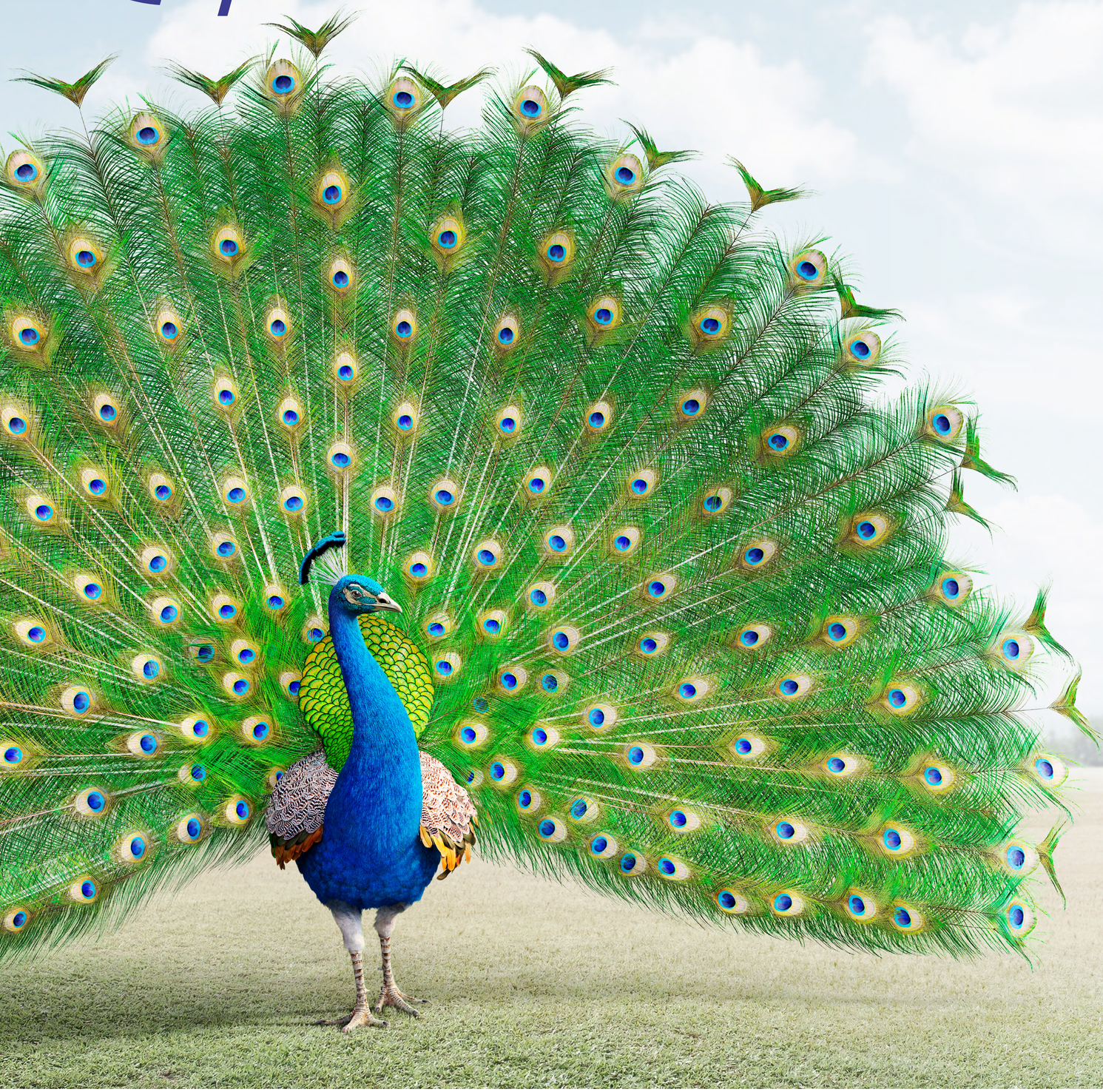

# BOSULIF® ▼ (bosutinib)

When choosing a treatment for adult patients with Ph+ CML

# EXPAND YOUR EXPECTATIONS of long-term BOSULIF treatment

## INDICATIONS

BOSULIF is indicated for the treatment of adult patients with:

