HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use POMALYST safely and effectively. See full prescribing information for POMALYST.

POMALYST® (pomalidomide) capsules, for oral use
Initial U.S. Approval: 2013

WARNING: EMBRYO-FETAL TOXICITY and VENOUS AND ARTERIAL THROMBOEMBOLISM
See full prescribing information for complete boxed warning

EMBRYO-FETAL TOXICITY

- **POMALYST is contraindicated in pregnancy. POMALYST is a thalidomide analogue. Thalidomide is a known human teratogen that causes severe life-threatening birth defects (4, 5.1, 8.1).**
- **For females of reproductive potential: Exclude pregnancy before start of treatment. Prevent pregnancy during treatment by the use of 2 reliable methods of contraception (5.1, 8.3).**

POMALYST is available only through a restricted program called POMALYST REMS® (5.2).

VENOUS AND ARTERIAL THROMBOEMBOLISM

- **Deep venous thrombosis (DVT), pulmonary embolism (PE), myocardial infarction, and stroke occur in patients with multiple myeloma treated with POMALYST. Antithrombotic prophylaxis is recommended (5.3).**

----------RECENT MAJOR CHANGES----------

Warnings and Precautions (5.1, 5.4, 5.7) 03/18

----------INDICATIONS AND USAGE----------
POMALYST is a thalidomide analogue indicated, in combination with dexamethasone, for 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 (1.1).

----------DOSAGE AND ADMINISTRATION----------
Multiple Myeloma: 4 mg per day taken orally on Days 1-21 of repeated 28-day cycles until disease progression (2.1). Refer to section 14.1 for dexamethasone dosing (14.1)

----------DOSAGE FORMS AND STRENGTHS----------
Capsules: 1 mg, 2 mg, 3 mg, and 4 mg (3)

----------CONTRAINDICATIONS----------

- Pregnancy (4)

----------WARNINGS AND PRECAUTIONS----------

- Increased Mortality: Observed in patients with multiple myeloma when pembrolizumab was added to dexamethasone and a thalidomide analogue (5.4).
- Hematologic Toxicity: Neutropenia was the most frequently reported Grade 3/4 adverse event. Monitor patients for hematologic toxicities, especially neutropenia (5.5).
- Hepatotoxicity: Hepatic failure including fatalities; monitor liver function tests monthly (5.6).
- Severe Cutaneous Reactions Including Hypersensitivity Reactions: Angioedema and severe cutaneous reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms have been reported. Discontinue POMALYST for angioedema and severe reactions (5.7).
- Tumor Lysis Syndrome (TLS): Monitor patients at risk of TLS (i.e., those with high tumor burden) and take appropriate precautions (5.11).

----------ADVERSE REACTIONS----------
Most common adverse reactions (≥30%) included fatigue and asthenia, neutropenia, anemia, constipation, nausea, diarrhea, dyspnea, upper-respiratory tract infections, back pain, and pyrexia (6.1).

To report SUSPECTED ADVERSE REACTIONS, contact Celgene Corporation at 1-888-423-5436 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

----------DRUG INTERACTIONS----------
Strong CYP1A2 Inhibitors: Avoid concomitant use of strong CYP1A2 inhibitors. If a strong CYP1A2 inhibitor must be used, reduce POMALYST dose by 50% (2.3, 7.1, 12.3).

----------USE IN SPECIFIC POPULATIONS----------

- Lactation: Advise women not to breastfeed (8.2).
- Renal Impairment: Reduce POMALYST dose by at least 25% in patients with severe renal impairment requiring dialysis. Take dose of POMALYST following hemodialysis on hemodialysis days (2.4, 8.6).
- Hepatic Impairment: Reduce POMALYST dose by 25% in patients with mild to moderate hepatic impairment, reduce POMALYST dose by 50% in patients with severe hepatic impairment (2.5, 8.7).

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

Revised: 05/2018

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING 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 *[see Contraindications (4), Warnings and Precautions (5.1), and Use in Specific Populations (8.1, 8.3)].***

POMALYST is only available through a restricted distribution program called POMALYST REMS *[see Warnings and Precautions (5.2)].*

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 *[see Warnings and Precautions (5.3)].***

1 INDICATIONS AND USAGE

1.1 Multiple Myeloma

POMALYST, in combination with dexamethasone, is indicated for 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.

2 DOSAGE AND ADMINISTRATION

2.1 Multiple Myeloma

Females of reproductive potential must have negative pregnancy testing and use contraception methods before initiating POMALYST *[see Warnings and Precautions (5.1) and Use in Specific Populations (8.3)]*.

The recommended starting dose of POMALYST is 4 mg once daily orally on Days 1-21 of repeated 28-day cycles until disease progression. POMALYST should be given in combination with dexamethasone *[see Clinical Studies (14.1)]*.

POMALYST may be taken with water. Inform patients not to break, chew, or open the capsules. POMALYST may be taken with or without food.

