INDICATION
EMPLICITI is indicated in combination with lenalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received one to three prior therapies.

SELECTED IMPORTANT SAFETY INFORMATION
Infusion Reactions
• EMPLICITI can cause infusion reactions. Common symptoms include fever, chills, and hypertension. Bradycardia and hypotension also developed during infusions. In the trial, 5% of patients required interruption of the administration of EMPLICITI for a median of 25 minutes due to infusion reactions, and 1% of patients discontinued due to infusion reactions. Of the patients who experienced an infusion reaction, 70% (23/33) had them during the first dose. If a Grade 2 or higher infusion reaction occurs, interrupt the EMPLICITI infusion and institute appropriate medical and supportive measures. If the infusion reaction recurs, stop the EMPLICITI infusion and do not restart it on that day. Severe infusion reactions may require permanent discontinuation of EMPLICITI therapy and emergency treatment.
• Premedicate with dexamethasone, H1 Blocker, H2 Blocker, and acetaminophen prior to infusing with EMPLICITI.

Please see additional Important Safety Information throughout. Click here for full Prescribing Information.
EMPLICITI + Rd dosing schedule

EMPLICITI is administered as a component of the ERd regimen

EMPLICITI 10 mg/kg | Lenalidomide 25 mg | Dexamethasone

Treatment should continue until disease progression or unacceptable toxicity

ERd=EMPLICITI + lenalidomide + dexamethasone; Rd=lenalidomide + dexamethasone.

*Oral dexamethasone (28 mg) taken between 3 and 24 hours before EMPLICITI infusion.

†On days that EMPLICITI is not administered, but a dose of dexamethasone is scheduled, dexamethasone 40 mg should be given orally.

SELECTED IMPORTANT SAFETY INFORMATION

Infections
- In a clinical trial of patients with multiple myeloma (N=635), infections were reported in 81.4% of patients in the EMPLICITI with lenalidomide/dexamethasone arm (ERd) and 74.4% in the lenalidomide/dexamethasone arm (Rd). Grade 3-4 infections were 28% (ERd) and 24.3% (Rd). Opportunistic infections were reported in 22% (ERd) and 12.9% (Rd). Fungal infections were 9.7% (ERd) and 5.4% (Rd). Herpes zoster was 13.5% (ERd) and 6.9% (Rd). Discontinuations due to infections were 3.5% (ERd) and 4.1% (Rd). Fatal infections were 2.5% (ERd) and 2.2% (Rd). Monitor patients for development of infections and treat promptly.

Please see additional Important Safety Information throughout. Click here for full Prescribing Information.
Premedication and infusion  

Patients must be premedicated before each dose of EMPLICITI

<table>
<thead>
<tr>
<th>Pretreatment on days that EMPLICITI is administered</th>
</tr>
</thead>
<tbody>
<tr>
<td>3–24 hours prior to infusion</td>
</tr>
<tr>
<td>Dexamethasone 28 mg orally</td>
</tr>
<tr>
<td>Completed 45–90 minutes prior to infusion</td>
</tr>
<tr>
<td>Dexamethasone 8 mg intravenously</td>
</tr>
<tr>
<td>+ H&lt;sub&gt;2&lt;/sub&gt; blocker: Diphenhydramine (25–50 mg orally or intravenously) or equivalent</td>
</tr>
<tr>
<td>+ H&lt;sub&gt;2&lt;/sub&gt; blocker: Ranitidine (50 mg intravenously or 150 mg orally) or equivalent</td>
</tr>
<tr>
<td>+ Acetaminophen (650–1000 mg orally)</td>
</tr>
</tbody>
</table>

EMPLICITI should be initiated at 0.5 mL/min. If no infusion reactions develop, the infusion rate may be increased in a stepwise fashion as shown below.

<table>
<thead>
<tr>
<th>Rate of infusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cycle 1, Dose 1</td>
</tr>
<tr>
<td>Time interval</td>
</tr>
<tr>
<td>0–30 min</td>
</tr>
<tr>
<td>30–60 min</td>
</tr>
<tr>
<td>60 min or more</td>
</tr>
</tbody>
</table>

*Continue this rate until infusion is complete.
† Infusion times for EMPLICITI are: 167.5 minutes (Dose 1), 72.5 minutes (Dose 2), and 52 minutes (all subsequent doses), based on an average patient weight of 75 kg. Presence and severity of infusion reactions may lengthen the infusion time for EMPLICITI.