- Newly diagnosed chronic phase (CP) Philadelphia chromosome-positive chronic myelogenous leukaemia (Ph+ CML)
- CP, accelerated phase (AP), and blast phase (BP) Ph+ CML previously treated with one or more tyrosine kinase inhibitor(s) and for whom imatinib, nilotinib and dasatinib are not considered appropriate treatment options

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 of the SmPC for how to report adverse reactions.



May 2021. PP-BOS-GLB-0092

Click here for the BOSULIF SmPC

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May 2021 PP-BOS-GLB-0082

## References

1. Bosulif® [summary of product characteristics]. Pfizer Inc.;2021.

mPC

# CONSIDER BOSULIF® FOR YOUR CML PATIENTS[1]

Rapid and deep molecular responses compared with imatinib[2]

A well-defined safety profile, comparable to imatinib, that shows low impact on cardiovascular health over time[2-5*]

Convenient once-daily dosing, taken with food[1]

*Low cardiac events occurrence defined as 5.2% for bosutinib vs 5.3% for imatinib in clinical trials.[2]

## Recommended by ELN Guidelines for use in 1L and 2L+ patients[6]

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## References


1. Bosulif® [summary of product characteristics]. Pfizer Inc.;2021.
2. Cortes JE, et al. *J Clin Oncol* 2018;36:231–237.
3. Gambacorti-Passerini C, et al. *Am J Hematol* 2014;89:732–742.
4. Gambacorti-Passerini C, et al. *Haematologica* 2018;103:1298–1307.
5. Valent P, et al. *Blood* 2015;125:901–906.
6. Hochhaus A, Baccarani M, Silver RT, et al. European LeukemiaNet 2020 recommendations for treating chronic myeloid leukemia. *Leukemia*. 2020;34(4):966-984.

# RAPID AND DEEP RESPONSES[1]

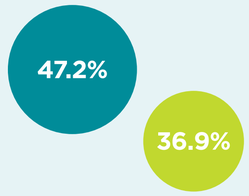
## Newly diagnosed adult CML patients

Compared with imatinib, BOSULIF® offers:[1]

- Superior MMR and CCyR at 12 months (48 weeks)
- Quicker reduction in BCR-ABL1 transcripts
- Consistently deeper molecular responses

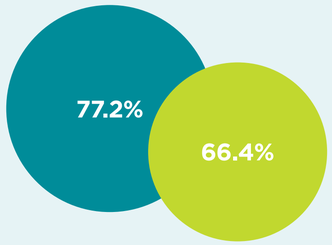
**mITT population**

**Primary endpoint[1]**
MMR response at 12 months (48 weeks)*



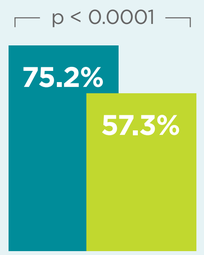

OR 1.55 (95% CI, 1.07–2.23)† p = 0.0200‡

**Secondary endpoint[1]**
CCyR response at 12 months (48 weeks)




OR 1.74 (95% CI, 1.16–2.61)† p = 0.0075‡

**Rapid responses[1]**




Patients achieving ≤ 10% *BCR-ABL1* transcripts at 3 months

BOSULIF®
Imatinib

## BOSULIF®: Confidence to achieve meaningful clinical outcomes

*MMR (≤ 0.1% BCR-ABL1 transcripts on the international scale with ≥ 3000 ABL1 assessed).
†Adjusted for Sokal risk group (low, intermediate, high) and geographic region at time of random assignment. 95% CIs for ORs based on asymptotic Wald confidence limits.
‡p-value based on a Cochran–Mantel–Haenszel test for general association between treatment and response with stratification by Sokal risk group (low, intermediate, high) and region as determined at time of random assignment.

