Mavacamten▼ Interactive Dosing Guide

Mavacamten is indicated for the treatment of symptomatic (NYHA class II, III) obstructive HCM in adult patients.[1]

Treatment monitoring and warnings for use

This is not an exhaustive list; please refer to the SmPC before prescribing.

CYP2C19 poor metabolisers may have up to three times increased mavacamten exposure vs normal metabolisers. If CYP2C19 phenotype is unknown then follow the poor metabolisers dosing guidance.

Certain CYP450 inhibitors and inducers are contraindicated in patients taking mavacamten because of increased heart failure risk. More information can be found here.

Mavacamten can cause heart failure due to systolic dysfunction; therefore, patients should be regularly monitored for obstructive HCM symptoms, LVOT gradient with Valsalva manoeuvre, and LVEF using echocardiogram.

In patients with an intercurrent illness, such as serious infection or arrhythmia (including AF or other uncontrolled tachyarrhythmia) that may impair systolic function, LVEF assessment is recommended, and dose increases are not recommended until the intercurrent illness is resolved.

Before initiation of treatment, women of childbearing potential must be informed of the potential risk to the foetus, must have had a negative pregnancy test, and must use effective contraception during treatment and for 6 months after treatment discontinuation.

Consider discontinuing treatment in patients who have shown no response (e.g. no improvement in symptoms, QoL, exercise capacity, LVOT gradient) after 4 to 6 months on the maximum tolerated dose.

This guide is intended to be used in its interactive form on a desktop device.

Click here to confirm that you have read and understood the information on this page

Adverse events should be reported. Reporting forms and information can be found at:
UK – www.mhra.gov.uk/yellowcard, or search for MHRA Yellow Card in the Google Play or Apple App Store;
Ireland – via HPRA Pharmacovigilance at www.hpra.ie. Adverse events should also be reported to Bristol-Myers Squibb via medical.information@bms.com or 0800 731 1736 (UK) | 1 800 749 749 (Ireland).

You can click the ! icon at the bottom of any page to review this information.

1. Mavacamten Summary of Product Characteristics. Available at: http://www.medicines.org.uk.

3500-GB-2600026 | March 2026

Please scan or click the QR code to access the UK PI.
Click the button at the bottom of the page to access the Ireland (IRE) PI.

Mavacamten BMS™
(mavacamten) 2.5, 5, 10, 15mg capsules

Interactive Dosing Guide

Bristol Myers Squibb

HOME PAGE

Use this guide to support appropriate dosing for your patients.

Click on each phase to view interactive dose recommendations for your patient.

Click this icon to export your treatment summary as text

Click this icon to view the full algorithm of the phase you are viewing

Click this icon to go back to the start of the algorithm

LVEF	Recommendation
<55%	**DO NOT INITIATE** mavacamten
<50% **at any visit**	**INTERRUPT** treatment for 4 weeks and until LVEF is ≥50% – see treatment interruption
<50% **twice on 2.5 mg** (lowest daily dose)	**PERMANENTLY DISCONTINUE**

Dose adjustments and close medical supervision may be needed for patients using certain CYP2C19 or CYP3A4 inhibitors or inducers.

Click here for more details.

INITIATION

Treatment should be initiated under the supervision of a physician experienced in the management of patients with cardiomyopathy. All patients should be assessed at **4**, **8**, and **12 weeks** after treatment initiation.

CYP2C19 poor or unknown metaboliser status

Other CYP2C19 metaboliser status

MAINTENANCE

Once an individualised dose is achieved, patients should be assessed by echocardiogram every 12 weeks and their dose maintained, up-titrated, or withheld as required.

Begin

INTERRUPTION

If at any visit the patient's LVEF is <50%, the treatment should be interrupted for 4 weeks and until LVEF returns to ≥50%.

Begin

Interactive Dosing Guide

INITIATION PHASE

LVEF should be determined at every visit. If LVEF is <50% at any visit, INTERRUPT treatment for 4 weeks and until LVEF is ≥50% – see treatment interruption.

Click here if your patient has a poor or unknown CYP2C19 metaboliser status

Week 0
LVEF

LVEF <55%	LVEF ≥55%
DO NOT INITIATE	5 mg OD

Click the box that describes your patient's echocardiogram results to view the next step in the algorithm

Interactive Dosing Guide

INITIATION PHASE

LVEF should be determined at every visit. If LVEF is <50% at any visit, INTERRUPT treatment for 4 weeks and until LVEF is ≥50% – see treatment interruption.

Click here if your patient has a poor or unknown CYP2C19 metaboliser status

Week 0
LVEF

- LVEF <55% → DO NOT INITIATE
- LVEF ≥55% → **5** mg OD

Week 4
Valsalva LVOT gradient

- <20 mmHg → **2.5** mg OD
- ≥20 mmHg → **5** mg OD

Legend Stop | Continue | Increase dose | Decrease dose | Withhold

Interactive Dosing Guide

INITIATION PHASE

LVEF should be determined at every visit. If LVEF is <50% at any visit, INTERRUPT treatment for 4 weeks and until LVEF is ≥50% – see treatment interruption.

Click here if your patient has a poor or unknown CYP2C19 metaboliser status

Week 0
LVEF

- LVEF <55% → DO NOT INITIATE
- LVEF ≥55% → 5 mg OD

Week 4
Valsalva LVOT gradient

- <20 mmHg → 2.5 mg OD
- ≥20 mmHg → 5 mg OD

Week 8
Valsalva LVOT gradient

- <20 mmHg → Withhold drug for 4 weeks
- ≥20 mmHg → 2.5 mg OD

Legend Stop | Continue | Increase dose | Decrease dose | Withhold

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INITIATION PHASE

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LVEF should be determined at every visit. If LVEF is <50% at any visit, INTERRUPT treatment for 4 weeks and until LVEF is ≥50% – see treatment interruption.

Click here if your patient has a poor or unknown CYP2C19 metaboliser status

Week 0
LVEF

- LVEF <55% → DO NOT INITIATE
- LVEF ≥55% → 5 mg OD

Week 4
Valsalva LVOT gradient

- <20 mmHg → 2.5 mg OD
- ≥20 mmHg → 5 mg OD

Week 8
Valsalva LVOT gradient

- <20 mmHg → Withhold drug for 4 weeks
- ≥20 mmHg → 2.5 mg OD

Week 12
LVEF

- LVEF <50% → View dose interruption
- LVEF ≥50% → 2.5 mg OD

Legend Stop | Continue | Increase dose | Decrease dose | Withhold

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Click here if your patient has a poor or unknown CYP2C19 metaboliser status

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LVEF

- LVEF <55% → DO NOT INITIATE
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Week 4
Valsalva LVOT gradient

- <20 mmHg → 2.5 mg OD
- ≥20 mmHg → 5 mg OD

Week 8
Valsalva LVOT gradient

- <20 mmHg → Withhold drug for 4 weeks
- ≥20 mmHg → 2.5 mg OD

Week 12
LVEF

- LVEF <50% → View dose interruption
- LVEF ≥50% → 2.5 mg OD

4 weeks later

Reassess clinical status, LVOT, and LVEF

8 weeks later

Enter maintenance phase

Legend Stop | Continue | Increase dose | Decrease dose | Withhold

Interactive Dosing Guide

INITIATION PHASE

LVEF should be determined at every visit. If LVEF is <50% at any visit, INTERRUPT treatment for 4 weeks and until LVEF is ≥50% – see treatment interruption.