Administer the entire EMPLICITI infusion with an infusion set and a sterile, nonpyrogenic, low-protein-binding filter (with a pore size of 0.2–1.2 micrometer) using an automated infusion pump.

Do not mix EMPLICITI with, or administer as an infusion with, other medicinal products. No physical or biochemical compatibility studies have been conducted to evaluate the coadministration of EMPLICITI with other agents.

See Dose modifications on the following page for infusion rate following a Grade 2 or higher infusion reaction.

Please see additional Important Safety Information throughout. Click here for full Prescribing Information.
Dose modifications

Dose delay, interruption, or discontinuation

EMPLICITI infusion reactions occurred in ~10% of patients (all grades). 1% were Grade 3 or higher, and 1% of patients discontinued due to infusion reactions.

If a Grade 2 or higher infusion reaction occurs during EMPLICITI administration:

1. **Interrupt the infusion and institute appropriate medical and supportive measures**
2. **Upon resolution to Grade 1 or lower, restart EMPLICITI at 0.5 mL per minute**
3. **Gradually increase infusion at a rate of 0.5 mL per minute every 30 minutes as tolerated to the rate at which the infusion reaction occurred**
4. **Resume the escalation regimen if there is no recurrence of the infusion reaction**

- In patients who experience an infusion reaction, monitor vital signs every 30 minutes for 2 hours after the end of the EMPLICITI infusion. If the infusion reaction recurs, stop the EMPLICITI infusion and do not restart on that day. Severe infusion reactions may require permanent discontinuation of EMPLICITI therapy and emergency treatment.
- If the dose of one drug in the regimen is delayed, interrupted, or discontinued, the treatment with the other drugs may continue as scheduled. However, if dexamethasone is delayed or discontinued, the administration of EMPLICITI should be based on clinical judgment (ie, risk of hypersensitivity).
- Dose delay and modification for dexamethasone and lenalidomide should be performed as recommended in their Prescribing Information.

**SELECTED IMPORTANT SAFETY INFORMATION**

**Second Primary Malignancies**
- In a clinical trial of patients with multiple myeloma (N=635), invasive second primary malignancies (SPM) were 9.1% [ERd] and 5.7% [Rd]. The rate of hematologic malignancies were the same between ERd and Rd treatment arms (1.6%). Solid tumors were reported in 3.5% [ERd] and 2.2% [Rd]. Skin cancer was reported in 4.4% [ERd] and 2.8% [Rd]. Monitor patients for the development of SPMs.

**Hepatotoxicity**
- Elevations in liver enzymes (AST/ALT greater than 3 times the upper limit, total bilirubin greater than 2 times the upper limit, and alkaline phosphatase less than 2 times the upper limit) consistent with hepatotoxicity were 2.5% [ERd] and 0.6% [Rd]. Two patients experiencing hepatotoxicity discontinued treatment; however, 6 out of 8 patients had resolution and continued treatment. Monitor liver enzymes periodically. Stop EMPLICITI upon Grade 3 or higher elevation of liver enzymes. After return to baseline values, continuation of treatment may be considered.

*Please see additional Important Safety Information throughout. Click here for full Prescribing Information.*
**Four-step preparation for EMPLICITI infusion**

### STEP 1: Determine vial quantity based on patient weight

Because dosing for EMPLICITI is weight-based, the dose of EMPLICITI will vary by patient, and may be provided through a combination of vial sizes.

<table>
<thead>
<tr>
<th>If the adult patient weighs:</th>
<th>Multiply by EMPLICITI dose:</th>
<th>For a total dose of:</th>
<th>Number of vials required to prepare the dose*:</th>
</tr>
</thead>
<tbody>
<tr>
<td>41-60 kg</td>
<td>10 mg/kg</td>
<td>410-600 mg</td>
<td><img src="images/0" alt="Vials" /> <img src="images/0" alt="Vials" /></td>
</tr>
<tr>
<td>61-70 kg</td>
<td>10 mg/kg</td>
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</tr>
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<td>121-130 kg</td>
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</tr>
</tbody>
</table>

*Depending on the weight-based dose, the full amount in the vials may not be used.