ABL, Abelson; BCR, breakpoint cluster region; CCyR, complete cytogenetic response; CI, confidence interval; CML, chronic myeloid leukaemia; mITT, modified intention-to-treat; MMR, major molecular response; MR, molecular response; OR, odds ratio.

# RAPID AND DEEP RESPONSES[1-3]

## Newly diagnosed adult CML patients

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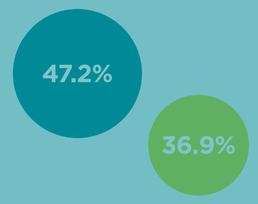


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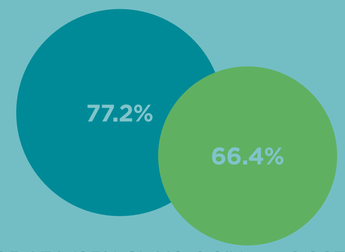


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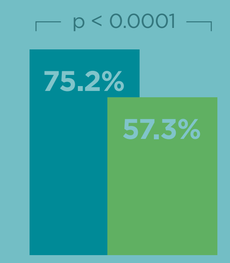
**Rapid responses[1]**

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## References

1. Cortes JE, et al. *J Clin Oncol* 2018;36:231–237.

# SUITABLE FOR YOUR INTOLERANT & RESISTANT PATIENTS[1–3]

BOSULIF® has been tested in a large number of patients and demonstrates efficacy in a wide range of patient types

**Patient cohorts** (N = 574* including patients receiving ≥ 1 dose of BOSULIF®)

**Chronic phase, second line[1]**

n = 288

**Primary cohort:**
Imatinib resistant (n = 200)

**Sub-group:**
Imatinib intolerant (n = 88)

**Chronic phase, third-/fourth-line[2]**

n = 119†

**Sub-groups:**
IM-R/I + dasatinib resistant (n = 38)
IM-R/I + dasatinib intolerant (n = 50)
IM-R/I + nilotinib resistant (n = 26)
IM-R/I + nilotinib intolerant (n = 5)

**Accelerated phase[3]**

n = 79

**Sub-group:**
Accelerated phase (n = 79)

**Blast phase[3]**

n = 64

**Sub-group:**
Blast phase (n = 64)

*Includes 24 patients who were Ph+ ALL.[3]
†Third- and fourth-line sub-groups comprise patients with CP CML that were imatinib resistant or imatinib intolerant and ≥ 1 of the following: Dasatinib resistant or dasatinib intolerant, nilotinib resistant, nilotinib intolerant or resistant/intolerant to dasatinib and nilotinib.
ALL, acute lymphoblastic leukaemia; CML, chronic myeloid leukaemia; CP, chronic phase; IM-R/I imatinib resistant or intolerant; Ph+, Philadelphia chromosome-positive.

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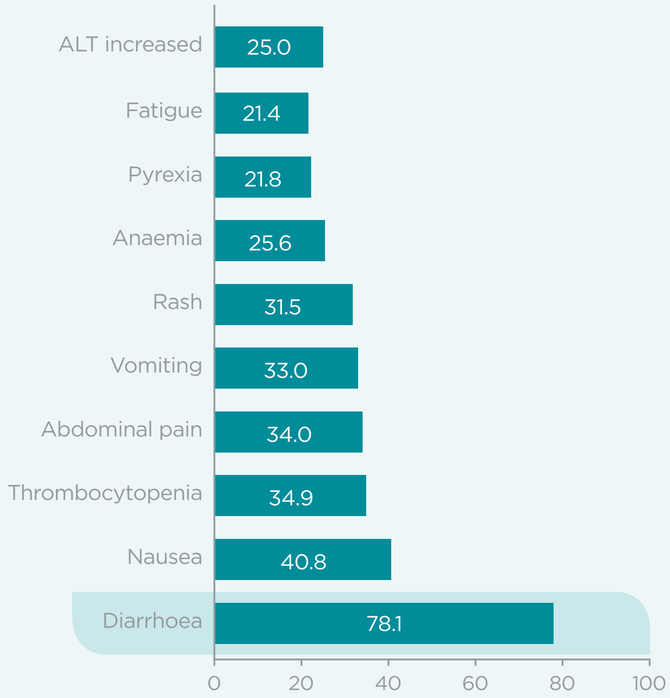
1. Cortes JE, et al. *Blood* 2011;118:4567–4576.
2. Cortes JE, et al. *Am J Hematol* 2016;91:1206–1214.
3. Gambacorti-Passerini C, et al. *Am J Hematol* 2015;90:755–768.

