



ZENBEXUS™ REMS

(Risk Evaluation and Mitigation Strategy)

Patient Guide

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Introduction

Your healthcare provider has prescribed a medication called ZENBEXUS™ (iberdomide). Because this medicine is associated with an increased risk of serious birth defects, ZENBEXUS is available only through a special program called ZENBEXUS™ REMS (Risk Evaluation and Mitigation Strategy).

To receive ZENBEXUS, patients must be enrolled in ZENBEXUS REMS and agree to follow its requirements. To enroll, you must work with your prescriber to complete and submit a **Patient Enrollment Form** to ZENBEXUS REMS.

What Is ZENBEXUS™ (iberdomide)?

ZENBEXUS is a prescription medicine in combination with the medicines daratumumab, and hyaluronidase-fihj and dexamethasone, to treat adults with multiple myeloma who have received at least 1 prior medicine, including a proteasome inhibitor and an immunomodulatory medicine.

What Are the Serious Risks of ZENBEXUS?

ZENBEXUS can cause serious birth defects or death to unborn babies if it is taken during pregnancy.

What Is ZENBEXUS™ REMS?

ZENBEXUS™ (iberdomide) is available only under a special program called ZENBEXUS REMS. To receive ZENBEXUS, all patients must be enrolled in ZENBEXUS REMS and agree to follow all of its requirements.

Only certified healthcare providers are permitted to prescribe ZENBEXUS, and only pharmacies that participate in the ZENBEXUS REMS can dispense ZENBEXUS.

How to Enroll in ZENBEXUS REMS

All patients:

- Review this **Patient Guide** with your prescriber
- Enroll in ZENBEXUS REMS by completing the Patient Enrollment Form with your prescriber
- Enrollment information will be provided to ZENBEXUS REMS. Upon completion of these steps, ZENBEXUS REMS will notify your prescriber of your successful enrollment

What Are the REMS Requirements?

For Females Who Can Become Pregnant

Before treatment:

- Review this **Patient Guide**
- Use 2 effective methods of birth control at the same time for 4 weeks before you start taking ZENBEXUS™ (iberdomide)
- Have 2 pregnancy tests completed in a medical setting (e.g., prescriber's office, clinic, or laboratory)
 - First pregnancy test 10–14 days before treatment initiation
 - Second pregnancy test within 24 hours before treatment initiation
- Be counseled about:
 - The risk of serious birth defects or death of an unborn baby
 - Using effective methods of birth control for at least 4 weeks before, during, and at least 4 weeks after stopping ZENBEXUS
 - Having pregnancy tests every 4 weeks
 - Completing a patient survey every 4 weeks
 - Not sharing ZENBEXUS
 - Not donating your eggs or blood during treatment and for 4 weeks after your last dose
 - Receiving counseling from the pharmacy every 4 weeks
 - Contacting your prescriber right away if you think that you may be pregnant and stop taking your medication

Every 4 weeks during treatment:

- Take a pregnancy test before each prescription
 - Weekly pregnancy tests for the first 4 weeks of treatment
 - Every 2 weeks after the first 4 weeks if irregular menstrual cycles
 - Every 4 weeks after the first 4 weeks if regular menstrual cycles
 - Repeat pregnancy test if 7-day prescription dispense window is missed
- Receive counseling from your prescriber and pharmacy about the serious risks of ZENBEXUS and the requirements of the REMS

For 4 weeks after your last dose of ZENBEXUS:

- Take a pregnancy test as directed by your prescriber
- Continue to use 2 effective methods of birth control
- Not breastfeed

At all times:

- Inform your prescriber right away if you think that you may be pregnant and stop taking ZENBEXUS
- Inform your prescriber if there is a change in your reproductive status
- Report results of all pregnancy tests to your prescriber as directed
- Not share ZENBEXUS
- Return any unused ZENBEXUS to a drug take back location

What Are Your Birth Control Options?

Unless you completely abstain from sexual intercourse, you will need to use at least 1 highly effective birth control method **and** at least 1 additional effective birth control method at the same time every time you have sex.

You must use these 2 methods of effective birth control beginning at least 4 weeks before taking ZENBEXUS™ (iberdomide), while taking ZENBEXUS, during breaks (dose interruptions) and for 4 weeks after stopping ZENBEXUS. You will talk to your healthcare provider about effective birth control methods. See examples in the chart below.

Effective Methods of Birth Control Used at the Same Time

Highly effective birth control methods		Additional effective birth control methods
• Intrauterine device (IUD) • Hormonal methods (birth control pills, hormonal patches, injections, vaginal rings, or implants) • Tubal ligation (having your tubes tied) • Partner’s vasectomy (tying of the tubes to prevent the passing of sperm)	+	• Male latex or synthetic condom • Diaphragm • Cervical cap

 **Remember, not having sexual intercourse is the only method of birth control that is 100% effective.**

What Are the REMS Requirements? (cont'd)

For Males

Before treatment:

- Review this **Patient Guide**
- Be counseled about:
 - The risk of serious birth defects or death of an unborn baby
 - Using a latex or synthetic condom during any sexual contact during your treatment even if you have had a successful vasectomy
 - Completing a patient survey every 4 weeks
 - Not donating sperm during treatment and 4 weeks after treatment
 - Not sharing ZENBEXUS™ (iberdomide)

Every 4 weeks during treatment:

- Receive counseling from the prescriber and the pharmacy on the serious risks of ZENBEXUS and the requirements of the REMS

For 4 weeks after your last dose:

- Use a latex or synthetic condom during any sexual contact
- Do not donate sperm
- Do not donate blood

At all times:

- Inform your prescriber about unprotected sexual contact with a female who can become pregnant, or about a sexual partner who might be pregnant
- Do not share your ZENBEXUS
- Return any unused ZENBEXUS to a drug take back location

What Are the REMS Requirements? (cont'd)

For Females Who Cannot Become Pregnant

Before treatment:

- Review this **Patient Guide**
- Be counseled about:
 - The risk of serious birth defects or death of an unborn baby if there is a change in your reproductive status
 - Not donating blood during treatment and for 4 weeks after treatment

Every 6 months during treatment:

- Be counseled about:
 - The risk of serious birth defects or death of an unborn baby if there is a change in your reproductive status
 - Not sharing ZENBEXUS™ (iberdomide)
 - Not donating blood during treatment and for 4 weeks after treatment
 - Returning any unused ZENBEXUS to a drug take back location

At all times:

- Inform your prescriber if there is a change in your reproductive status
- Do not share ZENBEXUS
- Return any unused ZENBEXUS to a drug take back location

How Will You Receive Your Medication?

ZENBEXUS is available only through pharmacies participating in the ZENBEXUS REMS. Your prescriber will send your prescription to an in-network pharmacy. A pharmacist will contact you to provide counseling on the serious risks and rules you must follow before you receive your prescription. They will also arrange your delivery of ZENBEXUS.

Contact Us

Suspected pregnancies	 1-888-423-5436 (REMS Call Center)
Suspected adverse events (side effects) or product quality complaints associated with ZENBEXUS™ (iberdomide)	 1-888-423-5436 (REMS Call Center)  1-800-FDA-1088  www.fda.gov/medwatch
Questions or concerns about ZENBEXUS	 Speak with your prescriber
For more information about ZENBEXUS™ REMS	 www.ZENBEXUSREMS.com  1-888-423-5436 (REMS Call Center)