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SCEMBLIX - Initiation and dosing - HCP

Prescribing information

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SCEMBLIX®▼ (asciminib) is indicated for the treatment of adult patients with Philadelphia chromosome-positive chronic myeloid leukaemia (Ph + CML) in chronic phase (CP), previously treated with two or more tyrosine kinase inhibitors, and without a known T315I mutation.[1]

Initiation and dosing

SCEMBLIX®▼ (asciminib) has a once- or twice-daily oral dosing[1]

Recommended dosage in adult patients with Ph+ CML-CP, previously treated with ≥2 TKIs and without a known T315I mutation.[1]

- Recommended dosage[1]

- Dose modification schedule[1]

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SCEMBLIX should be taken at approximately the same time every day.

If a SCEMBLIX dose is missed by more than 12 hours, advise the patient to skip the dose and take the next dose as scheduled.[1]

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40 mg BD

AM + PM

SCEMBLIX should be taken twice daily at approximately 12-hour intervals.[2]

If a SCEMBLIX dose is missed by more than 6 hours, advise the patient to skip the dose and take the next dose as scheduled.[1]

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Patients should avoid food for at least 2 hours before and 1 hour after taking SCEMBLIX.[1]

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SCEMBLIX tablets should be swallowed whole with a glass of water – patients should not break, crush or chew them.[1]

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SCEMBLIX is available as film-coated tablets.

- Recommended dosage[1]

- Dose modification schedule[1]

Patients changing from 40 mg twice daily to 80 mg once daily should start taking SCEMBLIX once daily approximately 12 hours after the last twice-daily dose, and then continue at 80 mg once daily.

Patients changing from 80 mg once daily to 40 mg twice daily should start taking SCEMBLIX twice daily approximately 24 hours after the last once-daily dose and then continue at 40 mg twice daily at approximately 12-hour intervals.

For the management of adverse reactions, the SCEMBLIX dose can be reduced based on individual tolerability.

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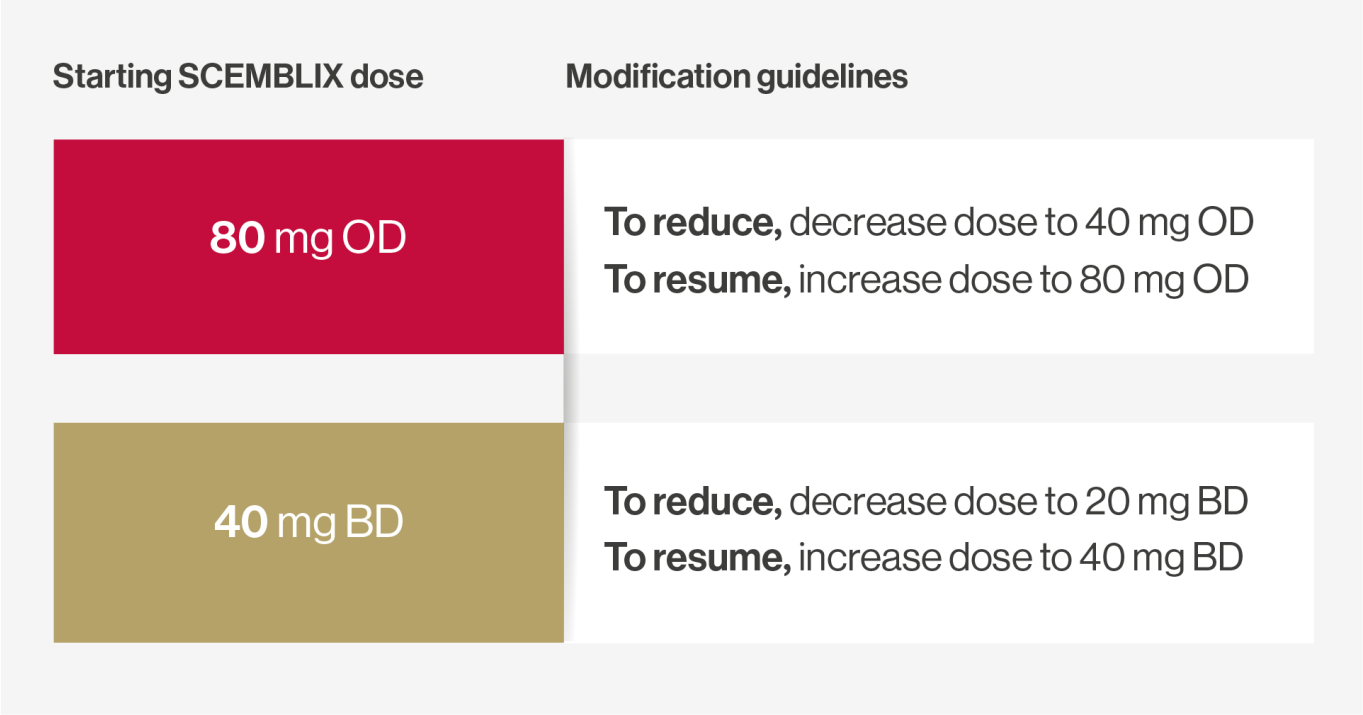