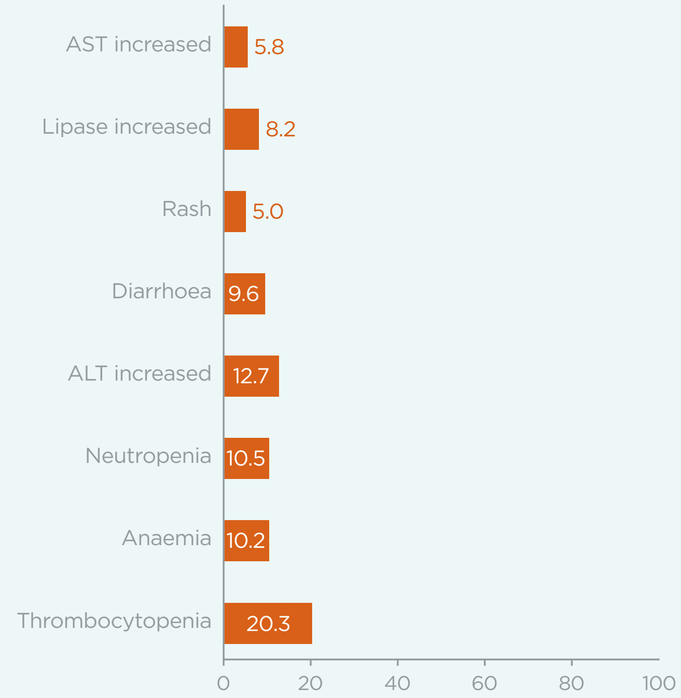
# A WELL-DEFINED AND MANAGEABLE SAFETY PROFILE[1]

**Overall safety population (N = 1272)***

## Any grade AEs reported for ≥ 20% of patients (%)




## Grade 3/4 AEs reported for ≥ 5% of patients (%)




**1% of the overall patient safety population discontinued due to diarrhoea**

**Please refer to the BOSULIF® SmPC for full details of adverse events**

*Patients who received one or more doses of study drug for either Newly diagnosed CP CML or were resistant or intolerant to prior therapy with CP, AP, BP CML or Ph+ ALL.
The data shown include real-world data in addition to safety data from the BFORE trial and Study 200.
AE, adverse event; ALL, acute lymphoblastic leukaemia; ALT, alanine aminotransferase; AP, accelerated phase; AST, aspartate aminotransferase; BP, blast phase; CML, chronic myeloid leukaemia; CP, chronic phase; Ph+, Philadelphia chromosome-positive; SmPC, Summary of Product Characteristics.

