

MEDICATION GUIDE
ZENBEXUS™ (zen-BEX-us)
(iberdomide)
capsules, for oral use

What is the most important information I should know about ZENBEXUS?

ZENBEXUS can cause serious side effects, including:

ZENBEXUS can harm your unborn baby, causing birth defects or death of an unborn baby.

Females who can become pregnant:

- **Do not** become pregnant during treatment with ZENBEXUS and for at least 4 weeks after your last dose of ZENBEXUS.
- You must agree to stop sexual activity with a male or use two different forms of birth control (contraception) for at least 4 weeks before starting treatment with ZENBEXUS, during treatment, during any breaks (interruptions) in treatment, and for 4 weeks after your last dose of ZENBEXUS. You must use birth control even if you have a history of infertility, unless you have had a hysterectomy.
- Talk to your healthcare provider about birth control methods that you can use before, during and after treatment with ZENBEXUS.
- Your healthcare provider will do 2 pregnancy tests before you start treatment with ZENBEXUS. After starting treatment with ZENBEXUS, your healthcare provider will do a pregnancy test every week for the first 4 weeks, then every 4 weeks if your menstrual cycle is regular or every 2 weeks if your menstrual cycle is not regular.
- If you miss your period or have unusual bleeding, your healthcare provider will do a pregnancy test and you will receive counseling.
- **Do not** donate eggs during treatment and for 4 weeks after your last dose of ZENBEXUS.

Stop taking ZENBEXUS right away and tell your healthcare provider if you:

- become pregnant
- miss your period or have unusual bleeding
- stop using birth control
- think **for any reason** that you may be pregnant

If your healthcare provider is not available, you can call the REMS Call Center at 1-888-423-5436.

Pregnancy Registry. There is a pregnancy exposure registry that monitors the outcomes of females exposed to ZENBEXUS during pregnancy. You should report all cases of pregnancy to FDA MedWatch at 1-800-FDA-1088 and the REMS Call Center at 1-888-423-5436.

Males with female partners who can become pregnant:

- **ZENBEXUS may pass into human semen:** Use a latex or synthetic condom during any sexual contact during your treatment, and for at least 4 weeks after your last dose of ZENBEXUS, even if you had a successful vasectomy.
- **Do not** donate sperm during treatment with ZENBEXUS and for 4 weeks after your last dose of ZENBEXUS. Tell your healthcare provider right away if your female partner becomes pregnant.

ZENBEXUS REMS Program

Because of the risk of harm to an unborn baby, ZENBEXUS is available only through a restricted program called the ZENBEXUS Risk Evaluation and Mitigation Strategy (REMS). Before you can take ZENBEXUS, you and your healthcare provider must be enrolled in the ZENBEXUS REMS. Your healthcare provider will explain the ZENBEXUS REMS to you.

You must:

- read and agree to all the instructions in the ZENBEXUS REMS.
- sign the Patient Enrollment Form.

ZENBEXUS is only available through pharmacies that participate in the ZENBEXUS REMS. Your healthcare provider will give you information about how to find a participating pharmacy. For more information, go to www.ZENBEXUSREMS.com or call 1-888-423-5436.

Increased risk of blood clots.

ZENBEXUS can cause serious and life-threatening blood clots in the veins of your legs (deep vein thrombosis), lungs (pulmonary embolism), and in your heart or brain that can cause heart attack or stroke (arterial thromboembolic events). Your healthcare provider may start you on medicine to help prevent blood clots if you have certain risk factors.

Tell your healthcare provider right away if you get any of the following signs and symptoms of blood clots during treatment with ZENBEXUS:

- swelling, pain or tenderness in your legs
- red or discolored skin on your leg
- chest pain that may spread to the arms, neck, jaw, back, or stomach area
- sudden shortness of breath
- dizziness or lightheadedness
- vomiting
- feeling sweaty
- sudden numbness or weakness in the face, arm, or leg, especially on one side of the body
- severe headache or confusion
- problems with vision, speech, or balance

See **"What are the possible side effects of ZENBEXUS?"** for more information about side effects.

What is ZENBEXUS?

ZENBEXUS is a prescription medicine used 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.

It is not known if ZENBEXUS is safe and effective in children.

Who should not take ZENBEXUS?