Click here if your patient has a poor or unknown CYP2C19 metaboliser status

Week 0
LVEF

- LVEF <55% → DO NOT INITIATE
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Week 4
Valsalva LVOT gradient

- <20 mmHg → 2.5 mg OD
- ≥20 mmHg → 5 mg OD

Week 8
Valsalva LVOT gradient

- <20 mmHg → Withhold drug for 4 weeks
- ≥20 mmHg → 2.5 mg OD

Week 12
LVEF

- Enter maintenance phase

Legend Stop | Continue | Increase dose | Decrease dose | Withhold

Interactive Dosing Guide

INITIATION PHASE

LVEF should be determined at every visit. If LVEF is <50% at any visit, INTERRUPT treatment for 4 weeks and until LVEF is ≥50% – see treatment interruption.

Click here if your patient has a poor or unknown CYP2C19 metaboliser status

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LVEF

- LVEF <55% → DO NOT INITIATE
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Valsalva LVOT gradient

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Valsalva LVOT gradient

- <20 mmHg → **2.5** mg OD
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Legend Stop | Continue | Increase dose | Decrease dose | Withhold

Interactive Dosing Guide

INITIATION PHASE

LVEF should be determined at every visit. If LVEF is <50% at any visit, INTERRUPT treatment for 4 weeks and until LVEF is ≥50% – see treatment interruption.

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LVEF

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Week 8
Valsalva LVOT gradient

- <20 mmHg → **2.5** mg OD
- ≥20 mmHg → **5** mg OD

Week 12
LVEF

- Enter maintenance phase

Legend Stop | Continue | Increase dose | Decrease dose | Withhold

Interactive Dosing Guide

INITIATION PHASE

LVEF should be determined at every visit. If LVEF is <50% at any visit, INTERRUPT treatment for 4 weeks and until LVEF is ≥50% – see treatment interruption.

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LVEF

- LVEF <55% → DO NOT INITIATE
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Valsalva LVOT gradient

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Valsalva LVOT gradient

- <20 mmHg → **2.5** mg OD
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Week 12
LVEF

- Enter maintenance phase

Legend Stop | Continue | Increase dose | Decrease dose | Withhold

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Week 0 LVEF

- LVEF <55% → DO NOT INITIATE
- LVEF ≥55% → 5 mg OD

Week 4 Valsalva LVOT gradient

- <20 mmHg → 2.5 mg OD
- ≥20 mmHg → 5 mg OD

Week 8 Valsalva LVOT gradient

- <20 mmHg → Withhold drug for 4 weeks
- ≥20 mmHg → 2.5 mg OD
- <20 mmHg → 2.5 mg OD
- ≥20 mmHg → 5 mg OD

Week 12 LVEF

- LVEF <50% → View dose interruption
- LVEF ≥50% → 2.5 mg OD
- Enter maintenance phase

4 weeks later

Reassess clinical status, LVOT, and LVEF

8 weeks later

Enter maintenance phase

Legend Stop | Continue | Increase dose | Decrease dose | Withhold

Interactive Dosing Guide

INITIATION PHASE

LVEF should be determined at every visit. If LVEF is <50% at any visit, INTERRUPT treatment for 4 weeks and until LVEF is ≥50% – see treatment interruption.

This algorithm is for patients with a poor or unknown CYP2C19 metaboliser status. **Click here** if your patient has another metaboliser status.

Week 0
LVEF

LVEF <55%	LVEF ≥55%
DO NOT INITIATE	**2.5 mg OD**

Click the box that describes your patient's echocardiogram results to view the next step in the algorithm

Legend Stop | Continue | Increase dose | Decrease dose | Withhold

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INITIATION PHASE

LVEF should be determined at every visit. If LVEF is <50% at any visit, INTERRUPT treatment for 4 weeks and until LVEF is ≥50% – see treatment interruption.

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Valsalva LVOT gradient

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Legend Stop | Continue | Increase dose | Decrease dose | Withhold

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- <20 mmHg → Withhold drug for 4 weeks
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Week 8 Valsalva LVOT gradient

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INITIATION PHASE

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Week 8 Valsalva LVOT gradient

- <20 mmHg → Withhold drug for 4 weeks
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Week 12 LVEF

- LVEF <50% → View dose interruption
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Legend Stop | Continue | Increase dose | Decrease dose | Withhold

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- <20 mmHg → Withhold drug for 4 weeks
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Week 12 LVEF

- LVEF <50% → View dose interruption
- LVEF ≥50% → **2.5** mg OD

4 weeks later

Reassess clinical status, LVOT, and LVEF

8 weeks later

Enter maintenance phase

Legend Stop | Continue | Increase dose | Decrease dose | Withhold

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Week 12 LVEF

- Enter maintenance phase

Legend Stop | Continue | Increase dose | Decrease dose | Withhold

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LVEF should be determined at every visit. If LVEF is <50% at any visit, INTERRUPT treatment for 4 weeks and until LVEF is ≥50% – see treatment interruption.

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Week 4 Valsalva LVOT gradient

- <20 mmHg → Withhold drug for 4 weeks
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Week 8 Valsalva LVOT gradient

- <20 mmHg → Withhold drug for 4 weeks
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Legend Stop | Continue | Increase dose | Decrease dose | Withhold

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Week 8 Valsalva LVOT gradient

- <20 mmHg → Withhold drug for 4 weeks
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Week 12 LVEF

- LVEF <50% → View dose interruption
- LVEF ≥50% → **2.5** mg OD

Legend Stop | Continue | Increase dose | Decrease dose | Withhold

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Week 0 LVEF

- LVEF <55% → DO NOT INITIATE
- LVEF ≥55% → **2.5** mg OD

Week 4 Valsalva LVOT gradient

- <20 mmHg → Withhold drug for 4 weeks
- ≥20 mmHg → **2.5** mg OD

Week 8 Valsalva LVOT gradient

- <20 mmHg → Withhold drug for 4 weeks
- ≥20 mmHg → **2.5** mg OD

Week 12 LVEF

- LVEF <50% → View dose interruption
- LVEF ≥50% → **2.5** mg OD

4 weeks later

Reassess clinical status, LVOT, and LVEF

8 weeks later

Enter maintenance phase

Legend Stop | Continue | Increase dose | Decrease dose | Withhold

Interactive Dosing Guide

INITIATION PHASE

LVEF should be determined at every visit. If LVEF is <50% at any visit, INTERRUPT treatment for 4 weeks and until LVEF is ≥50% – see treatment interruption.

This algorithm is for patients with a poor or unknown CYP2C19 metaboliser status. **Click here** if your patient has another metaboliser status.

Week 0
LVEF

- LVEF <55% → DO NOT INITIATE
- LVEF ≥55% → **2.5 mg OD**

Week 4
Valsalva LVOT gradient

- <20 mmHg → Withhold drug for 4 weeks
- ≥20 mmHg → **2.5 mg OD**

Week 8
Valsalva LVOT gradient

- <20 mmHg → Withhold drug for 4 weeks
- ≥20 mmHg → **2.5 mg OD**

Week 12
LVEF

- Enter maintenance phase

Legend Stop | Continue | Increase dose | Decrease dose | Withhold

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INITIATION PHASE

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LVEF should be determined at every visit. If LVEF is <50% at any visit, INTERRUPT treatment for 4 weeks and until LVEF is ≥50% – see treatment interruption.

This algorithm is for patients with a poor or unknown CYP2C19 metaboliser status. **Click here** if your patient has another metaboliser status.

Week 0 LVEF

- LVEF <55% → DO NOT INITIATE
- LVEF ≥55% → **2.5 mg OD**

Week 4 Valsalva LVOT gradient

- <20 mmHg → Withhold drug for 4 weeks
- ≥20 mmHg → **2.5 mg OD**

Week 8 Valsalva LVOT gradient

- <20 mmHg → Withhold drug for 4 weeks
- ≥20 mmHg → **2.5 mg OD**
- <20 mmHg → Withhold drug for 4 weeks
- ≥20 mmHg → **2.5 mg OD**

Week 12 LVEF

- LVEF <50% → View dose interruption
- LVEF ≥50% → **2.5 mg OD**
- Enter maintenance phase

4 weeks later

Reassess clinical status, LVOT, and LVEF

8 weeks later

Enter maintenance phase

Legend Stop | Continue | Increase dose | Decrease dose | Withhold

Interactive Dosing Guide

MAINTENANCE PHASE

LVEF should be determined at every visit. If LVEF is <50% at any visit, INTERRUPT treatment for 4 weeks and until LVEF is ≥50% – see treatment interruption.

