

What You Need to Know About Xenazine* (tetrabenazine)

Patient/Caregiver Counseling Guide

NOTE TO PRESCRIBER: Please provide this guide to your patient or your patient's caregiver.

What Is the Most Important Information About Xenazine?

- Xenazine (*ZEN-uh-zeen*) is a prescription medicine to treat involuntary movements of Huntington's disease. Involuntary movements, also called chorea, are a major feature of Huntington's disease.
- Take Xenazine exactly as directed by your doctor. Take the prescribed dose of Xenazine at the correct time each day. Never take more Xenazine than your doctor has prescribed for you.
- The dose of Xenazine will be increased slowly to the dose that reduces chorea and is well tolerated. Sleepiness, restlessness, parkinsonism (symptoms include slight shaking, body stiffness, trouble moving or keeping your balance), depression, and difficulty swallowing may occur.
- Xenazine does not cure the cause of chorea.
- Xenazine does not treat other symptoms of Huntington's disease, such as problems with thinking or emotions.
- It is not known if Xenazine is safe and effective in children.
- Xenazine is not for patients with Huntington's disease who are depressed or who have depression that is not well controlled by medication.
- Xenazine is not for patients who have thoughts of suicide.
- Xenazine may increase your risk of developing depression or suicidal thoughts or of acting on these thoughts.

Depression, thoughts of suicide, or suicide may occur in patients who have Huntington's disease. The chance that these changes in mood or behavior may occur is increased in patients who are taking Xenazine. All patients treated with Xenazine should be observed closely for new or worsening depression, thoughts of suicide, or attempted suicide. This is especially important when starting therapy with Xenazine or when changing the dose of Xenazine.

Tell your doctor at once if you become depressed or have thoughts about suicide while taking Xenazine.

What Are the Signs You May be Depressed or At Risk for Suicide?

- You feel sad or have crying spells.
- You are no longer interested in seeing your friends or doing things you used to enjoy.
- You are sleeping a lot *more* or a lot *less* than usual.
- You feel unimportant.
- You feel guilty.
- You feel hopeless or helpless.
- You are more irritable, angry, or aggressive than usual.
- You are *more* or *less* hungry than usual or notice a big change in your body weight.
- You have trouble paying attention.
- You feel tired or sleepy all the time.
- You have thoughts about hurting yourself or ending your life.

What Should I Do If I Have These Signs?

Call your doctor right away if you become depressed or develop any of the signs listed above. Talk to your doctor about it, especially if your feelings are new, they have become worse, or you are worried about them.

What Is Xenazine (tetrabenazine)?

Xenazine is a medication taken by mouth to treat involuntary movements of Huntington's disease. Involuntary movements, also called chorea, are a major feature of Huntington's disease. These movements are typically quick, jerky, and irregular, and they can make it difficult to walk or sit still.

Xenazine may reduce chorea while you are taking it. In clinical studies, Xenazine reduced chorea in more than half the people who took it. Xenazine does not cure the cause of chorea, nor does it treat other symptoms of Huntington's disease, such as problems with thinking or emotions.

How Does Xenazine Work?

Doctors are not sure what causes chorea. Overactivity of a chemical in the brain, dopamine (DOH-puh-meem), may cause it.

Doctors are not sure how Xenazine reduces chorea. Xenazine can reduce the activity of dopamine in the brain, which may lessen chorea.

Who Should Not Take Xenazine?

Some people should not take Xenazine. Tell your doctor if any of these things are true for you.

Do not take Xenazine if

- You are sad (depressed) much of the time. You may become more depressed while taking Xenazine.
- Medicine you take for depression has not helped enough.
- You think or talk about harming or killing yourself (suicide). You may become more likely to think about ending your life while taking Xenazine.

Please see Xenazine Medication Guide on pages 8-11.

- You have liver problems.
- You take a monoamine oxidase (MAO) inhibitor, or reserpine, or medicine that contains reserpine.

Examples of MAO inhibitors are Nardil® (phenelzine), Eldepryl® (selegiline), and Parnate® (tranylcypromine).