### STEP 2: Determine the volume of SWFI needed for reconstitution

<table>
<thead>
<tr>
<th>Strength</th>
<th>Amount of SWFI, USP required for reconstitution</th>
<th>Deliverable volume of reconstituted EMPLICITI in the vial</th>
<th>Post-reconstitution concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>300 mg vial</td>
<td>13 mL</td>
<td>12 mL*</td>
<td>25 mg/mL</td>
</tr>
<tr>
<td>400 mg vial</td>
<td>17 mL</td>
<td>16 mL*</td>
<td>25 mg/mL</td>
</tr>
</tbody>
</table>

SWFI=sterile water for injection; USP=United States Pharmacopeia.

*After reconstitution, each vial contains overfill to allow for withdrawal of 12 mL (300 mg) and 16 mL (400 mg), respectively.

(cont’d on next page)
STEP 3: Reconstitute lyophilized powder cake with appropriate volume of SWFI

Reconstitute
- Aseptically reconstitute each EMPLICITI vial with a syringe of adequate size and a less than or equal to 18-gauge needle (eg, 17-gauge)
- A slight back pressure may be experienced during administration of the SWFI, which is considered normal

Mix
- Hold the vial upright and swirl the solution by rotating the vial to dissolve the lyophilized cake
- Invert the vial a few times in order to dissolve any powder that may be present on top of the vial or the stopper. Avoid vigorous agitation. **DO NOT SHAKE**
- The lyophilized powder should dissolve in less than 10 minutes

Let stand
- After the remaining solids are completely dissolved, allow the reconstituted solution to stand for 5 to 10 minutes
- The reconstituted preparation results in a colorless to slightly yellow, clear to slightly opalescent solution
- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit
- Discard the solution if any particulate matter or discoloration is observed

SELECTED IMPORTANT SAFETY INFORMATION

Interference with Determination of Complete Response
- EMPLICITI is a humanized IgG kappa monoclonal antibody that can be detected on both the serum protein electrophoresis and immunofixation assays used for the clinical monitoring of endogenous M-protein. This interference can impact the determination of complete response and possibly relapse from complete response in patients with IgG kappa myeloma protein.

Pregnancy/Females and Males of Reproductive Potential
- There are no studies with EMPLICITI with pregnant women to inform any drug associated risks.
- There is a risk of fetal harm, including severe life-threatening human birth defects associated with lenalidomide and it is contraindicated for use in pregnancy. Refer to the lenalidomide full prescribing information for requirements regarding contraception and the prohibitions against blood and/or sperm donation due to presence and transmission in blood and/or semen and for additional information.

Please see additional Important Safety Information throughout. Click here for full Prescribing Information.
STEP 4: Dilute for infusion

- Once the reconstitution is completed, withdraw the necessary volume for the calculated dose from each vial, up to a maximum of 16 mL from 400 mg vial and 12 mL from 300 mg vial.
- Further dilute with 230 mL of either 0.9% Sodium Chloride Injection, USP or 5% Dextrose Injection (D5W), USP, into an infusion bag made of polyvinyl chloride or polyolefin.
- The volume of 0.9% Sodium Chloride Injection, USP or D5W can be adjusted so as not to exceed 5 mL/kg of patient weight at any given dose of EMPLICITI.

Complete the EMPLICITI infusion within 24 hours of reconstitution of the EMPLICITI lyophilized powder.
How EMPLICITI is supplied

EMPLICITI is supplied in 300 and 400 mg single-dose vials. EMPLICITI is a sterile, nonpyrogenic, preservative-free lyophilized powder that is white to off-white, whole or fragmented cake that is provided in 2 strengths.

