

# Convenient once-daily oral dosing<sup>1</sup>

Straightforward dosage, based on renal impairment

## MILD/MODERATE/SEVERE (NOT ON DIALYSIS)



## SEVERE (ON DIALYSIS)



Capsules shown are not actual size.

- For patients with severe renal impairment requiring dialysis, patients should take POMALYST following hemodialysis on the day of dialysis
- Recommended dosage for POMALYST is 4 mg once daily orally with or without food on Days 1-21 of each 28-day cycle
- Give POMALYST in combination with dexamethasone (dex)
  - In the Phase 3 MM-003 trial, low-dose dex was given on Days 1, 8, 15, and 22 of a 28-day cycle
  - Dex 40 mg for patients ≤75 years
  - Dex 20 mg for patients >75 years
- Repeat until disease progression or unacceptable toxicity. Dose interruptions and modifications may be required

## Indication

POMALYST® (pomalidomide) is a thalidomide analogue indicated, in combination with dexamethasone, for adult patients with multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor and have demonstrated disease progression on or within 60 days of completion of the last therapy.

## Selected Safety Information: Boxed WARNINGS

### WARNING: EMBRYO-FETAL TOXICITY and VENOUS AND ARTERIAL THROMBOEMBOLISM

#### Embryo-Fetal Toxicity

- **POMALYST is contraindicated in pregnancy. POMALYST is a thalidomide analogue. Thalidomide is a known human teratogen that causes severe birth defects or embryo-fetal death. In females of reproductive potential, obtain 2 negative pregnancy tests before starting POMALYST treatment.**
- **Females of reproductive potential must use 2 forms of contraception or continuously abstain from heterosexual sex during and for 4 weeks after stopping POMALYST treatment.**

**POMALYST is only available through a restricted distribution program called POMALYST REMS®.**

#### Venous and Arterial Thromboembolism

- **Deep venous thrombosis (DVT), pulmonary embolism (PE), myocardial infarction, and stroke occur in patients with multiple myeloma treated with POMALYST. Prophylactic antithrombotic measures were employed in clinical trials. Thromboprophylaxis is recommended, and the choice of regimen should be based on assessment of the patient's underlying risk factors.**

MM, multiple myeloma.

Please see [Important Safety Information](#) on pages 5-7 and full [Prescribing Information](#), including Boxed WARNINGS.

 **Pomalyst**  
(pomalidomide) capsules  
1 · 2 · 3 · 4 mg

# Tailor the POMALYST dosage to your patients' needs

4 DOSAGE STRENGTHS ARE AVAILABLE FOR DOSE MODIFICATIONS<sup>1</sup>



Capsules shown are not actual size.

**In the Phase 3 MM-003 trial, the majority of patients remained on POMALYST + dex until disease progression or unacceptable toxicity with dose modifications<sup>1,2</sup>**

- 67% of trial patients experienced at least one dose interruption of POMALYST, while 27% of patients experienced at least one dose reduction of POMALYST, and 8% discontinued treatment with POMALYST due to adverse reactions
- The median time to first dose interruption and first dose reduction of POMALYST was 4.1 weeks and 4.5 weeks, respectively

## Important Dosing Information

- POMALYST may be taken with or without food. Inform patients not to break, chew, or open the capsules. Swallow capsules whole with water
- Monitor CBCs every week for the first 8 weeks and monthly thereafter. Patients may require dose interruption and/or modification
- Monitor liver function tests monthly. Stop POMALYST upon elevation of liver enzymes and evaluate. After return to baseline values, treatment at a lower dose may be considered
- Reduce POMALYST dose to 3 mg orally daily in patients with mild to moderate hepatic impairment and to 2 mg in patients with severe hepatic impairment
- Avoid concomitant use of POMALYST with strong inhibitors of CYP1A2. If concomitant use of a strong CYP1A2 inhibitor is unavoidable, reduce POMALYST dose to 2 mg
- Reduce POMALYST dose to 3 mg orally daily in patients with severe renal impairment requiring dialysis. Take dose of POMALYST following hemodialysis on hemodialysis days

## Selected Safety Information

### WARNINGS AND PRECAUTIONS

- **Hematologic Toxicity:** Neutropenia (46%) was the most frequently reported Grade 3 or 4 adverse reaction in patients taking POMALYST in clinical trials, followed by anemia and thrombocytopenia. Monitor complete blood counts weekly for the first 8 weeks and monthly thereafter. Patients may require dose interruption and/or modification.