Examples of medicines that contain reserpine are Serpalan® or Renese®-R. You must stop taking reserpine for at least 20 days before you begin therapy with Xenazine.

- If you are not sure if you are taking an MAO inhibitor or a medicine that contains reserpine, ask your doctor or pharmacist.

Before You Start to Take Xenazine

Tell Your Doctor About Your Health Problems

Tell your doctor about all your medical conditions, including any health problems you have now or had in the past. Taking Xenazine may make some health conditions worse.

Tell your doctor if you have any of these health conditions:

Emotional or mental health conditions

- Sadness or depression
- Past thoughts of suicide or suicide attempts
- Nervousness or anxiety
- Anger or agitation
- Problems with your mental health

Physical conditions

- Liver problems.
- Allergies to any of the ingredients in Xenazine Tablets.

Xenazine contains the active ingredient tetrabenazine. It also contains these inactive ingredients: lactose, maize starch, talc, and magnesium stearate. The 25-mg tablet, which is pale yellow, also contains yellow iron oxide.

- Breast cancer or a history of breast cancer.

Xenazine may raise the level of the hormone prolactin. A high level of prolactin may affect some types of breast cancer.

- You have an irregular heart beat (cardiac arrhythmia).
- You are pregnant or plan to become pregnant.

The effect of Xenazine on an unborn baby is not known.

- You are nursing a baby.

It is not known if Xenazine passes into breast milk.

Tell Your Doctor and Pharmacist Which Medications You Are Taking

It is very important that you tell your doctor and pharmacist all the medications you are taking, including prescription medicines, nonprescription remedies, vitamins, and herbal products.

Xenazine may interact with some medications, sometimes causing serious side effects. If you take certain drugs, your doctor may make a change in your dose of Xenazine.

Know the medicines you take. Keep a list of all of them and the dose for each to show your doctor. While you are taking Xenazine, talk to your doctor before you

- Start taking any new drugs
- Change the dose of any of your medicines
- Stop taking any of your medicines

How Should I Take Xenazine?

Xenazine is a tablet you take by mouth. You may take it with or without food. There are 2 strengths of Xenazine:

- A white tablet with 12.5 mg of Xenazine
- A pale yellow tablet with 25 mg of Xenazine

Take Xenazine exactly as directed by your doctor. Never take more or less Xenazine than your doctor has prescribed for you. Take the prescribed dose of Xenazine at the correct time each day.

Skipping or Stopping Xenazine

- Before starting Xenazine, you should talk to your health care provider about what to do if you miss a dose. If you have missed the previous dose and it is time for your next dose, do not double the dose.
- If you stop taking Xenazine, your chorea may return or worsen in 12 to 18 hours after you took the last dose.
- Tell your doctor if you stop taking Xenazine for more than 5 days. Do not take another dose until you talk to your doctor.

Getting Started on Xenazine

- When you start taking Xenazine, your doctor may increase your dose each week. You will follow this schedule for several weeks until you and your doctor find the dose you can tolerate that reduces your chorea.
- Your doctor will start you on a low dose of Xenazine: 12.5 mg every morning for the first week.
- The second week, your doctor may increase your daily dose of Xenazine to 25 mg: 12.5 mg in the morning and another 12.5 mg 12 hours later in the evening.
- If your daily dose is increased to 37.5 mg or 50 mg, you will need to take Xenazine 3 times a day.
- If your doctor thinks you need to take more than 50 mg of Xenazine each day, you will need a blood test to see if that dose is safe for you.
- For most patients, the maximum recommended daily dose is 100 mg. For some patients, the maximum daily dose may be 50 mg.

While Taking Xenazine

Because the most common side effect of Xenazine is sleepiness (sedation), take these precautions:

Please see Xenazine Medication Guide on pages 8-11.

- Do not drive a car or operate dangerous machinery until you know how Xenazine affects you.
- Drinking alcohol and taking other drugs that may also cause sleepiness while you are taking Xenazine may increase any sleepiness caused by Xenazine.

Monitor Your Treatment With Xenazine

You and your caregiver should be alert for possible side effects with Xenazine.

