



Krascendo 1

BO45217

Krascendo 1 Participant Safety Booklet

BO45217_Safety Brochure_v2_16-Sep-24_Master_US ENG

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Participant Information

Study number: **BO45217**

Participant ID number: _____

Who to contact

For any issues or questions about your treatment or medication(s),
please contact the study staff.

Study doctor name: _____

Clinic or hospital name: _____

Office phone number: _____

After-hours phone number: _____

Other Study Site Contact: _____

Participants should be educated on the potential risks associated with treatments administered in this study and instructed to report adverse events as soon as possible. Participants should also be instructed to not delay the initiation of supportive treatments where they have been prophylactically prescribed, with the goal of maximizing participant safety and compliance.

Please follow your doctor’s advice. This booklet is to help you **prevent, identify and manage** certain side effects. You will find information about how to manage **nausea & vomiting and diarrhea** in the following pages.

The information in this Brochure is applicable to all study treatments.

Nausea & Vomiting

When receiving the study treatment, you may experience nausea and vomiting. It's important that you know how to prevent, identify and manage these side effects.

What you might experience?

Nausea is the feeling of being queasy or sick to your stomach. It can happen with or without vomiting (throwing up).

What can you do?

Take medication

You may need to take prescription anti-nausea medication. Follow your study doctor's advice on taking medication to prevent or treat nausea. The study doctor should give you anti-nausea medication before you start the study treatment in case you develop nausea with the study treatment.

–Your anti-nausea medication is: _____

Contact your study doctor if you have any questions about how to use anti-nausea medication or if nausea does not improve in 24-48 hours despite taking the medication.

Avoid strong odors

Strong odors can cause nausea. Here are some recommendations:

- Reduce strong odors by eating cold or room-temperature foods in well-ventilated rooms
- Avoid strong odors such as perfume, aftershave and scented body lotions

Change your eating habits

Changing eating habits may help control your nausea. Here are some examples:

- Eat 6-8 small meals instead of 3 large meals
- Eat bland foods (instead of sweet, fatty, greasy, or spicy)
- Eat dry foods every few hours when you are taking medications, when you wake up.

Drink plenty of fluids

Sip on beverages that provide calories. Drinking small amounts throughout the day will help you get enough calories, nutrients and fluids.

When to contact your medical expert?

Seek immediate medical care if you:

- Cannot keep liquids and/or study treatment down
- Cannot control nausea despite medication
- Continue to vomit or cannot stop vomiting
- See blood in your vomit
- Have signs of not drinking enough water (dry mouth, lips, or eyes; dark yellow urine)
- Are unable to take care of yourself

Diarrhea

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Diarrhea is common and can have many causes, including this study treatment. Diarrhea can be managed and controlled by following the steps below.

What you might experience?

Diarrhea is when you pass a loose, watery stool. You may also have more bowel movements than normal.

What can you do?

Stay hydrated

Diarrhea causes dehydration, which can quickly become dangerous. Drink plenty of fluids. Rehydration drinks and sports drinks can also help your body maintain its electrolyte (or essential mineral) balance.

Think about what you eat

Eating low fibre foods such as bananas, white rice, refined white flour bread and potatoes can help ease symptoms.

Take medication

Your study doctor should have discussed diarrhea with you. Follow your study doctor's advice on taking medication to treat diarrhea. The study doctor should give you anti-diarrheal medication before you start treatment in case you develop diarrhea with study treatment at home.

–Your anti-diarrheal medication is: _____

Contact your study doctor if you have any questions about how to use anti-diarrheal medication or if diarrhea occurs so as to manage your symptoms at the earliest.

Additional things to consider

- Be prepared for the possibility of diarrhea when you leave home.
- If your doctor recommended anti-diarrheal medicine, take it with you.

When to contact your medical expert?

If, after following these instructions, your diarrhea is not improving or worsens, let your study doctor know.

Seek immediate medical care if you:

- Cannot control diarrhea despite medication
- Have more than 3-4 loose watery stools/day
- Have a fever (temperature of 38°C / 100.4°F or higher)
- Have severe belly pain
- See blood in your stool
- Have signs of dehydration (dry mouth, lips, or eyes; dark yellow urine)