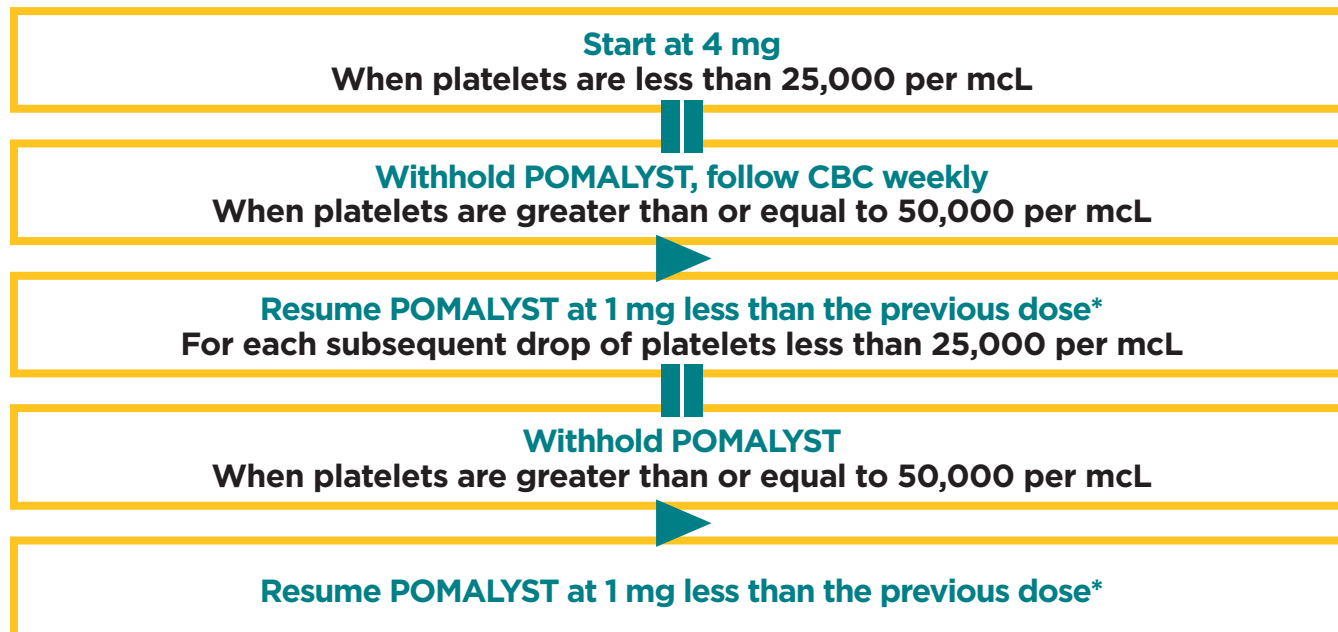
CBC, complete blood count.

Please see [Important Safety Information](#) on pages 5-7 and full [Prescribing Information](#), including **Boxed WARNINGS**.

 **Pomalyst**  
(pomalidomide) capsules  
1 • 2 • 3 • 4 mg

# Dose modifications may help patients stay on therapy<sup>1</sup>

## THROMBOCYTOPENIA



\*Permanently discontinue POMALYST if unable to tolerate 1 mg once daily.

- Initiate a new cycle of POMALYST when the platelet count is at least 50,000 per mcL



**In MM-003, thrombocytopenia of any grade was reported in 30% of patients treated with POMALYST + low-dose dex vs 29% treated with high-dose dex<sup>†</sup>**

**Permanently discontinue POMALYST for angioedema, anaphylaxis, Grade 4 rash, skin exfoliation, bullae, or any other severe dermatologic reaction**

### Selected Safety Information

#### ADVERSE REACTIONS

The most common adverse reactions for POMALYST (≥30%) included fatigue and asthenia, neutropenia, anemia, constipation, nausea, diarrhea, dyspnea, upper-respiratory tract infections, back pain, and pyrexia.