The Most Serious Side Effects that May Develop With Xenazine

- **Depression or thoughts of suicide.** Xenazine may worsen a patient's mood or ability to think clearly. It may be difficult to tell if these side effects are due to Huntington's disease or Xenazine.

Xenazine increases the chance of developing depression, having thoughts of suicide, or attempting suicide. You and your caregiver should be alert to these changes and tell your doctor if they occur. (See the section *What Is the Most Important Information About Xenazine?*)

Tell your doctor at once if you become depressed or have thoughts about suicide while taking Xenazine.

- **Neuroleptic Malignant Syndrome.** Neuroleptic malignant syndrome (NMS) is a very serious but rare side effect of Xenazine.

The signs of NMS are

- High fever
- Stiff muscles
- Problems thinking
- Very fast or uneven heartbeat
- Increased sweating

Call your doctor at once and go to the nearest hospital emergency room if you develop these signs of NMS and they have no other obvious cause.

- **Parkinsonism.** The signs of parkinsonism include slight shaking, body stiffness, and trouble moving or keeping your balance. Because body stiffness can develop as part of Huntington's disease, it may be difficult to tell if this side effect is due to Huntington's disease or Xenazine. If you develop the signs of parkinsonism, your doctor may reduce your dose of Xenazine or stop therapy with Xenazine.
- **Restlessness.** You may begin to feel a strong urge to move. This feeling may be a sign that you are developing a condition called akathisia. Tell your doctor if you have this feeling.
- **Trouble swallowing.** Xenazine may increase the chance that you will have trouble swallowing. Increased coughing may be the first sign that you are having trouble swallowing.
 Trouble swallowing increases your risk of pneumonia. Tell your doctor if you have trouble swallowing before you start or during your treatment with Xenazine.
- **Tardive dyskinesia (TD).** TD is a condition that may develop in patients treated with drugs that work like Xenazine.

TD is a condition where there is repeated facial grimacing that cannot be controlled. These movements may include sticking out the tongue, smacking the lips, puckering and pursing the lips, and rapid eye blinking. Rapid movements of the arms, legs, and body may also occur.

If you get TD while taking Xenazine, it is possible that the TD will not go away. The chance of developing TD and the chance that it will not go away appear to increase the longer you are being treated. There is no known treatment for TD, although it may partially or completely go away if you stop taking Xenazine.

- **Irregular heartbeat.** Xenazine increases your chance of having certain changes in the electrical activity in your heart that can be seen on an electrocardiogram (EKG). These changes can lead to a dangerous abnormal heartbeat. Taking Xenazine with certain medicines may increase this chance (See the section *Tell Your Doctor Which Medications You Are Taking*).
- **Dizziness.** Dizziness can occur when you change positions (sit up or stand up). This may happen because your blood pressure changes when you change positions. Xenazine may cause you to feel dizzy when you stand up.

You should change positions slowly from lying down to sitting up and from sitting up to standing while you are taking Xenazine. Tell your doctor right away if you get dizzy or faint while taking Xenazine. Your doctor may monitor your blood pressure closely.

The Most Common Side Effects that May Develop With Xenazine

The most common side effects with Xenazine include

- Sleepiness (sedation)
- Trouble sleeping
- Depression
- Tiredness (fatigue)
- Anxiety
- Restlessness
- Agitation
- Nausea

Tell your doctor if you have any side effects. Do not stop taking Xenazine without talking to your doctor first.

What Should I Do If I Have a Side Effect With Xenazine?

Call your doctor if you have any of the side effects listed above or any other possible side effects not listed above. Your doctor may lower the dose of Xenazine you are taking or prescribe a medicine to help with the side effect. Do not stop taking Xenazine without talking to your doctor first.

Talk to Your Doctor

You should also tell your doctor if Xenazine is helping you. Be sure you understand what your doctor tells you. Ask questions until everything is clear. To help you remember, write down what your doctor tells you.

MEDICATION GUIDE

XENAZINE* (ZEN-uh-zeen) (tetrabenazine) Tablets

Read the Medication Guide that comes with Xenazine before you start taking it and each time you refill the prescription. There may be new information. This information does not take the place of talking with your doctor about your medical condition or your treatment. You should share this information with your family members and caregivers.

