ZENBEXUS (IBERDOMIDE) RISK AWARENESS DIALOGUE FORM

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

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Bristol Myers Squibb®

RISK AWARENESS DIALOGUE FORM

The purpose of the Risk Awareness Dialogue Form is to facilitate the interaction between the prescribing healthcare professional (HCP) and all patients who can become pregnant, ensuring that patients are fully informed of and understand the risk of embryo-fetal toxicity associated with the use of iberdomide. It is advised to be read carefully before prescribing/dispensing/administering the product.

1. This Risk Awareness Dialogue Form is provided to assist the prescribing HCP with counseling the patient who can become pregnant before starting treatment with iberdomide.
2. The Risk Awareness Dialogue Form must be completed for each patient who can become pregnant before initiating iberdomide treatment.
3. All patients who can become pregnant must receive counseling about the risk of embryo-fetal toxicity associated with iberdomide and the intended actions for risk minimization.

Yes	Prior to Initiation of Treatment
	Provide counseling before treatment initiation regarding:
☐	• the embryo-fetal toxicity risk associated with iberdomide. Studies in animals have shown embryo-fetal toxicity, hence iberdomide may cause embryo-fetal harm in humans.
☐	• the need to avoid potential fetal exposure during pregnancy.
☐	• the required actions to avoid potential fetal exposure during pregnancy.
☐	• the need for a medically supervised negative pregnancy test before starting treatment.
	Advise the patient who can become pregnant that treatment with iberdomide will not be started:
☐	• if the patient suspects that they are pregnant or wants to become pregnant (medically supervised negative pregnancy test required before starting treatment).
☐	• if patients who can become pregnant do not use effective contraception or abstain from heterosexual activity for at least 4 weeks prior to treatment initiation. Examples of contraceptive methods are included in the Guide for Risk Minimization for HCPs.
☐	Provide the Guide for Risk Minimization for Patients and Patient Card to the patient who can become pregnant.

Yes	During Treatment
	Remind patients who can become pregnant that during treatment:
☐	• they must not become pregnant.
☐	• they must continue using effective contraception or abstain from heterosexual activity during treatment with iberdomide and in case of dose interruption.
☐	• they should inform the physician prescribing their contraception that they are taking iberdomide.
☐	• they should inform the physician prescribing iberdomide if they need to change or stop using contraception.
☐	• they need a medically supervised negative pregnancy test every week for the first 4 weeks of treatment and at least every 4 weeks thereafter in patients with regular menstrual cycles or every 2 weeks in patients with irregular menstrual cycles.
☐	The patient has been informed that it is unknown whether iberdomide passes into breast milk and that breastfeeding must be stopped during treatment with iberdomide.
☐	If a patient wants to become pregnant, their prescriber must be informed immediately.
Yes	**Discontinuation of Treatment**
☐	Counsel patients who can become pregnant that effective contraception should be maintained for at least 4 weeks following discontinuation of treatment with iberdomide.
☐	A pregnancy test must be carried out, and a negative test result must be verified in patients who can become pregnant at least 4 weeks after discontinuation of treatment in patients with regular menstrual cycles or every 2 weeks in patients with irregular menstrual cycles.
Yes	**In the Event of a Suspected Pregnancy***
☐	Inform the patient to stop treatment with iberdomide immediately in the event of a suspected pregnancy and inform you (the prescribing physician) immediately. Refer the patient to an HCP specialized or experienced in teratology for evaluation. *Not applicable if the patient did not become pregnant while on treatment or within 4 weeks of discontinuation of iberdomide.

The form should be retained with the patient's medical records, and a copy provided to the patient. It is not a contract and does not absolve anybody from their responsibilities regarding the safe use of the product and prevention of fetal exposure.

CONTACT DETAILS

Patient/Legal guardian name: _____

Patient/Legal guardian signature*: _____

Date of birth: _____

Counseling date: _____

Prescriber name: _____

Prescriber signature: _____

For further information or for reporting any suspected adverse reactions via the national reporting system :
Bristol Myers Squibb, Saudi Arabia :
At email: 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

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