Ibrutinib 560 mg Imbruvica 560mg tablets | 28 tablet PoM £5,723.20

Idelalisib

09-Dec-2019

● **DRUG ACTION** Idelalisib is a protein kinase inhibitor.

● **INDICATIONS AND DOSE**

Treatment of chronic lymphocytic leukaemia in patients who have received at least one previous therapy, or as first-line treatment in the presence of 17p deletion or TP53 mutation in patients who are not eligible for any other therapies (in combination with rituximab) | **Treatment of follicular lymphoma refractory to two lines of treatment (monotherapy)**

- BY MOUTH
- Adult: 150 mg twice daily, for dose adjustment due to side effects, consult product literature

IMPORTANT SAFETY INFORMATION

RISKS OF INCORRECT DOSING OF ORAL ANTI-CANCER MEDICINES

See Cytotoxic drugs p. 938.

MHRA/CHM ADVICE: IDELALISIB (ZYDELIG®): UPDATED INDICATIONS AND ADVICE ON MINIMISING THE RISK OF INFECTION (SEPTEMBER 2016)

In light of a recent safety review the indications for idelalisib have been updated. Manufacturer recommendations regarding monitoring for infection and prophylaxis of *Pneumocystis jirovecii* pneumonia have also been updated. Patients should be advised on the risk of serious or fatal infections during treatment, and idelalisib should not be initiated in patients with any evidence of infection.

● **CAUTIONS** Active hepatitis · diarrhoea—symptomatic management recommended (consult product literature) · pneumonitis—withhold treatment (consult product literature)

● **INTERACTIONS** → Appendix 1: idelalisib

● **SIDE-EFFECTS**

- **Common or very common** Colitis · diarrhoea · fever · infection · neutropenia · pneumonitis · rash
- **Rare or very rare** Severe cutaneous adverse reactions (SCARs)

● **CONCEPTION AND CONTRACEPTION** Highly effective contraception (in addition to barrier method) required during and for one month after treatment.

● **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 (risk of increased exposure-limited information available in severe impairment)—monitor for adverse reactions.

● **MONITORING REQUIREMENTS**

- Manufacturer advises monitor liver function—consult product literature.
- Manufacturer advises monitor for signs and symptoms of infection, including *cytomegalovirus* infection and respiratory infections; new symptoms should be reported promptly. Neutrophil count should be monitored in all patients every 2 weeks for the first 6 months of treatment; patients with neutrophil count <1000 per mm^3 should be monitored weekly.

● **NATIONAL FUNDING/ACCESS DECISIONS**

NICE decisions

- **Idelalisib for treating chronic lymphocytic leukaemia (October 2015)** NICE TA359

Idelalisib (*Zydelig*®), in combination with rituximab, is recommended as an option for treatment in adults:

- who have untreated chronic lymphocytic leukaemia with a 17p deletion or TP53 mutation, **or**
- who have chronic lymphocytic leukaemia when the disease has been treated but has relapsed within 24 months, **and**
- if the manufacturer provides idelalisib with the discount agreed in the simple discount agreement.

Patients whose treatment was started within the NHS before this guidance was published should have the option to continue treatment until they and their NHS clinician consider it appropriate to stop.

www.nice.org.uk/guidance/ta359

- **Idelalisib for treating refractory follicular lymphoma (October 2019)** NICE TA604

Idelalisib (*Zydelig*®) is not recommended, within its marketing authorisation, for treating follicular lymphoma that has not responded to 2 prior lines of treatment 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/ta604

Scottish Medicines Consortium (SMC) decisions

SMC No. 1026/15

The *Scottish Medicines Consortium* has advised (March 2015) that idelalisib (*Zydelig*®) is accepted for restricted use within NHS Scotland, in combination with rituximab, for the treatment of relapsed chronic lymphocytic leukaemia in patients who are unsuitable for chemotherapy and treatment naïve patients with 17p deletion or TP53 mutation who are unsuitable for chemo-immunotherapy, only whilst idelalisib is available at the price agreed in the patient access scheme.

SMC No. 1039/15

The *Scottish Medicines Consortium* has advised (May 2015) that idelalisib (*Zydelig*®) is accepted for restricted use within NHS Scotland as monotherapy for the treatment of patients with follicular lymphoma that is refractory to two prior lines of treatment. 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.

All Wales Medicines Strategy Group (AWMSG) decisions

AWMSG No. 2597

The *All Wales Medicines Strategy Group* has advised (April 2017) that idelalisib (*Zydelig*®) is recommended as an option for use within NHS Wales as monotherapy for the treatment of patients with follicular lymphoma, that is refractory to two prior lines of treatment. The recommendation applies only if the approved Wales Patient Access Scheme (WPAS) is used or where the list price 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 25

- **Zydelig** (Gilead Sciences International Ltd)

Idelalisib 100 mg Zydelig 100mg tablets | 60 tablet PoM £3,114.75 (Hospital only)

Idelalisib 150 mg Zydelig 150mg tablets | 60 tablet PoM £3,114.75 (Hospital only)