In the phase III trial, nearly all patients treated with POMALYST + low-dose dex experienced at least one adverse reaction (99%). Adverse reactions (≥15% in the POMALYST + low-dose dex arm and ≥2% higher than control) included neutropenia (51%), fatigue and asthenia (47%), upper respiratory tract infection (31%), thrombocytopenia (30%), pyrexia (27%), dyspnea (25%), diarrhea (22%), constipation (22%), back pain (20%), cough (20%), pneumonia (19%), bone pain (18%), edema peripheral (17%), peripheral neuropathy (17%), muscle spasms (15%), and nausea (15%). Grade 3 or 4 adverse reactions (≥15% in the POMALYST + low-dose dex arm and ≥1% higher than control) included neutropenia (48%), thrombocytopenia (22%), and pneumonia (16%).

<sup>†</sup>POMALYST + low-dose dex, n=300; high-dose dex, n=150.

Please see [Important Safety Information](#) on pages 5-7 and full [Prescribing Information](#), including **Boxed WARNINGS**.

 **Pomalyst**  
(pomalidomide) capsules  
1 · 2 · 3 · 4 mg

# Dose modifications may help patients stay on therapy<sup>1</sup>

## NEUTROPENIA

### Start at 4 mg

When ANC is less than 500 per mL or febrile neutropenia (fever greater than or equal to 38.5°C and ANC less than 1000 per mL)



### Withhold POMALYST, follow CBC weekly

When ANC is greater than or equal to 500 per mL



### Resume POMALYST at 1 mg less than the previous dose\*

For each subsequent drop of ANC to less than 500 per mL



### Withhold POMALYST

When ANC is greater than or equal to 500 per mL



### Resume POMALYST at 1 mg less than the previous dose\*

\*Permanently discontinue POMALYST if unable to tolerate 1 mg once daily.

- Initiate a new cycle of POMALYST when the neutrophil count is at least 500 per mL



**In MM-003, neutropenia of any grade was reported in 51% of patients treated with POMALYST + low-dose dex vs 21% treated with high-dose dex<sup>†</sup>**

**Permanently discontinue POMALYST for angioedema, anaphylaxis, Grade 4 rash, skin exfoliation, bullae, or any other severe dermatologic reaction**

### For other Grade 3 or 4 toxicities<sup>1</sup>:

- Hold treatment and restart treatment at 1 mg less than the previous dose when the toxicity has resolved to less than or equal to Grade 2 at the physician's discretion

<sup>†</sup>POMALYST + low-dose dex, n=300; high-dose dex, n=150.  
ANC, absolute neutrophil count.

Please see [Important Safety Information](#) on pages 5-7 and full [Prescribing Information](#), including Boxed WARNINGS.

 **Pomalyst**  
(pomalidomide) capsules  
1 · 2 · 3 · 4 mg

## Indication

POMALYST® (pomalidomide) is a thalidomide analogue indicated, in combination with dexamethasone, for adult patients with multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor and have demonstrated disease progression on or within 60 days of completion of the last therapy.

## Important Safety Information

### WARNING: EMBRYO-FETAL TOXICITY and VENOUS AND ARTERIAL THROMBOEMBOLISM

#### Embryo-Fetal Toxicity

- **POMALYST is contraindicated in pregnancy. POMALYST is a thalidomide analogue. Thalidomide is a known human teratogen that causes severe birth defects or embryo-fetal death. In females of reproductive potential, obtain 2 negative pregnancy tests before starting POMALYST treatment.**
- **Females of reproductive potential must use 2 forms of contraception or continuously abstain from heterosexual sex during and for 4 weeks after stopping POMALYST treatment.**

**POMALYST is only available through a restricted distribution program called POMALYST REMS®.**

#### Venous and Arterial Thromboembolism

- **Deep venous thrombosis (DVT), pulmonary embolism (PE), myocardial infarction, and stroke occur in patients with multiple myeloma treated with POMALYST. Prophylactic antithrombotic measures were employed in clinical trials. Thromboprophylaxis is recommended, and the choice of regimen should be based on assessment of the patient's underlying risk factors.**

## CONTRAINDICATIONS

- **Pregnancy:** POMALYST can cause fetal harm and is contraindicated in females who are pregnant. If the patient becomes pregnant while taking this drug, the patient should be apprised of the potential risk to a fetus.
- **Hypersensitivity:** POMALYST is contraindicated in patients who have demonstrated severe hypersensitivity (e.g., angioedema, anaphylaxis) to pomalidomide or any of the excipients.