Do not take ZENBEXUS if you are pregnant, plan to become pregnant, or become pregnant during treatment with ZENBEXUS. See **"What is the most important information I should know about ZENBEXUS?"**

Before taking ZENBEXUS, tell your healthcare provider about all of your medical conditions, including if you:

- have had a blood clot, heart attack, other heart problems, or stroke
- have high cholesterol
- have high blood pressure
- are a smoker
- have an infection
- have kidney problems
- are pregnant or plan to become pregnant. See **"What is the most important information I should know about ZENBEXUS?"**
- are breastfeeding or plan to breastfeed. It is not known if ZENBEXUS passes into your breast milk. **Do not** breastfeed during treatment with ZENBEXUS.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Certain medicines may affect how ZENBEXUS works or cause side effects.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I take ZENBEXUS?

- Take ZENBEXUS exactly as your healthcare provider tells you to take it. Follow all the instructions of the ZENBEXUS REMS program.
- Do not remove the capsule from the bottle until you are ready to take your dose.
- Take ZENBEXUS 1 time a day at about the same time each day.
- Take ZENBEXUS with or without food.
- Swallow ZENBEXUS capsules whole with water. Do not open, break, or chew the capsules.
- If you touch a broken ZENBEXUS capsule or the medicine inside the capsule, wash the area of your body right away with soap and water.
- If you miss a dose of ZENBEXUS and it has been less than 12 hours since your regular time, take it as soon as you remember. If it has been more than 12 hours, skip your missed dose. **Do not** take 2 doses at the same time.

What should I avoid while taking ZENBEXUS?

Do not donate blood during treatment with ZENBEXUS and for 4 weeks after your last dose of ZENBEXUS.

What are the possible side effects of ZENBEXUS?

ZENBEXUS can cause serious side effects, including:

- See **"What is the most important information I should know about ZENBEXUS?"**
- **Severe low white blood cell counts (neutropenia).** Your healthcare provider will do blood tests during treatment with ZENBEXUS. Tell your healthcare provider if you have a fever.

- **Infections.** ZENBEXUS can cause serious infections, including life-threatening infections or death. Tell your healthcare provider if you get signs and symptoms of an infection before or during treatment with ZENBEXUS, including fever, chills, or flu-like symptoms.
- **New cancers (secondary cancers).** Your healthcare provider will monitor you for new cancers.

The most common side effects of ZENBEXUS in combination with the medicines daratumumab and hyaluronidase-fihj, and dexamethasone include:

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| • decreased white blood cell count (neutropenia) | • tiredness | • sleep problems such as insomnia, restless leg syndrome |
| • decreased white blood cells (leukopenia) and lymphocytes (lymphopenia) | • muscle and joint pain | • abnormally low levels of antibodies (hypogammaglobulinemia) |
| • decreased platelets (thrombocytopenia) | • pneumonia | • COVID-19 |
| • decreased hemoglobin (anemia) | • diarrhea | • constipation |
| • upper respiratory infections | • trouble controlling your body movements (motor dysfunction) | |
| | • rash | |

Your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with ZENBEXUS if you have certain side effects.

ZENBEXUS may affect fertility in females and males, which may affect the ability to have children. Talk to your healthcare provider if this is a concern for you.

These are not all the possible side effects of ZENBEXUS.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store ZENBEXUS?

- Store ZENBEXUS at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep ZENBEXUS in the original bottle. The bottle contains a drying agent (desiccant) to keep the medicine dry. Keep the drying agent in the bottle.
- Put the bottle cap back on tightly after each use.
- Do not remove capsule from the bottle until you are ready to take ZENBEXUS.

Keep ZENBEXUS and all medicines out of the reach of children.

General information about the safe and effective use of ZENBEXUS.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use ZENBEXUS for a condition for which it was not prescribed. Do not give ZENBEXUS to other people, even if they have the same symptoms that you have. It may harm them and **may cause birth defects**. You can ask your pharmacist or healthcare provider for information about ZENBEXUS that is written for health professionals.

What are the ingredients in ZENBEXUS?

Active ingredients: iberdomide

Inactive ingredients: anhydrous lactose, pregelatinized starch, and stearic acid.

The capsule shell contains hypromellose, iron oxide black, iron oxide yellow, and titanium dioxide.

The 0.75 mg capsule shell also contains iron oxide red. The 0.75 mg capsule is imprinted with white ink that contains povidone, propylene glycol, shellac, sodium hydroxide, and titanium dioxide.

The 1 mg capsule is imprinted with white and black ink that contains iron oxide black, potassium hydroxide, povidone, propylene glycol, shellac, sodium hydroxide, strong ammonia solution, and titanium dioxide.

Manufactured by: Bristol-Myers Squibb Company, Princeton, NJ 08543 USA

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For more information, go to www.zenbexus.com or call 1-855-673-4861.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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