SCEMBLIX should be permanently discontinued in patients unable to tolerate a total daily dose of 40 mg.[1]

Since there are no data available in patients with moderate or severe hepatic impairment, caution should be exercised in these patients.[1]

Withholding SCEMBLIX followed by potential dose reductions and/or permanent discontinuations may be required in case of thrombocytopenia and/or neutropenia, asymptomatic amylase and/or lipase elevation and non-haematological grade ≥3 adverse reactions.

Asciminib dose modification schedule for the management of adverse reactions

Adverse reaction	**Dosage modification**
Thrombocytopenia and/or neutropenia	
ANC <1.0 x 10^9/l and/or PLT <50 x 10^9/l	Withhold asciminib until resolved to ANC ≥1 x 10^9/l and/or PLT ≥ 50 x10^9/l. If resolved: • Within 2 weeks: resume at starting dose. • After more than 2 weeks: resume at reduced dose. For recurrent severe thrombocytopenia and/or neutropenia, withhold asciminib until resolved to ANC ≥1 x 10^9/l and PLT ≥50 x 10^9/l, then resume at reduced dose.
Asymptomatic amylase and/or lipase elevation	

Elevation >2.0 x ULN	Withhold asciminib until resolved to <1.5 x ULN. • If resolved: resume at reduced dose. If events reoccur at reduced dose, permanently discontinue. • If not resolved: permanently discontinue. Perform diagnostic tests to exclude pancreatitis.
Non-haematological adverse reactions	
Grade 3 or higher adverse reactions[1]	Withhold asciminib until resolved to grade 1 or lower. • If resolved: resume at a reduced dose. • If not resolved: permanently discontinue.

ANC: absolute neutrophil count; PLT: platelets; ULN: upper limit of normal.

[1]Based on National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) v 4.03.

Please refer to the Summary of Product Characteristics for the detailed guidance on managing each of these adverse events and on dose modification of SCEMBLIX.[1]

Please refer to the Summary of Product Characteristics for further information on changing between dosing schedules for the recommended dose of SCEMBLIX.[1]

SCEMBLIX, an opportunity to manage ≥3rd-line patients with a flexible dosing schedule[1]

Regular monitoring is important to assess treatment benefits and inform a decision to switch[2,3]

Discover more

BD, twice daily; CML, chronic myeloid leukaemia; OD, once daily; Ph+ CML-CP, Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase; TKI, tyrosine kinase inhibitor.

For further information, please refer to the Summary of Product Characteristics.

References

1. SCEMBLIX (asciminib) Summary of Product Characteristics.

2. Smith G, et al. *Br J Haematol* 2020;191(2):171–193.

3. Hochhaus A, et al. *Leukemia* 2020;34:966–984.

UK | November 2024 | FA-11311714

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Novartis online through the pharmacovigilance intake (PVI) tool at www.novartis.com/report, or alternatively email medinfo.uk@novartis.com or call 01276 698370.

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