## WARNINGS AND PRECAUTIONS

- **Embryo-Fetal Toxicity & Females of Reproductive Potential: See Boxed WARNINGS**
  - **Males:** Pomalidomide is present in the semen of patients receiving the drug. Males must always use a latex or synthetic condom during any sexual contact with females of reproductive potential while taking POMALYST and for up to 4 weeks after discontinuing POMALYST, even if they have undergone a successful vasectomy. Males must not donate sperm.
  - **Blood Donation:** Patients must not donate blood during treatment with POMALYST and for 4 weeks following discontinuation of POMALYST therapy because the blood might be given to a pregnant female patient whose fetus must not be exposed to POMALYST.
- **POMALYST REMS® Program: See Boxed WARNINGS**
  - Prescribers and pharmacies must be certified with the **POMALYST REMS** program by enrolling and complying with the REMS requirements; pharmacies must only dispense to patients who are authorized to receive POMALYST. Patients must sign a Patient-Physician Agreement Form and comply with REMS requirements; female patients of reproductive potential who are not pregnant must comply with the pregnancy testing and contraception requirements and males must comply with contraception requirements.
  - Further information about the **POMALYST REMS** program is available at [www.CelgeneRiskManagement.com](http://www.CelgeneRiskManagement.com) or by telephone at 1-888-423-5436.

Please see additional [Important Safety Information](#) on pages 6 and 7 and full [Prescribing Information](#), including Boxed WARNINGS.



## Important Safety Information (continued)

- **Venous and Arterial Thromboembolism: See Boxed WARNINGS.** Patients with known risk factors, including prior thrombosis, may be at greater risk, and actions should be taken to try to minimize all modifiable factors (e.g., hyperlipidemia, hypertension, smoking). Thromboprophylaxis is recommended, and the choice of regimen should be based on assessment of the patient's underlying risk factors.
- **Increased Mortality With Pembrolizumab:** In clinical trials in patients with multiple myeloma, the addition of pembrolizumab to a thalidomide analogue plus dexamethasone resulted in increased mortality. Treatment of patients with multiple myeloma with a PD-1 or PD-L1 blocking antibody in combination with a thalidomide analogue plus dexamethasone is not recommended outside of controlled clinical trials.
- **Hematologic Toxicity:** Neutropenia (46%) was the most frequently reported Grade 3 or 4 adverse reaction in patients taking POMALYST in clinical trials, followed by anemia and thrombocytopenia. Monitor complete blood counts weekly for the first 8 weeks and monthly thereafter. Patients may require dose interruption and/or modification.
- **Hepatotoxicity:** Hepatic failure, including fatal cases, has occurred in patients treated with POMALYST. Elevated levels of alanine aminotransferase and bilirubin have also been observed in patients treated with POMALYST. Monitor liver function tests monthly. Stop POMALYST upon elevation of liver enzymes. After return to baseline values, treatment at a lower dose may be considered.
- **Severe Cutaneous Reactions:** Severe cutaneous reactions including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported. DRESS may present with a cutaneous reaction (such as rash or exfoliative dermatitis), eosinophilia, fever, and/or lymphadenopathy with systemic complications such as hepatitis, nephritis, pneumonitis, myocarditis, and/or pericarditis. These reactions can be fatal. Consider POMALYST interruption or discontinuation for Grade 2 or 3 skin rash. Permanently discontinue POMALYST for Grade 4 rash, exfoliative or bullous rash, or any other severe cutaneous reactions such as SJS, TEN or DRESS.
- **Dizziness and Confusional State:** In patients taking POMALYST in clinical trials, 14% experienced dizziness (1% Grade 3 or 4) and 7% a confusional state (3% Grade 3 or 4). Instruct patients to avoid situations where dizziness or confusional state may be a problem and not to take other medications that may cause dizziness or confusional state without adequate medical advice.
- **Neuropathy:** In patients taking POMALYST in clinical trials, 18% experienced neuropathy (2% Grade 3 in one trial) and 12% peripheral neuropathy.
- **Second Primary Malignancies:** Cases of acute myelogenous leukemia have been reported in patients receiving POMALYST as an investigational therapy outside of multiple myeloma.
- **Tumor Lysis Syndrome (TLS):** TLS may occur in patients treated with POMALYST. Patients at risk are those with high tumor burden prior to treatment. These patients should be monitored closely and appropriate precautions taken.
- **Hypersensitivity:** Hypersensitivity, including angioedema, anaphylaxis, and anaphylactic reactions to POMALYST have been reported. Permanently discontinue POMALYST for angioedema or anaphylaxis.

