

Patient Information
Guanfacine (GWAHN fa seen)
Extended-Release Tablets, USP
Rx only

Read the Patient Information that comes with guanfacine extended-release tablets before you start taking it and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your doctor about your medical condition or your treatment.

What are guanfacine extended-release tablets?

Guanfacine extended-release tablets are a prescription medicine used to treat the symptoms of attention deficit hyperactivity disorder (ADHD). Guanfacine extended-release tablets may be used alone or with ADHD stimulant medicines. Guanfacine extended-release tablets are not a central nervous system (CNS) stimulant.

It is not known if guanfacine extended-release tablets are safe and effective in children younger than 6 years of age.

Who should not take guanfacine extended-release tablets?

Do not take guanfacine extended-release tablets if you are allergic to guanfacine or any of the ingredients in guanfacine extended-release tablets. See the end of this leaflet for a complete list of ingredients in guanfacine extended-release tablets.

What should I tell my doctor before taking guanfacine extended-release tablets?

Before you take guanfacine extended-release tablets, tell your doctor if you:

- have heart problems or a low heart rate
- have fainted
- have low or high blood pressure
- have liver or kidney problems
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if guanfacine extended-release tablets will harm your unborn baby. Talk to your doctor if you are pregnant or plan to become pregnant.
 - There is a pregnancy registry for females who are exposed to ADHD medications, including guanfacine extended-release tablets, during pregnancy. The purpose of the registry is to collect information about the health of females exposed to guanfacine extended-release tablets and their baby. If you or your child becomes pregnant during treatment with guanfacine extended-release tablets, talk to your healthcare provider about registering with the National Pregnancy Registry of ADHD medications at 1-866-961-2388.
- are breastfeeding or plan to breastfeed. It is not known if guanfacine passes into your breast milk. Talk to your doctor about the best way to feed your baby while taking

guanfacine extended-release tablets.

Tell your doctor about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Guanfacine extended-release tablets may affect the way other medicines work, and other medicines may affect how guanfacine extended-release tablets work.

Especially tell your doctor if you take:

- ketoconazole
- medicines that can affect enzyme metabolism
- high blood pressure medicine
- sedatives
- benzodiazepines
- barbiturates
- antipsychotics

Ask your doctor or pharmacist for a list of these medicines, if you are not sure.

Know the medicines you take. Keep a list of them and show it to your doctor and pharmacist when you get a new medicine.

How should I take guanfacine extended-release tablets?

- Take guanfacine extended-release tablets exactly as your doctor tells you.
- Your doctor may change your dose. Do not change your dose of guanfacine extended-release tablets without talking to your doctor.
- Do not stop taking guanfacine extended-release tablets without talking to your doctor.
- Try not to miss your dose of guanfacine extended-release tablets. If you miss a dose of guanfacine extended-release tablets, take the next dose at your regular time. If you miss 2 or more doses, talk to your doctor, as you may need to restart guanfacine extended-release tablets with a lower dose.
- Do not take a double dose to make up for a missed dose.
- Guanfacine extended-release tablets should be taken 1 time a day in the morning or in the evening, either alone or in combination with an ADHD stimulant medicine that your doctor may prescribe. Your doctor will tell you when to take guanfacine extended-release tablets and when to take your ADHD stimulant medication.
- Guanfacine extended-release tablets should be swallowed whole with a small amount of water, milk, or other liquid.
- Do not crush, chew, or break guanfacine extended-release tablets. Tell your doctor if you cannot swallow guanfacine extended-release tablets whole.
- Do not take guanfacine extended-release tablets with a high-fat meal.
- Your doctor will check your blood pressure and heart rate while you take guanfacine extended-release tablets.
- If you take too much guanfacine extended-release tablets,

PIL Size : 150 x 200 mm

Font Size : 10 Pt.

Track : A10/12/2024

call your local Poison Control Center at 1-800-222-1222 or go to the nearest emergency room right away.

What should I avoid while taking guanfacine extended-release tablets?

- Do not drive, operate heavy machinery, or do other dangerous activities until you know how guanfacine extended-release tablets affects you. Guanfacine extended-release tablets can slow your thinking and motor skills.
- Do not drink alcohol or take other medicines that make you sleepy or dizzy while taking guanfacine extended-release tablets until you talk with your doctor. Guanfacine extended-release tablets taken with alcohol or medicines that cause sleepiness or dizziness may make your sleepiness or dizziness worse.
- Do not become dehydrated or overheated. This may increase your chance of having low blood pressure or fainting while taking guanfacine extended-release tablets.
- Do not suddenly stop guanfacine extended-release tablets. Tell your healthcare provider if you have been vomiting and cannot take guanfacine extended-release tablets, you may be at risk for rebound hypertension.

What are the possible side effects of guanfacine extended-release tablets?

Guanfacine extended-release tablets may cause serious side effects including:

- low blood pressure
- low heart rate
- fainting
- sleepiness
- increased blood pressure and heart rate after suddenly stopping guanfacine extended-release tablets (rebound hypertension). Suddenly stopping guanfacine extended-release tablets can cause increased blood pressure and heart rate and other withdrawal symptoms such as headache, confusion, nervousness, agitation, and tremors. If these symptoms continue to get worse and are left untreated, it could lead to a very serious condition including very high blood pressure, feeling very sleepy or tired, severe headache, vomiting, vision problems, seizures.

Get medical help right away, if you have any of the symptoms listed above.

The most common side effects of guanfacine extended-release tablets include:

- sleepiness
- tiredness
- trouble sleeping
- low blood pressure
- nausea
- stomach pain
- dizziness

- dry mouth
- irritability
- vomiting
- slow heart rate

Tell the doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of guanfacine extended-release tablets. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at **1-800-FDA-1088**.

How should I store guanfacine extended-release tablets?

- Store guanfacine extended-release tablets between 68° to 77° F (20° to 25° C).

Keep guanfacine extended-release tablets and all medicines out of the reach of children.

General Information about the safe and effective use of guanfacine extended-release tablets

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information Leaflet. Do not use guanfacine extended-release tablets for a condition for which it was not prescribed. Do not give guanfacine extended-release tablets to other people, even if they have the same symptoms that you have. It may harm them.

This leaflet summarizes the most important information about guanfacine extended-release tablets. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about guanfacine extended-release tablets that is written for health professionals.

For more information, call **1-800-818-4555**.

What are the ingredients in guanfacine extended-release tablets?

Active ingredient: guanfacine hydrochloride, USP

Inactive ingredients: colloidal silicon dioxide, fumaric acid, glyceryl dibehenate, hypromellose, lactose monohydrate, methacrylic acid copolymer, microcrystalline cellulose, and povidone. In addition, the 3 mg and 4 mg tablets also contain FD&C blue #2/indigo carmine aluminum lake, and ferric oxide yellow.

This Patient Information has been approved by the U.S. Food and Drug Administration.

Manufactured by:
Ohm Laboratories Inc.
New Brunswick, NJ 08901

Distributed by:
Sun Pharmaceutical Industries, Inc.
Cranbury, NJ 08512

August 2023

FDA-09