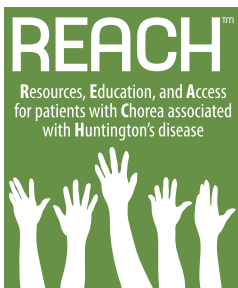


Note to Healthcare Professionals: Please provide this guide to your patient or your patient's caregiver.

# What You Need to Know About Xenazine® (tetrabenazine)

## Patient/Caregiver Counseling Guide



**Xenazine**®  
(tetrabenazine)  
12.5 and 25 mg Tablets

This guide explains Xenazine therapy, dosing, and potential side effects.

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## What Is the Important Safety Information About Xenazine?

- Xenazine (*ZEN-uh-zeen*) is a prescription medicine to treat involuntary movements of Huntington's disease (HD). Involuntary movements, also called chorea, are a major feature of HD.
- 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 HD, 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 HD 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 HD. The chance that these changes in mood or behavior may occur is increased in patients who are taking Xenazine.**

### What Are the Signs You May Be Depressed or at Risk for Suicide?

- Feel sad or have crying spells
- Lose interest in seeing your friends or doing things you used to enjoy
- Sleep a lot *more* or a lot *less* than usual
- Feel unimportant
- Feel guilty
- Feel hopeless or helpless
- Are more irritable, angry, or aggressive than usual
- Are *more* or *less* hungry than usual or notice a big change in your body weight
- Have trouble paying attention
- Feel tired or sleepy all the time
- Have thoughts about hurting yourself or ending your life

**Talk to your doctor if you have any of the signs of depression listed above.**

# What Is Xenazine?

Xenazine is a medication taken by mouth to treat involuntary movements of HD. Involuntary movements, also called chorea, are a major feature of HD. 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 HD, such as problems with thinking or emotions.

## How Does Xenazine Work?

Doctors are not sure what causes chorea or how Xenazine reduces chorea. Overactivity of a chemical in the brain, dopamine (*DOH-puh-meen*), may cause 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. See “What Is the Important Safety Information About Xenazine?” on page 2 for more details.
- Have liver problems
- Are taking monoamine oxidase (MAO) inhibitor medicine
  - Examples of MAO inhibitors are Nardil® (phenelzine), Eldepryl® (selegiline), and Parnate® (tranylcypromine)
- Are taking reserpine or medicine that contains reserpine
  - Examples of medicines that contain reserpine are Serpalan® or Renese®-R

You must stop taking reserpine for at least 20 days before you begin treatment 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:

### Physical conditions

- Liver problems
- Allergies to any of the ingredients in Xenazine tablets
  - Please see the Xenazine Medication Guide – General Information About Xenazine for a complete list of ingredients in Xenazine
- 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.
- Irregular heartbeat (cardiac arrhythmia)
- Pregnant or plan to become pregnant
  - The effect of Xenazine on an unborn baby is not known
- Nursing a baby
  - It is not known if Xenazine passes into breast milk

### 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

## 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 medications
- Change the dose of any of your medications
- Stop taking any of your medications

# What to Expect When Taking Xenazine

## 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.
- 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.
- Xenazine is a tablet you take by mouth. You may take it with or without food. Xenazine is available in 2 strengths: a white tablet with 12.5 mg of Xenazine and a pale yellow tablet with 25 mg of Xenazine.
- 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
- For most patients, the maximum recommended daily dose is 100 mg. For some patients, the maximum daily dose may be 50 mg.
- **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**

## Skipping or Stopping Xenazine

- You should talk to your doctor 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 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.

## While Taking Xenazine

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

- 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 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.

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

Call your doctor if you have any of the side effects listed below or any other possible side effects not listed. 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.**

## What Are the Possible Side Effects With Xenazine?

**Xenazine can cause serious side effects, including:**

- **Depression or thoughts of suicide.** Xenazine may worsen your mood or ability to think clearly. It may be difficult to tell if these side effects are due to HD 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 “What Is the Important Safety Information About Xenazine?” on page 2.)

**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. 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.

The signs of NMS are:

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

- **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 HD, it may be difficult to tell if this side effect is due to HD or Xenazine. If you develop the signs of parkinsonism, your doctor may reduce your dose of Xenazine or stop treatment 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.

→ **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.

→ **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.

→ **Tardive dyskinesia.** Tardive dyskinesia (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.

### 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.**

## Understanding Your Treatment With Xenazine

You will be given 2 guides to help you understand your therapy with Xenazine. This is the first guide, **What You Need to Know About Xenazine: Patient/Caregiver Counseling Guide**, which tells you about your treatment with Xenazine.

You will also be given the **Xenazine Medication Guide** every time your prescription is filled. The Medication Guide is a short version of this guide. 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.

For more information on your treatment with Xenazine, call the Xenazine Information Center at 1-888-882-6013 or visit [www.XenazineUSA.com](http://www.XenazineUSA.com).

### 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 toll-free Xenazine Information Center: 1-888-882-6013





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(tetrabenazine)  
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