NOTE: LVOT refers to Valsalva LVOT gradient throughout

Assess clinical status, LVOT, and LVEF

LVEF <50%	LVEF 50–<55% Regardless of LVOT	LVEF ≥55% AND LVOT <30 mmHg	LVEF ≥55% AND LVOT ≥30 mmHg
Withhold drug View dose interruption	Maintain current dose	Maintain current dose	Up-titrate to next OD dose

Click the box that describes your patient's echocardiogram results to view the next step in the algorithm

NOTE: The maximum dose for CYP2C19 poor or unknown metabolisers is 5 mg OD

Up-titration guide:

2.5 mg › 5 mg
5 mg › 10 mg
10 mg › 15 mg

Maximum daily dose is 15 mg

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MAINTENANCE PHASE

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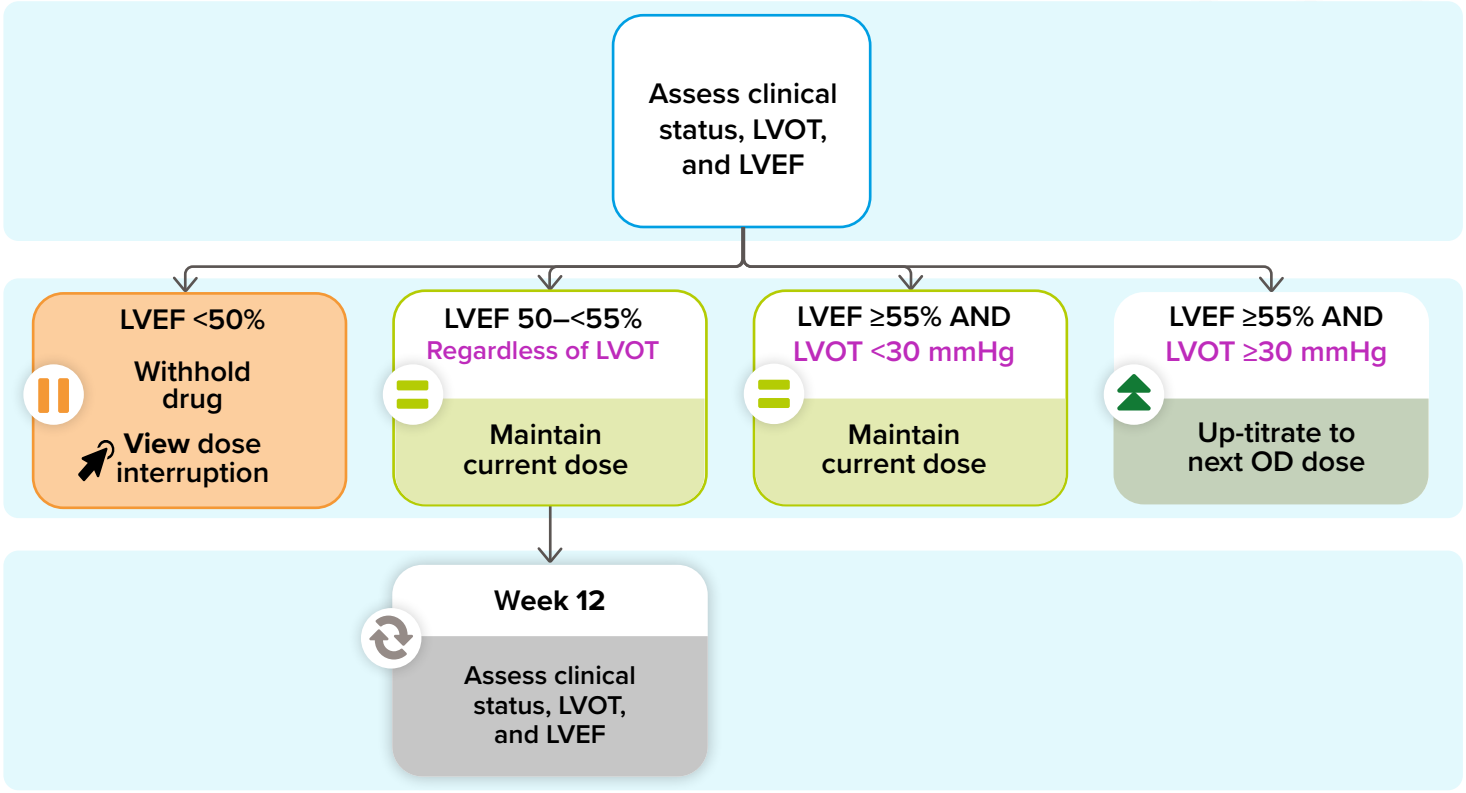
LVEF should be determined at every visit. If LVEF is <50% at any visit, INTERRUPT treatment for 4 weeks and until LVEF is ≥50% – see treatment interruption.

NOTE: LVOT refers to Valsalva LVOT gradient throughout



NOTE: The maximum dose for CYP2C19 poor or unknown metabolisers is 5 mg OD

Up-titration guide:
2.5 mg › 5 mg
5 mg › 10 mg
10 mg › 15 mg

Maximum daily dose is 15 mg

Legend Stop | Continue | Increase dose | Decrease dose | Withhold

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MAINTENANCE PHASE

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LVEF should be determined at every visit. If LVEF is <50% at any visit, INTERRUPT treatment for 4 weeks and until LVEF is ≥50% – see treatment interruption.

NOTE: LVOT refers to Valsalva LVOT gradient throughout

Assess clinical status, LVOT, and LVEF

- **LVEF <50%**: Withhold drug → View dose interruption
- **LVEF 50–<55%** (Regardless of LVOT): Maintain current dose
- **LVEF ≥55% AND LVOT <30 mmHg**: Maintain current dose
- **LVEF ≥55% AND LVOT ≥30 mmHg**: Up-titrate to next OD dose

During the first 6-month cycle

Assess clinical status after approx. **12 weeks**

Every 6 months

Assess clinical status, LVOT, and LVEF

NOTE: The maximum dose for CYP2C19 poor or unknown metabolisers is 5 mg OD

Up-titration guide:

2.5 mg › 5 mg
5 mg › 10 mg
10 mg › 15 mg

Maximum daily dose is 15 mg

Legend Stop | Continue | Increase dose | Decrease dose | Withhold

Interactive Dosing Guide

MAINTENANCE PHASE

LVEF should be determined at every visit. If LVEF is <50% at any visit, INTERRUPT treatment for 4 weeks and until LVEF is ≥50% – see treatment interruption.