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

- **Xenazine may increase the chance of depression, suicidal thoughts, or suicidal actions in some patients.**
- You should not start taking Xenazine if you are depressed (have untreated depression or depression that is not well controlled by medicine) **or** have suicidal thoughts.
- Pay close attention to any changes, especially sudden changes, in mood, behaviors, thoughts or feelings. This is especially important when Xenazine is started and when the dose is changed.

Call the doctor right away if you become depressed or have any of the following symptoms, especially if they are new, worse, or worry you:

- You feel sad or have crying spells.
- You are no longer interested in seeing your friends or doing things you used to enjoy.
- You are sleeping a lot *more* or a lot *less* than usual.
- You feel unimportant.
- You feel guilty.
- You feel hopeless or helpless.
- You are more irritable, angry, or aggressive than usual.
- You are more or less hungry than usual or notice a big change in your body weight.
- You have trouble paying attention.
- You feel tired or sleepy all the time.
- You have thoughts about hurting yourself or ending your life.

What is Xenazine?

Xenazine is a medicine that is used to treat the involuntary movements (chorea) of Huntington's disease. Xenazine does not cure the cause of the involuntary movements, and it does not treat other symptoms of Huntington's disease, such as problems with thinking or emotions.

It is not known whether Xenazine is safe and effective in children.

Who should not take Xenazine?

Do not take Xenazine if you:

- are depressed or have thoughts of suicide. See "What is the most important information I should know about Xenazine?"
- have liver problems.

Please see Xenazine Medication Guide on pages 8-11.

- are taking a monoamine oxidase inhibitor (MAOI) medicine. Ask your doctor or pharmacist if you are not sure.
- are taking reserpine. **Do not take medicines that contain reserpine (such as Serpalan[®] and Renese[®]-R) with Xenazine. If your doctor plans to switch you from taking reserpine to Xenazine, you must wait at least 20 days after your last dose of reserpine before you start taking Xenazine.**

What should I tell my doctor before taking Xenazine?

Tell your doctor about all your medical conditions, including if you:

- have emotional or mental problems (for example, depression, nervousness, anxiety, anger, agitation, psychosis, previous suicidal thoughts or suicide attempts).
- have liver disease.
- have any allergies. See the end of this Medication Guide for a complete list of the ingredients in Xenazine.
- have breast cancer or a history of breast cancer.
- have heart disease that is not stable, have heart failure or recently had a heart attack.
- have an irregular heart beat (cardiac arrhythmia).
- are pregnant or plan to become pregnant. It is not known if Xenazine can harm your unborn baby.
- are breast-feeding. It is not known if Xenazine passes into breast milk.

Tell your doctor about all the medicines you take, including prescription medicines and nonprescription medicines, vitamins and herbal products. Using Xenazine with certain other medicines may cause serious side effects. **Do not start any new medicines while taking Xenazine without talking to your doctor first.**

How should I take Xenazine?

- Xenazine is a tablet that you take by mouth.
- **Take Xenazine exactly as prescribed by your doctor.**
- You may take Xenazine with or without food.
- Your doctor will increase your dose of Xenazine each week for several weeks, until you and your doctor find the best dose for you.
- If you stop taking Xenazine or miss a dose, your involuntary movements may return or worsen in 12 to 18 hours after the last dose.
- Before starting Xenazine, you should talk to your health care provider about what to do if you miss a dose. If you miss a dose and it is time for your next dose, do not double the dose.
- Tell your doctor if you stop taking Xenazine for more than **5 days. Do not take another dose until you talk to your doctor.**
- **If your doctor thinks you need to take more than 50 mg of Xenazine each day, you will need to have a blood test to see if it is safe for you.**

What should I avoid while taking Xenazine?

Sleepiness (sedation) is a common side effect of Xenazine. While taking Xenazine **do not drive a car or operate dangerous machinery until you know how Xenazine affects you.** Drinking alcohol and taking other drugs that may also cause sleepiness while you are taking Xenazine may increase any sleepiness caused by Xenazine.