2.2 Dose Adjustments for Toxicities

Table 1: Dose Modification Instructions for POMALYST for Hematologic Toxicities

Toxicity	Dose Modification
Neutropenia • ANC <500 per mcL or febrile neutropenia (fever more than or equal to 38.5°C and ANC <1,000 per mcL) • ANC return to more than or equal to 500 per mcL	• Interrupt POMALYST treatment, follow CBC weekly • Resume POMALYST treatment at 3 mg daily
• For each subsequent drop <500 per mcL • Return to more than or equal to 500 per mcL	• Interrupt POMALYST treatment • Resume POMALYST treatment at 1 mg less than the previous dose
Thrombocytopenia • Platelets <25,000 per mcL • Platelets return to >50,000 per mcL	• Interrupt POMALYST treatment, follow CBC weekly • Resume POMALYST treatment at 3 mg daily
• For each subsequent drop <25,000 per mcL • Return to more than or equal to 50,000 per mcL	• Interrupt POMALYST treatment • Resume POMALYST treatment at 1 mg less than previous dose

ANC, absolute neutrophil count

To initiate a new cycle of POMALYST, the neutrophil count must be at least 500 per mcL and the platelet count must be at least 50,000 per mcL. If toxicities occur after dose reductions to 1 mg, then discontinue POMALYST.

Permanently discontinue POMALYST for angioedema, skin exfoliation, bullae, or any other severe dermatologic reaction *[see Warnings and Precautions (5.7)]*.

For other Grade 3 or 4 toxicities, hold treatment and restart treatment at 1 mg less than the previous dose when toxicity has resolved to less than or equal to Grade 2 at the physician's discretion.

2.3 Dosage Adjustment for Strong CYP1A2 Inhibitors

Avoid concomitant use of POMALYST with strong inhibitors of CYP1A2. Consider alternative treatments. If a strong CYP1A2 inhibitor must be used, reduce POMALYST dose by 50% *[see Drug Interactions (7.1) and Clinical Pharmacology (12.3)]*.

2.4 Dosage Adjustment for Patients with Severe Renal Impairment on Hemodialysis

For patients with severe renal impairment requiring dialysis, the recommended starting dose is 3 mg daily (25% dose reduction). Take POMALYST after completion of dialysis procedure on hemodialysis days *[see Use in Specific Populations (8.6) and Clinical Pharmacology (12.3)]*.

2.5 Dosage Adjustment for Patients with Hepatic Impairment

For patients with mild or moderate hepatic impairment (Child-Pugh classes A or B), the recommended starting dose is 3 mg daily (25% dose reduction). For patients with severe hepatic impairment (Child-Pugh class C), the

recommended dose is 2 mg (50% dose reduction) *[see Use in Specific Populations (8.7) and Clinical Pharmacology (12.3)]*.

3 DOSAGE FORMS AND STRENGTHS

POMALYST is available in the following capsule strengths:

- 1 mg: Dark blue opaque cap and yellow opaque body, imprinted "POML" on the cap in white ink and "1 mg" on the body in black ink
- 2 mg: Dark blue opaque cap and orange opaque body, imprinted "POML" on the cap and "2 mg" on the body in white ink
- 3 mg: Dark blue opaque cap and green opaque body, imprinted "POML" on the cap and "3 mg" on the body in white ink
- 4 mg: Dark blue opaque cap and blue opaque body, imprinted "POML" on the cap and "4 mg" on the body in white ink

4 CONTRAINDICATIONS

Pregnancy

POMALYST can cause fetal harm when administered to a pregnant female *[see Warnings and Precautions (5.1) and Use in Specific Populations (8.1)]*. POMALYST is contraindicated in females who are pregnant. Pomalidomide is a thalidomide analogue and is teratogenic in both rats and rabbits when administered during the period of organogenesis. If this drug is used during pregnancy or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential risk to a fetus.

5 WARNINGS AND PRECAUTIONS

5.1 Embryo-Fetal Toxicity

POMALYST is a thalidomide analogue and is contraindicated for use during pregnancy. Thalidomide is a known human teratogen that causes severe birth defects or embryo-fetal death *[see Use in Specific Populations (8.1)]*. POMALYST is only available through the POMALYST REMS program *[see Warnings and Precautions (5.2)]*.

Females of Reproductive Potential

Females of reproductive potential must avoid pregnancy for at least 4 weeks before beginning POMALYST therapy, during therapy, during dose interruptions and for at least 4 weeks after completing therapy.

Females must commit either to abstain continuously from heterosexual sexual intercourse or to use 2 methods of reliable birth control, beginning 4 weeks prior to initiating treatment with POMALYST, during therapy, during dose interruptions, and continuing for 4 weeks following discontinuation of POMALYST therapy.

Two negative pregnancy tests must be obtained prior to initiating therapy. The first test should be performed within 10-14 days and the second test within 24 hours prior to prescribing POMALYST therapy and then weekly during the first month, then monthly thereafter in females with regular menstrual cycles, or every 2 weeks in females with irregular menstrual cycles *[see Use in Specific Populations (8.3)]*.

Males

Pomalidomide is present in the semen of patients receiving the drug. Therefore, males must always use a latex or synthetic condom during any sexual contact with females of reproductive potential while taking

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