Important Safety Information

ZENBEXUS (IBERDOMIDE) GUIDE FOR RISK MINIMIZATION FOR PATIENTS

WHO CAN BECOME PREGNANT

This document has been reviewed and approved by the Saudi Food and Drug Authority (SFDA).

Date of Health Authority Approval: September 2026
Local Approval Number: 2070-SA-2600004

Bristol Myers Squibb™

1 INTRODUCTION

Iberdomide may cause embryo-fetal harm in humans. Therefore, you need to avoid potential fetal exposure during pregnancy.

You have been provided with this guide because you have been prescribed iberdomide and have the potential to become pregnant. This guide will help you understand this risk of potential fetal exposure during pregnancy and what you need to do before, during, and after taking iberdomide.

You will also receive a Patient Card from your doctor to remind you of what you need to know; **the Patient Card should be kept with you at all times.**

In order to ensure that an unborn baby is not exposed to iberdomide, your doctor will complete a Risk Awareness Dialogue Form documenting that you have been informed of the requirement for you NOT to become pregnant throughout the duration of your treatment with iberdomide including during dose interruptions and for at least 4 weeks after stopping iberdomide.

For additional information, please refer to the Saudi package Leaflet.

2 RISK OF EMBRYO-FETAL HARM ASSOCIATED WITH TAKING IBERDOMIDE

In order to avoid potential fetal exposure, you must never take iberdomide if:

- You are pregnant, suspect you may be pregnant, or are planning to become pregnant.
- You can become pregnant and are not using effective contraception.

Your doctor will explain to you that iberdomide may cause embryo-fetal harm in humans and how to avoid a potential fetal exposure during pregnancy.

- Please make sure that you understand what your doctor has told you before starting treatment.
- If you don't understand something, please ask your doctor to explain it again.

3 REQUIREMENTS FOR PATIENTS WHO CAN BECOME PREGNANT

- You must not take iberdomide if you are pregnant or trying to become pregnant.
- You must not become pregnant while taking iberdomide including during dose interruption or within 4 weeks after stopping iberdomide.
- If you have regular or no menstrual cycles,
    - a medical supervised pregnancy test must be performed weekly for the first 4 weeks and then every 4 weeks while taking iberdomide and for at least 4 weeks following the last dose of iberdomide.
- If you have irregular menstrual cycles,
    - a medically supervised pregnancy test must be performed weekly for the first 4 weeks and then every 2 weeks while taking iberdomide and every 2 weeks for at least 4 weeks following the last dose of iberdomide.
- Your doctor will write a prescription for iberdomide for no more than 4 weeks at a time, <*provided you have had a valid negative pregnancy test within 3 days before your prescription date, and you must have the medication dispensed within 7 days of the prescription date*.
- You must use effective contraception for at least 4 weeks before treatment with iberdomide, at all times while taking iberdomide (including dose interruptions), and for at least 4 weeks after stopping iberdomide.
- It is not known whether iberdomide is excreted in breast milk. Therefore, breast-feeding should be discontinued during therapy with iberdomide.

If you are pregnant, suspect you may be pregnant, or are planning to become pregnant, you must contact the doctor who prescribed iberdomide and STOP taking iberdomide immediately.

4 BEFORE YOU BEGIN TREATMENT WITH IBERDOMIDE:

- Read this guide.
- Tell your doctor if you are pregnant, if you suspect you may be pregnant, or if you are planning to become pregnant, as iberdomide may cause embryo-fetal harm to an unborn baby.
- Ask your doctor any questions you have about iberdomide, including the benefits and risks.
- Receive counseling about the potential risk of embryo-fetal harm in an unborn baby.
- Have a medically supervised negative pregnancy test immediately before starting iberdomide, even if you agree and confirm every month that you will not engage in heterosexual activity.
- Use effective contraception for at least 4 weeks before treatment with iberdomide **OR** commit to absolute and continuous abstinence from heterosexual activity while taking iberdomide.

5 DURING TREATMENT WITH IBERDOMIDE:

- Have a medically supervised negative pregnancy every week for the first 4 weeks of treatment and at least every 4 weeks thereafter if you have regular menstrual cycles or every 2 weeks if you have irregular menstrual cycles, even if you agree and confirm every month that you will not engage in heterosexual activity.
- Use effective contraception at all times while taking iberdomide as directed by your HCP **OR** commit to absolute and continuous abstinence from heterosexual activity while taking iberdomide.

Before starting iberdomide, use effective contraception for at least 4 weeks. Continue using contraception throughout and for at least 4 weeks after stopping treatment.

6 AFTER TREATMENT WITH IBERDOMIDE:

- Have a medically supervised negative pregnancy test at least 4 weeks after discontinuing treatment if you have regular menstrual cycles or every 2 weeks if you have irregular menstrual cycles.
- Use effective contraception at all times for at least 4 weeks after stopping iberdomide as directed by your doctor **OR** commit to absolute and continuous abstinence from heterosexual activity for at least 4 weeks after stopping iberdomide.

For at least 4 weeks after stopping iberdomide, if you are pregnant, suspect you may be pregnant, or are planning to become pregnant, you must contact the doctor who prescribed iberdomide immediately.

7 TALK TO YOUR HEALTHCARE PROFESSIONAL IMMEDIATELY IF:

- You have a positive pregnancy test.
- You suspect your contraception has failed.
- You unexpectedly missed your period.
- You suspect you are pregnant or are planning to become pregnant.

You MUST tell your doctor immediately if you experience any symptom of pregnancy.

The package leaflet also provides possible side effects and details of how to report them.> Reporting side effects to the "Saudi Food and Drug Authority" helps collect additional safety information on iberdomide.

If you have any questions or concerns regarding iberdomide, please discuss them with your doctor, pharmacist, or any member of your healthcare team.

For further information or for reporting any suspected adverse reactions via the national reporting system :
Bristol Myers Squibb, Saudi Arabia :
At: medinfo.SaudiArabia@bms.com
or call: 800 844 7710

The National Pharmacovigilance Centre (NPC)
Saudi Food and Drug Authority (SFDA):
SFDA call center: 19999
E-mail: npc.drug@sfda.gov.sa
Website: https://ade.sfda.gov.sa

Date of Health Authority Approval: September 2026
Local Approval Number: 2070-SA-2600004