REZZAYO™
(rezafungin for injection)

A Once-Weekly Echinocandin for Adult Patients with Candidemia and Invasive Candidiasis*

Simplified Echinocandin Dosing & Administration

REZZAYO™
(rezafungin for injection)

ONE IV infusion once weekly, for ***ONE*** hour[1]

Recommended dose[1]

400 mg / **200 mg**

400-mg loading dose

200-mg dose once weekly thereafter

- The safety of REZZAYO has not been established beyond 4 weekly doses
- If infusion-related reactions occur, the infusion may be slowed, or paused and restarted at a lower rate.

Weekly dosing of REZZAYO™ (rezafungin for injection) gives patients with invasive candidiasis 7 days of systemic antifungal coverage[1]

- ✓ No dose adjustments for special populations: Same dosing for patient populations based on age, sex, race, weight, with renal impairment, or undergoing hemodialysis
- ✓ No requirement for a PICC or central line
- ✓ No known clinically significant drug-drug interactions, and no dose adjustment is needed for any known factors

*INDICATION AND USAGE

REZZAYO™ (rezafungin for injection) is an echinocandin antifungal indicated in patients 18 years of age or older who have limited or no alternative options for the treatment of candidemia and invasive candidiasis. Approval of this indication is based on limited clinical safety and efficacy data.

Limitations of Use

REZZAYO™ has not been studied in patients with endocarditis, osteomyelitis, and meningitis due to *Candida*.

IMPORTANT SAFETY INFORMATION

Contraindications

REZZAYO™ is contraindicated in patients with known hypersensitivity to rezafungin or other echinocandins.

Warnings and Precautions

- Infusion-related Reactions: REZZAYO™ may cause infusion-related reactions, including flushing, sensation of warmth, urticaria, nausea, or chest tightness. If these reactions occur, slow or pause the infusion.
- Photosensitivity: REZZAYO™ may cause photosensitivity. Advise patients to use protection from sun exposure and other sources of UV radiation.
- Hepatic Adverse Reactions: Abnormalities in liver tests have been seen in clinical trial patients treated with REZZAYO™. Monitor patients who develop abnormal liver tests and evaluate patients for their risk/benefit of continuing REZZAYO™ therapy.

Adverse Reactions

Most common adverse reactions (incidence ≥ 5%) are hypokalemia, pyrexia, diarrhea, anemia, vomiting, nausea, hypomagnesemia, abdominal pain, constipation, and hypophosphatemia.

Please see accompanying Prescribing Information for REZZAYO™ (rezafungin for injection).

PREPARATION AND ADMINISTRATION of REZZAYO™ (rezafungin for injection)

How Supplied:

Single-dose vial containing 200 mg of rezafungin. Discard any unused portion.

Reconstitution

- For the 400 mg dose, aseptically reconstitute two vials each with 9.5 mL of sterile Water for Injection, for a concentration of 20 mg/mL in each vial.
- For the 200 mg dose, aseptically reconstitute one vial with 9.5 mL of sterile Water for Injection, for a concentration of 20 mg/mL.
- Swirl gently to dissolve the white to pale yellow cake or powder. Avoid shaking to minimize foaming. The solution should be clear to pale yellow after dissolution.
- Check for particulate matter and discoloration prior to administration. Do not use if the reconstituted solution is cloudy or has precipitated.
- The reconstituted solution is not for direct injection and must be diluted before intravenous infusion.

Storage of the Reconstituted Solution

Can be stored between 5°C to 25°C (41°F to 77°F) for up to 24 hours.

Preparation of Intravenous Infusion Solution

See table below for the dilution requirements for infusion solution.

Dilution Requirements for REZZAYO Prior to Administration

Dose	Number of 200 mg Vials Required	Total Reconstituted Volume Required	Infusion Diluent Volume Discarded	Infusion Diluent Volume Used	Total Infusion Volume
400 mg	2	20 mL	20 mL	230 mL	250 mL[1]
200 mg	1	10 mL	10 mL	240 mL	250 mL[2]

[1] Infusion solution concentration for the 400 mg dose = 1.6 mg/mL
[2] Infusion solution concentration for the 200 mg dose = 0.8 mg/mL

First, aseptically withdraw and discard the appropriate volume of diluent from the intravenous bag containing 250 mL of 0.9% Sodium Chloride Injection, or 5% Dextrose Injection. Next, aseptically transfer the indicated volume of reconstituted solution (10 mL per vial) into the intravenous bag. REZZAYO vials are single-dose vials. Discard any unused portion.

Storage of the Intravenous Infusion Solution

Can be stored between 5°C to 25°C (41°F to 77°F) for up to 48 hours. Do not freeze infusion solution.

Administration of Intravenous Infusion Solution

Administer REZZAYO by intravenous infusion over approximately one hour (~250 mL/h). If infusion-related reactions occur, the infusion may be slowed, or paused and restarted at a lower rate.

Please see Important Safety Information on reverse side and accompanying Prescribing Information for REZZAYO™ (rezafungin for injection).

melinta therapeutics

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