

ATEBRIOZ is indicated to reduce the volume of total new heterotopic ossification (HO) in adults and pediatric patients aged 12 years and older with fibrodysplasia ossificans progressiva (FOP).



ATEBRIOZTM
zilurgisertib tablets 25mg

IMPORTANT SAFETY INFORMATION

Who should not take ATEBRIOZ?

Do not take ATEBRIOZ if you are pregnant. ATEBRIOZ can harm your unborn baby, including birth defects.

What should I tell my health care provider before taking ATEBRIOZ?

Before taking ATEBRIOZ, tell your health care provider about all of your medical conditions, including if you:

- are pregnant or plan to become pregnant. ATEBRIOZ can harm your unborn baby, including birth defects.
- can become pregnant. Your health care provider should verify that you are not pregnant before you start ATEBRIOZ. Use effective birth control during treatment and for one week after your final dose. If you become pregnant while taking ATEBRIOZ, stop taking it immediately and contact your health care provider.
- are breastfeeding or plan to breastfeed. Breastfeeding is not recommended during treatment with ATEBRIOZ and for at least one week after the final dose.

Please see Important Safety Information throughout and full [Prescribing Information](#), including the Medication Guide, for ATEBRIOZ.





Actual size:
10.5 mm

What is ATEBRIOZ?

ATEBRIOZ is a once-daily oral treatment used to reduce the amount of new abnormal bone growth outside of the skeleton (heterotopic ossification) in people aged 12 years and older with FOP.



What are the most important things I should know about ATEBRIOZ?

ATEBRIOZ should not be taken during pregnancy and can harm your unborn baby if taken while pregnant.

IMPORTANT SAFETY INFORMATION (cont'd)

Tell your health care provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, herbal products, and dietary supplements. Some medicines can affect ATEBRIOZ, and ATEBRIOZ can affect some other medicines.

- If you take a strong CYP3A4 inhibitor, your health care provider will reduce your ATEBRIOZ dose to 50 mg one time each day.
- Avoid taking ATEBRIOZ with strong or moderate CYP3A4 inducers.
- Avoid taking ATEBRIOZ with medicines that are MATE1 or MATE2-K substrates, such as metformin. If taking them together cannot be avoided, your health care provider may monitor you for side effects and may change the dose of the other medicine.

Please see Important Safety Information throughout and full Prescribing Information, including the Medication Guide, for ATEBRIOZ.

How do I take ATEBRIOZ?



The recommended dosage of ATEBRIOZ for adults and pediatric patients aged 12 years and older is 100 mg (four 25-mg pills) orally once daily with or without food



You may take ATEBRIOZ tablets whole or crushed



If tablets are crushed, mix 4 tablets (100 mg total) with 4 tablespoons of water, orange juice, applesauce, or plain yogurt and consume immediately. Do not store mixture for future use



Do not administer ATEBRIOZ with grapefruit, pomelo, or juices containing these fruits

IMPORTANT SAFETY INFORMATION (cont'd) INDICATION

ATEBRIOZ is a prescription medicine used to reduce the volume of total new heterotopic ossification (HO) in adults and children 12 years of age and older with fibrodysplasia ossificans progressiva (FOP).

It is not known if ATEBRIOZ is safe and effective in children younger than 12 years of age.

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What are the possible side effects?

The most common side effects of ATEBRIOZ include:

- headache
- joint pain (arthralgia)
- common cold, sinus infections, or sore throat (upper respiratory tract infections)
- nosebleed (epistaxis)
- nausea

These are not all the possible side effects of ATEBRIOZ.

If you experience these or any other symptoms, tell your doctor immediately. They can help you manage side effects.

IMPORTANT SAFETY INFORMATION (cont'd)

What are the possible side effects of ATEBRIOZ?

The most common side effects of ATEBRIOZ include:

- headache
- joint pain
- common cold, sinus infections, or sore throat (upper respiratory tract infections)
- nosebleeds
- nausea

These are not all of the possible side effects of ATEBRIOZ. For more information, ask your health care provider or pharmacist. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

Take ATEBRIOZ exactly as your health care provider tells you. ATEBRIOZ is taken by mouth one time each day with or without food.

Please see Important Safety Information throughout and full Prescribing Information, including the Medication Guide, for ATEBRIOZ.



How should I store ATEBRIOZ?

Store ATEBRIOZ tablets between 68 °F to 77 °F (20 °C-25 °C) in the original container.

Keep ATEBRIOZ and all medicines out of reach from children.



Before taking ATEBRIOZ

Tell your health care provider about all of your medical conditions, including:

- if you are breastfeeding or plan to breastfeed
- all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements

ATEBRIOZ and certain other medicines can interact, sometimes causing serious side effects. Keep a list of medicines you are currently taking to show to your health care provider and pharmacist when you get a new medicine.

IMPORTANT SAFETY INFORMATION (cont'd)

ATEBRIOZ tablets may be swallowed whole or crushed. If crushed, mix 4 tablets (100 mg total) with four tablespoons of water, orange juice, apple sauce, or plain yogurt and take immediately. Do not store the mixture for future use. Do not take ATEBRIOZ with grapefruit, pomelo, or juices containing these fruits.



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How can MAP assist me?

If you are unable to pay for ATEBRIOZ, help may be available.

Mirum Access Plus (MAP) is a support program with a dedicated team that helps patients, caregivers, and their healthcare providers access medication and connect with helpful resources. MAP can help with understanding insurance coverage and eligibility for financial support programs, getting medication as quickly as possible, and connecting you with information and resources about Mirum medications.



If you have any questions about
Mirum Access Plus, contact us at

1-855-MRM-4YOU (1-855-676-4968)

Monday to Friday, 8:00 AM to 8:00 PM ET



Scan the QR code to access:
mirumaccessplus.com