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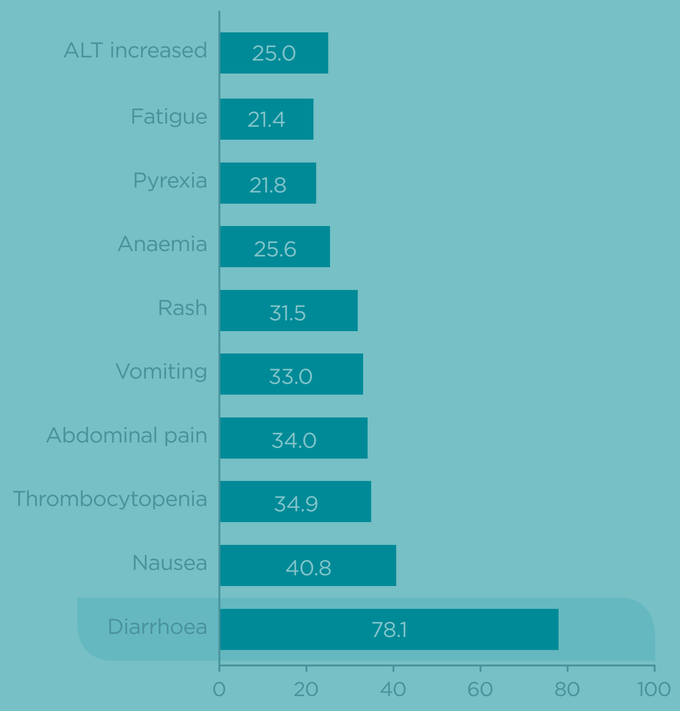


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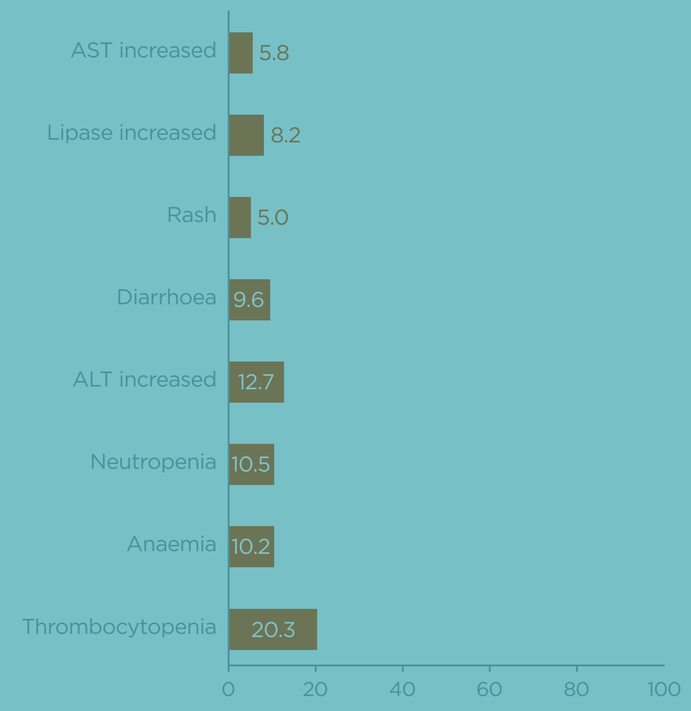


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## References


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# FLEXIBLE DOSING TO FIT YOUR PATIENTS' NEEDS[1]

## Adult patients with Newly diagnosed CP Ph+ CML

**Bosulif®** 400 mg film-coated tablets bosutinib

The recommended starting dose is **400 mg BOSULIF®** once daily with food

## Adult patients resistant or intolerant to prior TKI therapy*

**Bosulif®** 500 mg film-coated tablets bosutinib

The recommended starting dose is **500 mg BOSULIF®** once daily with food

## Dose adjustments

**Bosulif®** 100 mg film-coated tablets bosutinib

*CP, AP and BP Ph+ CML previously treated with one or more TKI(s) and for whom imatinib, nilotinib and dasatinib are not considered appropriate treatment.
Colour and size of tablets shown are not representative of the actual tablets and are for illustrative purposes only.
100 mg tablets width: 5.6 mm, length: 10.7 mm; 400 mg tablets width: 8.8 mm, length: 16.9 mm; 500 mg tablets width: 9.5 mm, length: 18.3 mm.[1]
AP, accelerated phase; BP, blast phase; CML, chronic myeloid leukaemia; CP, chronic phase; Ph+, Philadelphia chromosome-positive; TKI, tyrosine kinase inhibitor.

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**Dose adjustments**

**Bosulif®** 100 mg film-coated tablets bosutinib

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