NOTE: LVOT refers to Valsalva LVOT gradient throughout

Assess clinical status, LVOT, and LVEF

- **LVEF <50%** → Withhold drug → View dose interruption
- **LVEF 50–<55%** (Regardless of LVOT) → Maintain current dose
- **LVEF ≥55% AND LVOT <30 mmHg** → Maintain current dose
- **LVEF ≥55% AND LVOT ≥30 mmHg** → Up-titrate to next OD dose

Week 4

Assess clinical status, LVOT, and LVEF. Maintain dose for further **8 weeks** unless LVEF <50%

Week 12

Assess clinical status, LVOT, and LVEF

NOTE: The maximum dose for CYP2C19 poor or unknown metabolisers is 5 mg OD

Up-titration guide:

2.5 mg › 5 mg
5 mg › 10 mg
10 mg › 15 mg

Maximum daily dose is 15 mg

Legend Stop | Continue | Increase dose | Decrease dose | Withhold

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MAINTENANCE PHASE

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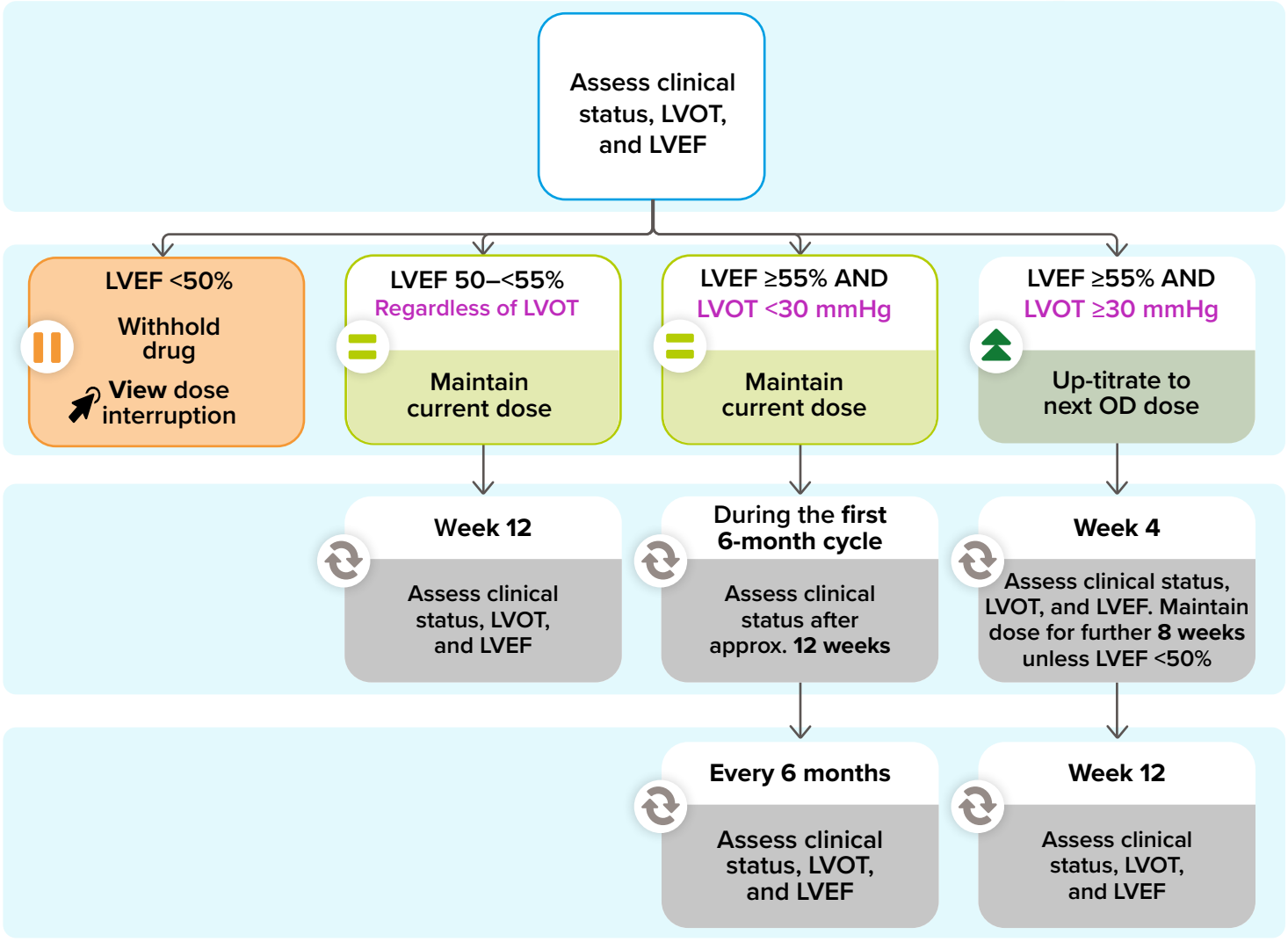
LVEF should be determined at every visit. If LVEF is <50% at any visit, INTERRUPT treatment for 4 weeks and until LVEF is ≥50% – see treatment interruption.

NOTE: LVOT refers to Valsalva LVOT gradient throughout



NOTE: The maximum dose for CYP2C19 poor or unknown metabolisers is 5 mg OD

Up-titration guide:
2.5 mg › 5 mg
5 mg › 10 mg
10 mg › 15 mg

Maximum daily dose is 15 mg

Legend Stop | Continue | Increase dose | Decrease dose | Withhold

Interactive Dosing Guide

TREATMENT INTERRUPTION

LVEF should be determined at every visit. If LVEF is <50% at any visit, INTERRUPT treatment for 4 weeks and until LVEF is ≥50% – see treatment interruption.

NOTE: LVOT refers to Valsalva LVOT gradient throughout

Current dose

LVEF <50%
Regardless of LVOT

Withhold drug if true at ANY clinic visit

4 weeks later

LVEF <50%
Regardless of LVOT

Recheck clinical status every 4 weeks until LVEF ≥50%

LVEF <50% on two consecutive occasions on 2.5 mg OD

Permanently discontinue treatment

LVEF ≥50%
Regardless of LVOT

Restart at one lower dose level or restart on 2.5 mg

Click the box that describes your patient's echocardiogram results to view the next step in the algorithm

NOTE: The maximum dose for CYP2C19 poor or unknown metabolisers is 5 mg OD

Down-titration guide:

15 mg › 10 mg
10 mg › 5 mg
5 mg › 2.5 mg

Legend Stop | Continue | Increase dose | Decrease dose | Withhold

Interactive Dosing Guide

TREATMENT INTERRUPTION

LVEF should be determined at every visit. If LVEF is <50% at any visit, INTERRUPT treatment for 4 weeks and until LVEF is ≥50% – see treatment interruption.

NOTE: LVOT refers to Valsalva LVOT gradient throughout

Current dose

LVEF <50%
Regardless of LVOT

Withhold drug if true at ANY clinic visit

4 weeks later

LVEF <50%
Regardless of LVOT

Recheck clinical status every 4 weeks until LVEF ≥50%

LVEF <50% on two consecutive occasions on 2.5 mg OD

Permanently discontinue treatment

LVEF ≥50%
Regardless of LVOT

Restart at one lower dose level or restart on 2.5 mg

4 weeks later

Recheck clinical status, LVOT, and LVEF

Maintain current dose

8 weeks later (12 weeks since restart)

View maintenance phase

NOTE: The maximum dose for CYP2C19 poor or unknown metabolisers is 5 mg OD

Down-titration guide:
15 mg › 10 mg
10 mg › 5 mg
5 mg › 2.5 mg

Legend Stop | Continue | Increase dose | Decrease dose | Withhold

Interactive Dosing Guide

TREATMENT INTERRUPTION

LVEF should be determined at every visit. If LVEF is <50% at any visit, INTERRUPT treatment for 4 weeks and until LVEF is ≥50% – see treatment interruption.

NOTE: LVOT refers to Valsalva LVOT gradient throughout

Current dose

LVEF <50%
Regardless of LVOT

Withhold drug if true at ANY clinic visit

4 weeks later

LVEF <50%
Regardless of LVOT

Recheck clinical status every 4 weeks until LVEF ≥50%

LVEF <50% on two consecutive occasions on 2.5 mg OD

Permanently discontinue treatment

LVEF ≥50%
Regardless of LVOT

Restart at one lower dose level or restart on 2.5 mg

4 weeks later

Recheck clinical status, LVOT, and LVEF

Maintain current dose

8 weeks later (12 weeks since restart)

View maintenance phase

NOTE: The maximum dose for CYP2C19 poor or unknown metabolisers is 5 mg OD

Down-titration guide:

15 mg › 10 mg
10 mg › 5 mg
5 mg › 2.5 mg

Legend Stop | Continue | Increase dose | Decrease dose | Withhold

Interactive Dosing Guide

CYP450 INHIBITORS AND INDUCERS

LVEF should be determined at every visit. If LVEF is <50% at any visit, INTERRUPT treatment for 4 weeks and until LVEF is ≥50% – see treatment interruption.