SELECTED IMPORTANT SAFETY INFORMATION

Adverse Reactions
- Infusion reactions were reported in approximately 10% of patients treated with EMPLICITI with lenalidomide and dexamethasone. All reports of infusion reaction were Grade 3 or lower. Grade 3 infusion reactions occurred in 1% of patients.
- Serious adverse reactions were 65.4% (ERd) and 56.5% (Rd). The most frequent serious adverse reactions in the ERd arm compared to the Rd arm were: pneumonia (15.4%, 11%), pyrexia (6.9%, 4.7%), respiratory tract infection (3.1%, 1.3%), anemia (2.8%, 1.9%), pulmonary embolism (3.1%, 2.5%), and acute renal failure (2.5%, 1.9%).
- The most common adverse reactions in ERd and Rd, respectively (>20%) were fatigue (61.6%, 51.7%), diarrhea (46.9%, 36.0%), pyrexia (37.4%, 24.6%), constipation (35.5%, 27.1%), cough (34.3%, 18.9%), peripheral neuropathy (26.7%, 20.8%), nasopharyngitis (24.5%, 19.2%), upper respiratory tract infection (22.6%, 17.4%), decreased appetite (20.8%, 12.6%), and pneumonia (20.1%, 14.2%).

Please see additional Important Safety Information throughout. Click here for full Prescribing Information.
Storage of EMPLICITI

Storage of reconstituted solution
If not used immediately, the infusion solution may be stored under refrigeration conditions:
2°C to 8°C (36°F–46°F) and protected from light for up to 24 hours
• A maximum of 8 hours of the total 24 hours can be at room temperature, 20°C to 25°C (68°F–77°F), and room light

Storage of non-reconstituted vials
Refrigerate at 2°C to 8°C (36°F–46°F)
Protect EMPLICITI from light by storing in the original package until time of use
Do not freeze
Do not shake
How to order EMPLICITI

Because dosing for EMPLICITI is weight-based, the dose of EMPLICITI will vary by patient and may be provided through a combination of vial sizes. EMPLICITI is supplied in 300 and 400 mg single-dose vials.

Determining your order for EMPLICITI

1. Calculate total dose in mg needed: \( \text{weight in kg} \times 10 = \text{total dose in mg} \)

2. Determine quantity of single-dose vials needed based on total dose (see examples in table below)

### Examples of vial quantities needed for weight-based dosing of EMPLICITI

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</tr>
</tbody>
</table>

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## Distribution of EMPLICITI

### Physician offices

<table>
<thead>
<tr>
<th>Specialty Distributor</th>
<th>Phone Number</th>
<th>Website</th>
</tr>
</thead>
</table>
| Cardinal Health Specialty Pharmaceutical Distribution | 1-866-677-4844  
Monday-Friday, 7 AM–6 PM CT  
(24-hour emergency on-call) | https://specialtyonline.cardinalhealth.com |
| CuraScript SD Specialty Distribution         | 1-877-599-7748  
Monday-Friday, 8:30 AM–7 PM ET | https://www.curascriptsd.com                 |
| McKesson Specialty Health                   | 1-800-482-6700  
Monday-Friday, 7 AM–7 PM CT | https://mscs.mckesson.com                    |
| Oncology Supply                              | 1-800-633-7555  
Monday-Thursday, 8 AM–7:30 PM CT;  
Friday 8 AM–7 PM CT | https://www.oncologysupply.com             |

For offices that prefer to use the services of a specialty pharmacy, specialty pharmacies can obtain EMPLICITI from the distributors listed below.

### Hospitals and infusion centers

<table>
<thead>
<tr>
<th>Specialty Distributor</th>
<th>Phone Number</th>
<th>Fax Number</th>
<th>Website</th>
</tr>
</thead>
</table>
| ASD Healthcare                               | 1-800-744-6273  
Monday-Thursday, 7:30 AM–6:30 PM CT;  
Friday 7 AM–6 PM CT  
(24-hour emergency on-call) | 1-800-547-9413 | https://www.asdhealthcare.com |
| Cardinal Health Specialty Pharmaceutical Distribution | 1-866-677-4844  
Monday-Friday, 7 AM–6 PM CT  
(24-hour emergency on-call) | 1-888-345-4916 | https://OrderExpress.cardinalhealth.com |
| DMS Pharmaceutical Group, Inc.               | 1-877-788-1100  
Monday-Friday, 8 AM–6 PM CT | 1-847-518-1105 | www.dmspharma.com                             |
| McKesson Plasma and Biologics                | 1-877-625-2566  
Monday-Friday, 8 AM–6:30 PM CT | 1-888-752-7626 | https://connect.mckesson.com                 |
| Smith Medical Partners                       | 1-800-292-9653  
Monday-Thursday, 8 AM–6 PM CT;  
Friday 8 AM–4:30 PM CT | 1-630-227-9220 | www.smpspecialty.com                         |

The distribution program for EMPLICITI includes extended payment terms to Bristol-Myers Squibb’s authorized distributors. Healthcare providers and institutions should contact their distributor to understand specific payment terms that may be available to them from their distributor.

