tablets | 14 tablet [PoM] £59.87
Venetoclax 50 mg Venlyxto 50mg tablets | 7 tablet [PoM] £149.67
Venetoclax 100 mg Venlyxto 100mg tablets | 7 tablet [PoM] £299.34 | 14 tablet [PoM] £598.68 | 112 tablet [PoM] £4,789.47

Vismodegib

17-Jan-2018

- **DRUG ACTION** Vismodegib is a hedgehog pathway inhibitor.

INDICATIONS AND DOSE

Symptomatic metastatic basal cell carcinoma | Locally advanced basal cell carcinoma not appropriate for surgery or radiotherapy

- ▶ BY MOUTH
- ▶ Adult: 150 mg once daily

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RISKS OF INCORRECT DOSING OF ORAL ANTI-CANCER MEDICINES

See Cytotoxic drugs p. 938.

- **INTERACTIONS** → Appendix 1: vismodegib
- **SIDE-EFFECTS**
- ▶ **Common or very common** Alopecia · amenorrhoea · appetite decreased · arthralgia · asthenia · constipation · dehydration · diarrhoea · gastrointestinal discomfort · hair growth abnormal · muscle complaints · nausea · pain · skin reactions · taste altered · vomiting · weight decreased
- ▶ **Frequency not known** Epiphyses premature fusion