Dose modification with concomitant medicinal products

CYP450 inhibitors

Strong
CYP2C19 inhibitor
(e.g. ticlopidine, fluconazole, fluvoxamine)

Strong
CYP3A4 inhibitor
(e.g. clarithromycin, itraconazole, ketoconazole, voriconazole, ritonavir, cobicistat, ceritinib, idelalisib, tucatinib)

strong
CYP2C19 inhibitor
combined with
strong
CYP3A4 inhibitor
CONTRAINDICATED

Moderate
CYP2C19 inhibitor
(e.g. fluconazole, fluoxetine, omeprazole)

Moderate or weak
CYP3A4 inhibitor
(e.g. erythromycin, grapefruit, verapamil, diltiazem, cimetidine, esomeprazole, omeprazole, pantoprazole)

Click the appropriate box to see dose modifications required.

CYP450 inducers

Discontinuing or decreasing dose of
moderate or weak
CYP2C19 inducer
(e.g. letermovir, norethindrone, prednisone)

Discontinuing or decreasing dose of
moderate or weak
CYP3A4 inducer
(e.g. phenobarbital, primidone)

Discontinuing or decreasing dose of
strong
CYP2C19 and CYP3A4 inducer
(e.g. rifampicin, apalutamide, enzalutamide, mitotane, phenytoin, carbamazepine, efavirenz, St. John's wort)

Interactive Dosing Guide

CYP450 INHIBITORS

LVEF should be determined at every visit. If LVEF is <50% at any visit, INTERRUPT treatment for 4 weeks and until LVEF is ≥50% – see treatment interruption.

Dose modification with a strong CYP2C19 inhibitor

Strong
CYP2C19 inhibitor
(e.g. ticlopidine, fluconazole, fluvoxamine)

BACK

CYP2C19 metaboliser phenotype

	Poor	Unknown	Other
Starting dose	2.5 mg OD	2.5 mg OD	2.5 mg OD

Current maintenance dose	Dose adjustment		
	Poor	Unknown	Other
2.5 mg OD	2.5 mg OD	Pause treatment	Pause treatment
5 mg OD	5 mg OD	2.5 mg OD	2.5 mg OD
10 mg OD			2.5 mg OD
15 mg OD			5 mg OD

ALL: Monitor LVEF 4 weeks later, and then follow maintenance phase.

Legend Stop | Continue | Increase dose | Decrease dose | Withhold

Interactive Dosing Guide

CYP450 INHIBITORS

LVEF should be determined at every visit. If LVEF is <50% at any visit, INTERRUPT treatment for 4 weeks and until LVEF is ≥50% – see treatment interruption.

Dose modification with a moderate CYP2C19 inhibitor

Moderate
CYP2C19 inhibitor
(e.g. fluconazole, fluoxetine, omeprazole)

BACK

CYP2C19 metaboliser phenotype

	Poor	Unknown	Other
Starting dose	2.5 mg OD	2.5 mg OD	5 mg OD
Current maintenance dose	**Dose adjustment**		
2.5 mg OD	2.5 mg OD	Pause treatment	Pause treatment
5 mg OD	5 mg OD	2.5 mg OD	2.5 mg OD
10 mg OD			5 mg OD
15 mg OD			10 mg OD

ALL: Monitor LVEF 4 weeks later, and then follow maintenance phase.

Legend Stop | Continue | Increase dose | Decrease dose | Withhold

Interactive Dosing Guide

CYP450 INHIBITORS

LVEF should be determined at every visit. If LVEF is <50% at any visit, INTERRUPT treatment for 4 weeks and until LVEF is ≥50% – see treatment interruption.

Dose modification with a strong CYP3A4 inhibitor

BACK

Strong

CYP3A4 inhibitor

(e.g. clarithromycin, itraconazole, ketoconazole, voriconazole, ritonavir, cobicistat, ceritinib, idelalisib, tucatinib)

CYP2C19 metaboliser phenotype

Poor	Unknown	Other
CONTRAINDICATED	CONTRAINDICATED	No dose adjustment

ALL: Monitor LVEF 4 weeks later, and then follow maintenance phase.

Interactive Dosing Guide

CYP450 INHIBITORS

LVEF should be determined at every visit. If LVEF is <50% at any visit, INTERRUPT treatment for 4 weeks and until LVEF is ≥50% – see treatment interruption.

Dose modification with a moderate or weak CYP3A4 inhibitor

Moderate or weak CYP3A4 inhibitor

(e.g. erythromycin, grapefruit, verapamil, diltiazem, cimetidine, esomeprazole, omeprazole, pantoprazole)

BACK

CYP2C19 metaboliser phenotype

	Poor	Unknown	Other
Starting dose	2.5 mg OD	2.5 mg OD	5 mg OD

Current maintenance dose	Dose adjustment		
	Poor	Unknown	Other
2.5 mg OD	Pause treatment	Pause treatment	2.5 mg OD
5 mg OD	2.5 mg OD	2.5 mg OD	5 mg OD
10 mg OD			10 mg OD
15 mg OD			15 mg OD

ALL: Monitor LVEF 4 weeks later, and then follow maintenance phase.

Legend Stop | Continue | Increase dose | Decrease dose | Withhold

Interactive Dosing Guide

CYP450 INDUCERS

LVEF should be determined at every visit. If LVEF is <50% at any visit, INTERRUPT treatment for 4 weeks and until LVEF is ≥50% – see treatment interruption.

Discontinuing or decreasing the dose of a moderate or weak CYP2C19 inducer

BACK

Discontinuing or decreasing dose of
moderate or weak
CYP2C19 inducer

(e.g. letermovir, norethindrone, prednisone)

CYP2C19 metaboliser phenotype

	Poor	Unknown	Other
Starting dose	= 2.5 mg OD	= 2.5 mg OD	= 5 mg OD

Current maintenance dose	Dose adjustment		
	Poor	Unknown	Other
2.5 mg OD	= 2.5 mg OD	= 2.5 mg OD	= 2.5 mg OD
5 mg OD	= 5 mg OD	= 5 mg OD	↓↓ 2.5 mg OD
10 mg OD			↓↓ 5 mg OD
15 mg OD			↓↓ 10 mg OD

ALL: Monitor LVEF 4 weeks later, and then follow maintenance phase.

Legend Stop | Continue | Increase dose | Decrease dose | Withhold

Interactive Dosing Guide

CYP450 INDUCERS

LVEF should be determined at every visit. If LVEF is <50% at any visit, INTERRUPT treatment for 4 weeks and until LVEF is ≥50% – see treatment interruption.

Discontinuing or decreasing the dose of a moderate or weak CYP3A4 inducer

BACK

Discontinuing or decreasing dose of
moderate or weak
CYP3A4 inducer
(e.g. phenobarbital, primidone)

CYP2C19 metaboliser phenotype

	Poor	Unknown	Other
Starting dose	2.5 mg OD	2.5 mg OD	5 mg OD

Current maintenance dose	Dose adjustment		
	Poor	Unknown	Other
2.5 mg OD	Pause treatment	Pause treatment	2.5 mg OD
5 mg OD	2.5 mg OD	2.5 mg OD	5 mg OD
10 mg OD			10 mg OD
15 mg OD			15 mg OD

ALL: Monitor LVEF 4 weeks later, and then follow maintenance phase.