Please see additional [Important Safety Information](#) on pages 5 and 7 and full [Prescribing Information](#), including Boxed WARNINGS.





## Important Safety Information (continued)

### ADVERSE REACTIONS

The most common adverse reactions for POMALYST ( $\geq 30\%$ ) included fatigue and asthenia, neutropenia, anemia, constipation, nausea, diarrhea, dyspnea, upper-respiratory tract infections, back pain, and pyrexia.

In the phase III trial, nearly all patients treated with POMALYST + low-dose dex experienced at least one adverse reaction (99%). Adverse reactions ( $\geq 15\%$  in the POMALYST + low-dose dex arm and  $\geq 2\%$  higher than control) included neutropenia (51%), fatigue and asthenia (47%), upper respiratory tract infection (31%), thrombocytopenia (30%), pyrexia (27%), dyspnea (25%), diarrhea (22%), constipation (22%), back pain (20%), cough (20%), pneumonia (19%), bone pain (18%), edema peripheral (17%), peripheral neuropathy (17%), muscle spasms (15%), and nausea (15%). Grade 3 or 4 adverse reactions ( $\geq 15\%$  in the POMALYST + low-dose dex arm and  $\geq 1\%$  higher than control) included neutropenia (48%), thrombocytopenia (22%), and pneumonia (16%).

### DRUG INTERACTIONS

Avoid concomitant use of POMALYST with strong inhibitors of CYP1A2. If concomitant use of a strong CYP1A2 inhibitor is unavoidable, reduce POMALYST dose to 2 mg.

### USE IN SPECIFIC POPULATIONS

- **Pregnancy: See Boxed WARNINGS.** If pregnancy does occur during treatment, immediately discontinue the drug and refer patient to an obstetrician/gynecologist experienced in reproductive toxicity for further evaluation and counseling. There is a POMALYST pregnancy exposure registry that monitors pregnancy outcomes in females exposed to POMALYST during pregnancy as well as female partners of male patients who are exposed to POMALYST. This registry is also used to understand the root cause for the pregnancy. Report any suspected fetal exposure to POMALYST to the FDA via the MedWatch program at 1-800-FDA-1088 and also to Celgene Corporation at 1-888-423-5436.
- **Lactation:** There is no information regarding the presence of pomalidomide in human milk, the effects of POMALYST on the breastfed child, or the effects of POMALYST on milk production. Pomalidomide was excreted in the milk of lactating rats. Because many drugs are excreted in human milk and because of the potential for adverse reactions in a breastfed child from POMALYST, advise women not to breastfeed during treatment with POMALYST.
- **Pediatric Use:** Safety and effectiveness have not been established in pediatric patients.
- **Geriatric Use:** No dosage adjustment is required for POMALYST based on age. Patients  $>65$  years of age were more likely than patients  $\leq 65$  years of age to experience pneumonia.
- **Renal Impairment:** For patients with severe renal impairment requiring dialysis, reduce the recommended dosage to 3 mg orally daily. Take dose of POMALYST following hemodialysis on hemodialysis days.
- **Hepatic Impairment:** In patients with mild to moderate hepatic impairment, reduce POMALYST dosage to 3 mg orally daily and to 2 mg orally daily in patients with severe hepatic impairment.
- **Smoking Tobacco:** Advise patients that smoking may reduce the efficacy of POMALYST. Cigarette smoking reduces pomalidomide AUC due to CYP1A2 induction.

Please see full [Prescribing Information](#), including Boxed WARNINGS.





Visit [POMALYSTHCP.com/OralDosing](https://POMALYSTHCP.com/OralDosing)  
for more information

**References:** 1. POMALYST [package insert]. Summit, NJ: Celgene Corp. 2. Data on file. Bristol-Myers Squibb Co; 2018.

Please see [Important Safety Information](#) on pages 5-7 and full [Prescribing Information](#), including Boxed WARNINGS.



POMALYST®, POMALYST REMS®, and associated logos are trademarks of Celgene Corporation, a Bristol Myers Squibb company.

© 2020 Bristol-Myers Squibb Company.

06/20

US-POM-20-0172

