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, 8.6).**

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----------

Boxed Warning	04/15
Indications and Usage (1.1)	04/15
Dosage and Administration (2.1, 2.2)	04/15
Warnings and Precautions (5.3, 5.4, 5.5, 5.6, 5.7, 5.8)	04/15
Warnings and Precautions (5.10)	05/14

----------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----------
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----------

- Hematologic Toxicity: Neutropenia was the most frequently reported Grade 3/4 adverse event. Monitor patients for hematologic toxicities, especially neutropenia (5.4).
- Hepatotoxicity: Hepatic failure including fatalities; monitor liver function tests monthly (5.5).
- Hypersensitivity Reactions: Angioedema and severe dermatologic reactions have been reported. Discontinue POMALYST for angioedema and severe dermatologic reactions (5.6).
- Tumor Lysis Syndrome (TLS): Monitor patients at risk of TLS (i.e., those with high tumor burden) and take appropriate precautions (5.10).

----------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 the use of strong CYP1A2 inhibitors unless medically necessary (2.3, 7.1, 12.3).

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

- Nursing Mothers: Discontinue drug or nursing taking into consideration importance of drug to mother (8.3).
- Avoid POMALYST in patients with serum creatinine >3.0 mg/dL (8.7).

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

Revised: 04/2015

FULL PRESCRIBING INFORMATION: CONTENTS*

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

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, 8.6)*].**

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 (8.6)*].

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 should be taken without food (at least 2 hours before or 2 hours after a meal).

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)	• Interrupt POMALYST treatment, follow CBC weekly
• ANC return to more than or equal to 500 per mcL	• Resume POMALYST treatment at 3 mg daily
• For each subsequent drop <500 per mcL	• Interrupt POMALYST treatment
• Return to more than or equal to 500 per mcL	• Resume POMALYST treatment at 1 mg less than the previous dose
Thrombocytopenia	
• Platelets <25,000 per mcL	• Interrupt POMALYST treatment, follow CBC weekly
• Platelets return to >50,000 per mcL	• Resume POMALYST treatment at 3 mg daily
• For each subsequent drop <25,000 per mcL	• Interrupt POMALYST treatment
• Return to more than or equal to 50,000 per mcL	• 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 (5.6)*].

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 Dose Adjustment for Strong CYP1A2 Inhibitors in the Presence of Strong CYP3A4 and P-gp Inhibitors

Avoid co-administration of strong inhibitors of CYP1A2. If necessary to co-administer strong inhibitors of CYP1A2 in the presence of strong inhibitors of CYP3A4 and P-gp, reduce POMALYST dose by 50%. No clinical efficacy or safety data exist [see *Drug Interactions (7.1) 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 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 hazard 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 while taking POMALYST 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 women with regular menstrual cycles, or every 2 weeks in women with irregular menstrual cycles [see *Use in Specific Populations (8.6)*].

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 POMALYST and for up to 28 days after discontinuing POMALYST, even if they have undergone a successful vasectomy. Male patients taking POMALYST must not donate sperm [see *Use in Specific Populations (8.6)*].

Blood Donation
Patients must not donate blood during treatment with POMALYST and for 1 month following discontinuation of the drug because the blood might be given to a pregnant female patient whose fetus must not be exposed to POMALYST.

5.2 POMALYST REMS Program

Because of the embryo-fetal risk [see *Warnings and Precautions (5.1)*], POMALYST is

Required components of the **POMALYST REMS** program include the following:

- Prescribers must be certified with the **POMALYST REMS** program by enrolling and complying with the REMS requirements.
- Patients must sign a Patient-Physician Agreement Form and comply with the REMS requirements. In particular, female patients of reproductive potential who are not pregnant must comply with the pregnancy testing and contraception requirements [see *Use in Specific Populations (8.6)*] and males must comply with contraception requirements [see *Use in Specific Populations (8.6)*].
- Pharmacies must be certified with the **POMALYST REMS** program, must only dispense to patients who are authorized to receive POMALYST, and comply with REMS requirements.

Further information about the **POMALYST REMS** program is available at www.CelgeneRiskManagement.com or by telephone at 1-888-423-5436.

5.3 Venous and Arterial Thromboembolism

Venous thromboembolic events (deep venous thrombosis and pulmonary embolism) and arterial thromboembolic events (myocardial infarction and stroke) have been observed in patients treated with POMALYST. In Trial 2, where anticoagulant therapies were mandated, thromboembolic events occurred in 8.0% of patients treated with POMALYST and low dose-dexamethasone (Low-dose Dex), and 3.3% of patients treated with high-dose dexamethasone. Venous thromboembolic events (VTE) occurred in 4.7% of patients treated with POMALYST and Low-dose Dex, and 1.3% of patients treated with high-dose dexamethasone. Arterial thromboembolic events include terms for arterial thromboembolic events, ischemic cerebrovascular conditions, and ischemic heart disease. Arterial thromboembolic events occurred in 3.0% of patients treated with POMALYST and Low-dose Dex, and 1.3% of patients treated with high-dose dexamethasone.

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.

5.4 Hematologic Toxicity

In trials 1 and 2 in patients who received POMALYST + Low-dose Dex, neutropenia was the most frequently reported Grade 3/4 adverse reaction, followed by anemia and thrombocytopenia. Neutropenia of any grade was reported in 51% of patients in both trials. The rate of Grade 3/4 neutropenia was 46%. The rate of febrile neutropenia was 8%.

Monitor patients for hematologic toxicities, especially neutropenia. Monitor complete blood counts weekly for the first 8 weeks and monthly thereafter. Patients may require dose interruption and/or modification [see *Dosage and Administration (2.2)*].

5.5 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 and evaluate. After return to baseline values, treatment at a lower

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