Legend Stop | Continue | Increase dose | Decrease dose | Withhold

Interactive Dosing Guide

CYP450 INDUCERS

LVEF should be determined at every visit. If LVEF is <50% at any visit, INTERRUPT treatment for 4 weeks and until LVEF is ≥50% – see treatment interruption.

Discontinuing or decreasing the dose of a strong CYP2C19 and CYP3A4 inducer

BACK

Discontinuing or decreasing dose of

strong

CYP2C19 and CYP3A4 inducer

(e.g. rifampicin, apalutamide, enzalutamide, mitotane, phenytoin, carbamazepine, efavirenz, St. John's wort)

CYP2C19 metaboliser phenotype

	Poor	Unknown	Other
Starting dose	2.5 mg OD	2.5 mg OD	5 mg OD

Current maintenance dose	Dose adjustment		
	Poor	Unknown	Other
2.5 mg OD	Pause treatment	Pause treatment	2.5 mg OD
5 mg OD	2.5 mg OD	2.5 mg OD	2.5 mg OD
10 mg OD			5 mg OD
15 mg OD			10 mg OD

ALL: Monitor LVEF 4 weeks later, and then follow maintenance phase.

Legend Stop | Continue | Increase dose | Decrease dose | Withhold

ABRV

Abbreviations

ABRV	abbreviations
AF	atrial fibrillation
CYP450	cytochrome P450 enzymes
HCM	hypertrophic cardiomyopathy
HCP	healthcare professional
LVEF	left ventricular ejection fraction
LVOT	left ventricular outflow tract
NYHA	New York Heart Association
OD	omni die (once daily)
PI	Prescribing Information
QoL	quality of life
SmPC	Summary of Product Characteristics

Export text

(Initiation W0: W0 LVEF ≥55%)

At Week 0, the patient had a LVEF of at least 55% and was initiated on 5 mg OD mavacamten.

(Copy and paste to use; ensure that you review the details before saving in your notes.)

Export text

(Initiation W4: W0 LVEF ≥55%, W4 LVOT ≥20)

At Week 0, the patient had a LVEF of at least 55% and was initiated on 5 mg OD mavacamten.

At Week 4, LVEF remained at least 50% and Valsalva LVOT gradient at least 20 mmHg so the dose was continued at 5 mg OD.

(Copy and paste to use; ensure that you review the details before saving in your notes.)

Export text

(Initiation W4: W0 LVEF ≥55%, W4 LVOT <20)

At Week 0, the patient had a LVEF of at least 55% and was initiated on 5 mg OD mavacamten.

At Week 4, LVEF remained at least 50% and Valsalva LVOT gradient less than 20 mmHg so the dose was decreased to 2.5 mg OD.

(Copy and paste to use; ensure that you review the details before saving in your notes.)

Export text

(Initiation W8: W0 LVEF ≥55%, W4 LVOT ≥20, W8 LVOT ≥20)

At Week 0, the patient had a LVEF of at least 55% and was initiated on 5 mg OD mavacamten.

At Week 4, LVEF remained at least 50% and Valsalva LVOT gradient at least 20 mmHg so the dose was continued at 5 mg OD.

At Week 8, LVEF remained at least 50% and Valsalva LVOT gradient at least 20 mmHg so the dose was continued at 5 mg OD.

At Week 12, the patient will proceed to the maintenance phase for mavacamten.

(Copy and paste to use; ensure that you review the details before saving in your notes.)

Export text

(Initiation in poor/unknown metaboliser W0: W0 LVEF ≥55%)

At Week 0, the patient had an LVEF of at least 55% and was initiated on 2.5 mg OD mavacamten.

(Copy and paste to use; ensure that you review the details before saving in your notes.)

Export text

(Initiation in poor/unknown metaboliser W4: W0 LVEF ≥55%, W4 LVOT ≥20)

At Week 0, the patient had an LVEF of at least 55% and was initiated on 2.5 mg OD mavacamten.

At Week 4, LVEF remained at least 50% and Valsalva LVOT gradient at least 20 mmHg so the dose was continued at 2.5 mg OD.

(Copy and paste to use; ensure that you review the details before saving in your notes.)

Export text

(Initiation in poor/unknown metaboliser W4: W0 LVEF ≥55%, W4 LVOT <20)

At Week 0, the patient had an LVEF of at least 55% and was initiated on 2.5 mg OD mavacamten.

At Week 4, LVEF remained at least 50% and Valsalva LVOT gradient less than 20 mmHg so mavacamten will be withheld for 4 weeks.

(Copy and paste to use; ensure that you review the details before saving in your notes.)

Export text

(Initiation in poor/unknown metaboliser W8: W0 LVEF ≥55%, W4 LVOT <20, W8 LVOT <20)

At Week 0, the patient had an LVEF of at least 55% and was initiated on 2.5 mg OD mavacamten.

At Week 4, LVEF remained at least 50% and Valsalva LVOT gradient less than 20 mmHg so mavacamten was withheld for 4 weeks.

At Week 8, LVEF remained at least 50% and Valsalva LVOT gradient less than 20 mmHg so mavacamten will be withheld for a further 4 weeks.

(Copy and paste to use; ensure that you review the details before saving in your notes.)

Export text

(Initiation in poor/unknown metaboliser W8: W0 LVEF ≥55%, W4 LVOT ≥20, W8 LVOT ≥20)

At Week 0, the patient had an LVEF of at least 55% and was initiated on 2.5 mg OD mavacamten.

At Week 4, LVEF remained at least 50% and Valsalva LVOT gradient at least 20 mmHg so the dose was continued at 2.5 mg OD.

At Week 8, LVEF remained at least 50% and Valsalva LVOT gradient at least 20 mmHg so the dose was continued at 2.5 mg OD.

At Week 12, the patient will proceed to the maintenance phase for mavacamten.

(Copy and paste to use; ensure that you review the details before saving in your notes.)

Export text

(Initiation in poor/unknown metaboliser W8: W0 LVEF ≥55%, W4 LVOT <20, W8 LVOT ≥20)

At Week 0, the patient had an LVEF of at least 55% and was initiated on 2.5 mg OD mavacamten.

At Week 4, LVEF remained at least 50% and Valsalva LVOT gradient less than 20 mmHg so mavacamten was withheld for 4 weeks.

At Week 8, LVEF remained at least 50% and Valsalva LVOT gradient at least 20 mmHg so mavacamten was restarted at 2.5 mg OD.

At Week 12, the patient will proceed to the maintenance phase for mavacamten.

(Copy and paste to use; ensure that you review the details before saving in your notes.)

Export text

(Initiation in poor/unknown metaboliser W8: W0 LVEF ≥55%, W4 LVOT ≥20, W8 LVOT <20)

At Week 0, the patient had an LVEF of at least 55% and was initiated on 2.5 mg OD mavacamten.

At Week 4, LVEF remained at least 50% and Valsalva LVOT gradient at least 20 mmHg so the dose was continued at 2.5 mg OD.

At Week 8, LVEF remained at least 50% and Valsalva LVOT gradient less than 20 mmHg so mavacamten will be withheld for 4 weeks.

(Copy and paste to use; ensure that you review the details before saving in your notes.)

Export text

(Initiation in poor/unknown metaboliser W12: W0 LVEF ≥55%, W4 LVOT <20, W8 LVOT <20, LVEF ≥50%)

At Week 0, the patient had an LVEF of at least 55% and was initiated on 2.5 mg OD mavacamten.

At Week 4, LVEF remained at least 50% and Valsalva LVOT gradient less than 20 mmHg so mavacamten was withheld for 4 weeks.

At Week 8, LVEF remained at least 50% and Valsalva LVOT gradient less than 20 mmHg so mavacamten was withheld for a further 4 weeks.

At Week 12, LVEF remained at least 50% so mavacamten was restarted at 2.5 mg OD.

Clinical status will be reassessed in 4 weeks.