Please see Xenazine Medication Guide on pages 8-11.

What are the possible side effects of Xenazine?

Xenazine can cause serious side effects, including:

- **Depression, suicidal thoughts, or actions.** See “What is the most important information I should know about Xenazine?”
- **Neuroleptic Malignant Syndrome (NMS).** Call your doctor right away and go to the nearest emergency room if you develop these signs and symptoms that do not have another obvious cause:
 - high fever
 - stiff muscles
 - problems thinking
 - very fast or uneven heartbeat
 - increased sweating
- **Parkinsonism.** Symptoms of Parkinsonism include: slight shaking, body stiffness, trouble moving or keeping your balance.
- **Restlessness.** You may get a condition where you feel a strong urge to move. This is called akathisia.
- **Trouble swallowing.** Xenazine may increase the chance that you will have trouble swallowing. Increased coughing may be the first sign that you are having trouble swallowing. Trouble swallowing increases your risk of pneumonia.
- **Irregular heartbeat.** Xenazine increases your chance of having certain changes in the electrical activity in your heart which can be seen on an electrocardiogram (EKG). These changes can lead to a dangerous abnormal heartbeat. Taking Xenazine with certain medicines may increase this chance.
- **Dizziness due to blood pressure changes when you change position (orthostatic hypotension).** Change positions slowly from lying down to sitting up and from sitting up to standing when taking Xenazine. Tell your doctor right away if you get dizzy or faint while taking Xenazine. Your doctor may need to watch your blood pressure closely.
- **Tardive dyskinesia (TD).** TD is a condition where there is repeated facial grimacing that cannot be controlled, sticking out of the tongue, smacking of the lips, puckering and pursing of the lips, and rapid eye blinking. Xenazine works like other drugs that can cause TD. If you get TD with Xenazine, it is possible that the TD will not go away.

Common side effects with Xenazine include:

- | | |
|-------------------------|----------------|
| • sleepiness (sedation) | • anxiety |
| • trouble sleeping | • restlessness |
| • depression | • agitation |
| • tiredness (fatigue) | • nausea |

Tell your doctor if you have any side effects. Do not stop taking Xenazine without talking to your doctor first.

Call your doctor for medical advice about side effects. You may report side effects to the Food and Drug Administration (FDA) at 1-800-FDA-1088.

General information about Xenazine

Xenazine contains the active ingredient tetrabenazine. It also contains these inactive ingredients: lactose, maize starch, talc, and magnesium stearate. The 25-mg tablet, which is pale yellow, also contains yellow iron oxide.

Medicines are sometimes prescribed for conditions that are not listed in a Medication Guide. Do not use Xenazine for a condition for which it was not prescribed. Do not give Xenazine to other people, even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about Xenazine. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about Xenazine that is written for healthcare professionals. You can also call the Xenazine Information Center at **1-888-882-6013** or visit **www.xenazineusa.com**.

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

Marketed by:



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Understanding Your Therapy With Xenazine* (tetrabenazine)

You will be given 2 guides to help you understand your therapy with Xenazine. The first is this guide, What You Need to Know About Xenazine® (tetrabenazine), which tells you about your treatment with Xenazine.

You will also be given the Xenazine® (tetrabenazine) Medication Guide every time your prescription is filled. The medication guide is a short version of this guide. You will also receive an Initial Dosing Plan.

For more information on your treatment with Xenazine, call the Xenazine Information Center at 1-888-882-6013 or visit www.xenazineusa.com on the Internet. All this information does not take the place of talking to your doctor about your medical condition or your treatment.

You Are Not Alone

Call the people listed below any time you have a question or are worried about your treatment with Xenazine. Talking to them may help you. Keep their phone numbers near your telephone.

- Your doctor or nurse: _____
- The Xenazine toll-free medical information line: 1-888-882-6013.

Do You Have Questions About
Your Treatment With Xenazine?
Call the Xenazine toll-free
medical information line
any time you have questions or worries.
1-888-882-6013
For more information about Xenazine,
visit our web site at www.xenazineusa.com

Xenazine[®]
(tetrabenazine)
12.5 and 25 mg Tablets



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