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Please see additional Important Safety Information throughout. Click here for full Prescribing Information.
Usable and unopened

If product is usable and unopened and the return is due to:
- A patient’s unavailability for treatment with EMPLICITI due to one of the following:
  - Patient refusal
  - Adverse event
  - Patient illness or death
  - Patient ineligibility
- Ordering error

Please contact your specialty distributor directly for assistance.

Not usable

If product is not usable and the return is due to:
- Compromised refrigeration
- Damage (for example, dropped or mishandled vial)
- Opened product (for example, incorrect preparation or mixed prior to patient unavailability)

Please contact Bristol-Myers Squibb Customer Service by either:

Emailing CustomerServiceOperations@BMS.com

or

Calling 1-800-631-5244, 9 AM to 5 PM ET, Monday–Friday

Request must be made within 90 days of invoice date. Be prepared to provide date and reason for return, number of vials affected, invoice number, and date.

Eligibility
- Dispensing customers: physicians, infusion centers, hospitals, specialty pharmacies, other healthcare providers
- $400,000 credit cap per rolling year will be applied per customer across all Bristol-Myers Squibb products that are covered by the policy

Product disposal
- If a product is damaged or the vial is leaking, please properly dispose of product according to institution guidelines. Bristol-Myers Squibb cannot pick up or dispose of the damaged product

(cont’d on next page)
Infusible product return policy (cont’d)

Return policy steps for product that is not usable

Bristol-Myers Squibb offers an EMPLICITI Product Return Policy that credits customers at the Wholesale List Price or direct contract price at the time of purchase in the event of loss occurring within 90 days of the invoice date.

To request a return, contact Bristol-Myers Squibb Customer Service by either:

- Emailing CustomerServiceOperations@BMS.com
- Calling 1-800-631-5244, 9 am to 5 pm ET, Monday–Friday

Representatives are available to assist you by:

- Providing request form and instructions
- Clarifying policy or required information
- Helping with form submission

Within 48 hours of form submission, you will receive an email with a return request reference number or an email notifying you that further documentation is required.

Within 1 week from submission, you will receive an approval or denial notice by email. If approved, product pick-up will be initiated.

After product has been received by Bristol-Myers Squibb, Bristol-Myers Squibb will provide credit to the corresponding wholesaler/distributor within 30 days and will email a credit reference number.

- Distributor issues credit to dispensing customer

Please see additional Important Safety Information throughout. Click here for full Prescribing Information.
For physicians and patients who have chosen a BMS medication:

**Patient Access, Reimbursement, and Co-Pay Support**
Available through:

![BMS Access Support](image)

### Three Simple Ways to Get Support

1. **Contact your Area Reimbursement Manager** for assistance and to schedule an office visit.

2. **Call BMS Access Support® at 1-800-861-0048**
   8 AM to 8 PM ET, Monday–Friday to speak with your dedicated team of regionally assigned specialists.

3. **Visit www.BMSAccessSupport.com** for information and resources, including the enrollment form, to help you and your patients with access to Bristol-Myers Squibb oncology products.

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**BMS Access Support** is committed to providing access and reimbursement support, including co-pay assistance for eligible commercially-insured patients.

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The accurate completion of reimbursement- or coverage-related documentation is the responsibility of the healthcare provider and patient. Bristol-Myers Squibb and its agents make no guarantee regarding reimbursement for any service or item.
Responding to your needs in 24 hours or less

Bristol-Myers Squibb remains committed to helping you and your patients throughout treatment with EMPLICITI.

1-844-EMPLICITI
(1-844-367-5424)
for live support and assistance

Responses provided during business hours, 8:00 AM to 8:00 PM ET, Monday–Friday

EMPLICITI patient support at EmplicitiHCP.com

• Learn about available patient support
• Download educational materials for your patients
• Contact a Care Navigator

Meet with an EMPLICITI representative

• Call to schedule a visit from one of our EMPLICITI representatives for product information

Please see additional Important Safety Information throughout. Click here for full Prescribing Information.