(Copy and paste to use; ensure that you review the details before saving in your notes.)

Export text

(Initiation in poor/unknown metaboliser W12: W0 LVEF ≥55%, W4 LVOT ≥20, W8 LVOT <20, LVEF ≥50%)

At Week 0, the patient had an LVEF of at least 55% and was initiated on 2.5 mg OD mavacamten.

At Week 4, LVEF remained at least 50% and Valsalva LVOT gradient at least 20 mmHg so the dose was continued at 2.5 mg OD.

At Week 8, LVEF remained at least 50% and Valsalva LVOT gradient less than 20 mmHg so mavacamten was withheld for 4 weeks.

At Week 12, LVEF remained at least 50% so mavacamten was restarted at 2.5 mg OD.

Clinical status will be reassessed in 4 weeks.

(Copy and paste to use; ensure that you review the details before saving in your notes.)

Export text

(Initiation W8: W0 LVEF ≥55%, W4 LVOT ≥20, W8 LVOT <20)

At Week 0, the patient had a LVEF of at least 55% and was initiated on 5 mg OD mavacamten.

At Week 4, LVEF remained at least 50% and Valsalva LVOT gradient at least 20 mmHg so the dose was continued at 5 mg OD.

At Week 8, LVEF remained at least 50% and Valsalva LVOT gradient less than 20 mmHg so the dose was decreased to 2.5 mg OD.

At Week 12, the patient will proceed to the maintenance phase for mavacamten.

(Copy and paste to use; ensure that you review the details before saving in your notes.)

Export text

(Initiation W8: W0 LVEF ≥55%, W4 LVOT <20, W8 LVOT ≥20)

At Week 0, the patient had a LVEF of at least 55% and was initiated on 5 mg OD mavacamten.

At Week 4, LVEF remained at least 50% and Valsalva LVOT gradient less than 20 mmHg so the dose was decreased to 2.5 mg OD.

At Week 8, LVEF remained at least 50% and Valsalva LVOT gradient at least 20 mmHg so the dose was continued at 2.5 mg OD.

At Week 12, the patient will proceed to the maintenance phase for mavacamten.

(Copy and paste to use; ensure that you review the details before saving in your notes.)

Export text

(Initiation W8: W0 LVEF ≥55%, W4 LVOT <20, W8 LVOT <20)

At Week 0, the patient had a LVEF of at least 55% and was initiated on 5 mg OD mavacamten.

At Week 4, LVEF remained at least 50% and Valsalva LVOT gradient less than 20 mmHg so the dose was decreased to 2.5 mg OD.

At Week 8, LVEF remained at least 50% and Valsalva LVOT gradient less than 20 mmHg so mavacamten will be withheld for 4 weeks.

(Copy and paste to use; ensure that you review the details before saving in your notes.)

Export text

(Initiation W12: W0 LVEF ≥55%, W4 LVOT <20, W8 LVOT <20, W12 LVEF ≥50%)

At Week 0, the patient had a LVEF of at least 55% and was initiated on 5 mg OD mavacamten.

At Week 4, LVEF remained at least 50% and Valsalva LVOT gradient less than 20 mmHg so the dose was decreased to 2.5 mg OD.

At Week 8, LVEF remained at least 50% and Valsalva LVOT gradient less than 20 mmHg so mavacamten was withheld for 4 weeks.

At Week 12, LVEF remained at least 50% so mavacamten was restarted at 2.5 mg OD.

Clinical status will be reassessed in 4 weeks.

(Copy and paste to use; ensure that you review the details before saving in your notes.)

Export text

(Maintenance W0: W0 LVEF 50–<55%)

At maintenance Week 0, the patient had a LVEF of 50–<55% and was maintained at their current dose of mavacamten.

Clinical status will be reassessed in 12 weeks.

(Copy and paste to use; ensure that you review the details before saving in your notes.)

Export text

(Maintenance W0: W0 LVEF ≥55% and LVOT <30)

At maintenance Week 0, the patient had a LVEF of at least 55% and Valsalva LVOT less than 30 mmHg so was maintained at their current dose of mavacamten.

Clinical status will be reassessed every 12 weeks during the first 6-month cycle, then every 6 months.

(Copy and paste to use; ensure that you review the details before saving in your notes.)

Export text

(Maintenance W0: W0 LVEF ≥55% and LVOT ≥30)

At maintenance Week 0, the patient had a LVEF of at least 55% and Valsalva LVOT of at least 30 mmHg so the dose was increased.

Clinical status will be reassessed in 4 weeks and dose maintained for the next 8 weeks.

(Copy and paste to use; ensure that you review the details before saving in your notes.)

Export text

(Interruption W4: W0 LVEF <50%, W4 LVEF ≥50%)

LVEF was less than 50% so mavacamten was withheld for 4 weeks.

At Week 4, LVEF was at least 50% so mavacamten was restarted at one lower dose level.

Clinical status will be rechecked in 4 and 8 weeks.

(Copy and paste to use; ensure that you review the details before saving in your notes.)

Export text

(Interruption W4: W0 LVEF <50%, W4 LVEF <50%)

LVEF was less than 50% so mavacamten was withheld for 4 weeks.

At Week 4, LVEF remained less than 50% so the clinical status will be reassessed every 4 weeks until LVEF is at least 50%.

(Copy and paste to use; ensure that you review the details before saving in your notes.)

Interactive Dosing Guide

Ireland PI (Page 1)

Ireland

Consult Summary of Product Characteristics (SmPC) before prescribing.

▼ **This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information.**

PRESENTATION: Hard capsule (capsule); 2.5 mg, 5 mg, 10 mg, 15 mg mavacamten.

INDICATION: Treatment of symptomatic (New York Heart Association, NYHA, class II-III) obstructive hypertrophic cardiomyopathy (oHCM) in adult patients.

DOSAGE AND ADMINISTRATION: Treatment should be initiated under the supervision of a physician experienced in the management of patients with cardiomyopathy. Before treatment initiation, patients' left ventricular ejection fraction (LVEF) should be assessed by echocardiography. If LVEF is < 55%, treatment should not be initiated. Before initiation of treatment, females of childbearing potential must have a negative pregnancy test. Patients should be genotyped for Cytochrome P450 (CYP) 2C19 (CYP2C19) in order to determine appropriate mavacamten dose. Patients with CYP2C19 poor metaboliser phenotype may have increased mavacamten exposures (up to 3 times) that can lead to increased risk of systolic dysfunction compared to normal metabolisers. If treatment initiation occurs prior to determination of CYP2C19 phenotype, patients should follow dosing instructions for poor metabolisers until CYP2C19 phenotype is determined. *Posology:* The dose range is 2.5 mg to 15 mg (either 2.5 mg, 5 mg, 10 mg or 15 mg).

CYP2C19 poor metaboliser phenotype: The recommended starting dose is 2.5 mg orally once daily. The maximum dose is 5 mg once daily. The patient should be assessed for early clinical response by left ventricular outflow tract (LVOT) gradient with Valsalva manoeuvre 4 and 8 weeks after treatment initiation. *CYP2C19 intermediate, normal, rapid and ultra rapid metaboliser phenotype:* The recommended starting dose is 5 mg orally once daily. The maximum dose is 15 mg once daily. The patient should be assessed for early clinical response by LVOT gradient with Valsalva manoeuvre 4 and 8 weeks after treatment initiation.

Once an individualised maintenance dose is achieved with LVEF ≥ 55%, patients should be assessed every 6 months. During the first 6-month cycle if LVEF ≥ 55% and Valsalva LVOT gradient < 30 mmHg check clinical status after approximately 3 months. For patients with LVEF 50 - < 55% regardless of Valsalva LVOT gradient, patients should be assessed every 3 months. If at any visit the patient's LVEF is < 50%, the treatment should be interrupted for 4 weeks and until LVEF returns to ≥ 50%. In patients experiencing an intercurrent illness such as serious infection or arrhythmia (including atrial fibrillation or other uncontrolled tachyarrhythmia) which may impair systolic function, LVEF assessment is recommended, and dose increases are not recommended until intercurrent illness is resolved. Consideration should be given to discontinue treatment in patients who have shown no response (e.g., no improvement in symptoms, quality of life, exercise capacity, LVOT gradient) after 4-6 months on the maximum tolerated dose. Refer to SmPC for further details. *Missed or delayed doses:* If a dose is missed, it should be taken as soon as possible, and the next scheduled dose should be taken at the usual time the following day. Two doses should not be taken on the same day. *Special populations: Elderly:* No dose adjustment to the standard dose and titration scheme is required for patients aged 65 years and older. *Renal impairment:* No dose adjustment to the standard dose and titration scheme is required for patients with mild (estimated glomerular filtration rate [eGFR] 60-89 mL/min/1.73m^2) to moderate (eGFR 30-59 mL/min/1.73m^2) renal impairment. No dose recommendation can be made for patients with severe (eGFR < 30 mL/min/1.73m^2) renal impairment because mavacamten has not been studied in patients with severe renal impairment. *Hepatic impairment:* The mavacamten starting dose should be 2.5 mg in all patients with mild (Child-Pugh class A) and moderate (Child-Pugh class B) hepatic impairment since mavacamten exposure is likely to be increased. No dose recommendation can be made for patients with severe hepatic impairment (Child-Pugh class C) because mavacamten has not been studied in patients with severe hepatic impairment. *Paediatric population:* The safety and efficacy of mavacamten in children and adolescents below 18 years have not been established. No data are available. Mavacamten should not be used in children less than 12 years because of potential safety concerns. *Method of administration:* For oral use. Treatment should be taken once daily with or without meals at about the same time each day. The capsule should be swallowed whole with water.

CONTRAINDICATIONS: Hypersensitivity to the active substance or to any of the excipients (refer to SmPC). During pregnancy and in females of childbearing potential not using effective contraception. Concomitant treatment with strong CYP3A4 inhibitors in patients with CYP2C19 poor metaboliser phenotype and undetermined CYP2C19 phenotype. Concomitant treatment with the combination of a strong CYP2C19 inhibitor and a strong CYP3A4 inhibitor. Refer to SmPC for further details.

WARNINGS AND PRECAUTIONS: *Systolic dysfunction defined as symptomatic LVEF < 50%*:* Mavacamten reduces LVEF and may cause heart failure due to systolic dysfunction defined as symptomatic LVEF < 50%. Patients with a serious intercurrent illness such as infection or arrhythmia (including atrial fibrillation or other uncontrolled tachyarrhythmia), or those undergoing major cardiac surgery may be at greater risk of systolic dysfunction and progress to heart failure. New or worsening dyspnoea, chest pain, fatigue, palpitations, leg oedema or elevations in N-terminal pro-B-type natriuretic peptide (NT-proBNP) may be signs and symptoms of systolic dysfunction and should prompt an evaluation of cardiac function. LVEF should be measured prior to initiating treatment and closely monitored thereafter. Treatment interruption may be necessary to ensure that LVEF remains ≥ 50%. *Heart failure risk or loss of response to mavacamten due to interactions*:* Mavacamten is primarily metabolised by CYP2C19 and to a lesser extent by CYP3A4 and mostly by CYP3A4 in CYP2C19 poor metabolisers, which may lead to the following interactions: Starting or increasing the dose of a strong or moderate CYP3A4 inhibitor or any CYP2C19 inhibitor may increase risk of heart failure due to systolic dysfunction. Stopping or decreasing dose of any inhibitor of CYP3A4 or CYP2C19 may lead to a loss of therapeutic response to mavacamten. Starting a strong CYP3A4 or strong CYP2C19 inducer may lead to a loss of therapeutic response to mavacamten. Stopping a strong CYP3A4 or strong CYP2C19 inducer may increase risk of heart failure due to systolic dysfunction. Prior to and during mavacamten treatment, the potential for interactions, including over the counter medicinal products (such as omeprazole or esomeprazole), should be considered.

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Interactive Dosing Guide

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Concomitant treatment with strong CYP3A4 inhibitors in patients with CYP2C19 poor metaboliser phenotype and undetermined CYP2C19 phenotype is contraindicated. Concomitant treatment with the combination of a strong CYP2C19 inhibitor and a strong CYP3A4 inhibitor is contraindicated. Dose adjustment of mavacamten and/or close monitoring may be required in patients initiating or discontinuing treatment with, or changing the dose of concomitant medicinal products that are inhibitors or inducers of CYP2C19 or CYP3A4. Intermittent administration of these medicinal products is not recommended. *Concomitant use of negative inotropes:* The safety of concomitant use of mavacamten with disopyramide, or use of mavacamten in patients taking beta blockers in combination with verapamil or diltiazem has not been established. Therefore, patients should be closely monitored when taking these concomitant medicinal products. *Embryo-foetal toxicity*:* Based on animal studies, mavacamten is suspected to cause embryo-foetal toxicity when administered to a pregnant female. Due to risk to the foetus, mavacamten is contraindicated during pregnancy and in females of childbearing potential not using effective contraception. Before initiation of treatment, females of childbearing potential must be informed of this risk to the foetus, must have a negative pregnancy test and must use effective contraception during treatment and for 6 months after treatment discontinuation. *Sodium content:* This medicinal product contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'. Refer to SmPC section 4.5 for other drug-drug interactions.

*serious adverse drug reaction

PREGNANCY AND LACTATION: *Pregnancy:* There are no data from the use of mavacamten in pregnant females. Mavacamten is suspected to cause embryo-foetal toxicity when administered during pregnancy. Therefore, mavacamten is contraindicated during pregnancy. Mavacamten should be stopped 6 months before planning a pregnancy. If a patient becomes pregnant, mavacamten must be discontinued. Medical advice should be given regarding the risk of harmful effects to the foetus associated with treatment and ultrasonography examinations should be performed. *Breast-feeding:* It is unknown whether mavacamten or its metabolites are excreted in human milk. Because of the unknown adverse effects of mavacamten in breastfed newborns/infants, females must not breast-feed during treatment with mavacamten.

UNDESIRABLE EFFECTS: The most commonly reported adverse reactions with mavacamten are dizziness (17%), dyspnoea (12%), systolic dysfunction (5%) and syncope (5%). *Very common (≥ 1/10):* Dizziness, Dyspnoea. *Common (≥ 1/100 to < 1/10):* Syncope*, Systolic dysfunction (LVEF < 50% with or without symptoms)*. Refer to SmPC for full details on adverse reactions.

*serious adverse drug reaction

LEGAL CATEGORY: POM

MARKETING AUTHORISATION NUMBER: Carton of 28 hard capsules 2.5 mg (EU/1/23/1716/002); Carton of 28 hard capsules 5 mg (EU/1/23/1716/004); Carton of 28 hard capsules 10 mg (EU/1/23/1716/006); Carton of 28 hard capsules 15 mg (EU/1/23/1716/008).

MARKETING AUTHORISATION HOLDER: Bristol-Myers Squibb Pharma EEIG, Plaza 254, Blanchardstown Corporate Park 2, Dublin 15, D15 T867, Ireland

FOR FURTHER INFORMATION CONTACT:
medical.information@bms.com or 1 800 749 749 (Ireland)

DATE OF PREPARATION: March 2025

ADDITIONAL INFORMATION AVAILABLE ON REQUEST

Approval code: 3500-IE-2500001

**Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance at www.hpra.ie.
Adverse reactions should also be reported to Bristol-Myers Squibb Medical Information on 1 800 749 749 or medical.information@bms.com.**

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