

GUANFACINE VIATRIS

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

1. Why am I using GUANFACINE VIATRIS?

GUANFACINE VIATRIS contains the active ingredient guanfacine hydrochloride. GUANFACINE VIATRIS is used to treat the symptoms of Attention Deficit Hyperactivity Disorder (ADHD) in children and adolescents.

For more information, see Section [1. Why am I using GUANFACINE VIATRIS?](#) in the full CMI.

2. What should I know before I use GUANFACINE VIATRIS?

Do not use if you have ever had an allergic reaction to GUANFACINE VIATRIS or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, have history or current mental health problems, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use GUANFACINE VIATRIS?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with GUANFACINE VIATRIS and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use GUANFACINE VIATRIS?

- Your doctor will tell you what dose to take each day based on you/your child's body weight and the dose if it is used together with a stimulant medicine.
- Swallow the tablet whole with a full glass of water. Do not break, crush or chew the tablet. Follow all directions given to you by your doctor or pharmacist carefully.

More instructions can be found in Section [4. How do I use GUANFACINE VIATRIS?](#) in the full CMI.

5. What should I know while using GUANFACINE VIATRIS? ("You" means either yourself or your child)

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using GUANFACINE VIATRIS. If you become pregnant while using this medicine, tell the doctor immediately.
Things you should not do	• Do not stop using this medicine or change dosage without checking with your doctor.
Driving or using machines	• Be careful driving or operating machinery until you know how GUANFACINE VIATRIS affects you.
Drinking alcohol	• Be careful when drinking alcohol while taking GUANFACINE VIATRIS because it could make you sleepy and drowsy.
Looking after your medicine	• Store GUANFACINE VIATRIS in a cool dry place where the

	temperature is below 25°C.
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For more information, see Section [5. What should I know while using GUANFACINE VIATRIS?](#) in the full CMI.

6. Are there any side effects?

Common side effects include feeling drowsy, headache, restless, trouble sleeping, weight gain, loss of appetite, dry mouth, diarrhoea, constipation. Serious side effects include allergic reaction, chest pain, seizures, loss of strength, need to urinate frequently, itchy skin, high blood pressure, irregular heart rhythms.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

GUANFACINE VIATRIS

Active ingredient(s): *guanfacine hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about using GUANFACINE VIATRIS. It does not take the place of talking to your doctor or pharmacist. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using GUANFACINE VIATRIS.** The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available. You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on this medicine.

Where to find information in this leaflet:

- [1. Why am I using GUANFACINE VIATRIS?](#)
- [2. What should I know before I use GUANFACINE VIATRIS?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use GUANFACINE VIATRIS?](#)
- [5. What should I know while using GUANFACINE VIATRIS?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using GUANFACINE VIATRIS?

GUANFACINE VIATRIS contains the active ingredient guanfacine hydrochloride.

GUANFACINE VIATRIS is a medicine used to treat the symptoms of Attention Deficit Hyperactivity Disorder (ADHD) in children and adolescents 6-17 years old. It can be used alone or with another medicine called a psychostimulant. GUANFACINE VIATRIS can help improve your attention, concentration and make you less impulsive and hyperactive.

GUANFACINE VIATRIS should be used as part of a comprehensive treatment program which usually includes psychological, educational and social therapy.

This medicine is not addictive.

2. What should I know before I use GUANFACINE VIATRIS?

Warnings

Do not use GUANFACINE VIATRIS if:

- you are allergic to guanfacine hydrochloride, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

- Do not give this medicine to a child under the age of 6 years. Do not use if you are an adult or are elderly. Safety and effectiveness in children younger than 6 years, and adults and the elderly have not been established.

Check with your doctor if you/your child:

- have heart problems or a low heart rate
- have fainted
- have low blood pressure
- have history or current suicidal thoughts or behaviour
- have liver or kidney problems
- have any other medical conditions or take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you/your child are pregnant or intend to become pregnant.

Talk to your doctor if you/your child are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may be affected by GUANFACINE VIATRIS or may affect how well GUANFACINE VIATRIS works.

You/your child may need different amounts of your medicines, or you/your child may need to take different medicines. These include:

- medicines that lower blood pressure (antihypertensives)
- medicines used to treat epilepsy such as valproic acid
- medicines that make you sleepy
- medicines for mental health problems such as sedatives, benzodiazepines, barbiturates and antipsychotics
- medicines that can affect liver metabolism such as ketoconazole, rifampin
- medicines that can affect enzyme metabolism
- medicines that contain metformin (used for treatment of type 2 diabetes).

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect GUANFACINE VIATRIS.

4. How do I use GUANFACINE VIATRIS?

How much to take

- Your doctor will normally start you/your child on a low dose. Your doctor will increase the dose based on you/your child's body weight and how GUANFACINE VIATRIS is working for you/your child. Your doctor will tell you what dose to take each day and will calculate the dose based on your/your child's body weight. The daily dose will be between 1-7 mg, but not more than 7 mg. When used together with a stimulant, the usual daily recommended dose is not more than 4 mg.
- Follow the instructions provided and use GUANFACINE VIATRIS until your doctor tells you to stop.

When to take GUANFACINE VIATRIS

- Take GUANFACINE VIATRIS once a day either in the morning or evening.

How to take GUANFACINE VIATRIS

- GUANFACINE VIATRIS can be taken with or without food. Swallow the tablet whole with a full glass of water. Do not break, crush or chew the tablet.
- Do not take GUANFACINE VIATRIS with fatty foods
- Do not eat or drink products and juices containing grapefruit while you/your child are being treated with GUANFACINE VIATRIS. It may interact

with GUANFACINE VIATRIS and affect how GUANFACINE VIATRIS works in the body.

If you/your child forget(s) to use GUANFACINE VIATRIS

GUANFACINE VIATRIS should be used regularly at the same time each day. If you/your child miss(es) a dose, wait until the next day and take the usual dose.

Do not take a double dose to make up for the dose you/your child missed.

If you use too much GUANFACINE VIATRIS

If you think that you/your child have/has used too much GUANFACINE VIATRIS, you/your child may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

Some of the signs and symptoms of an overdose may include high blood pressure at the beginning turning into low blood pressure, slow heart rate, lack of energy, difficulty breathing.

5. What should I know while using GUANFACINE VIATRIS?

Things you should do

- Make sure that all of your doctors, dentists, and pharmacists know you/your child are taking GUANFACINE VIATRIS. Remind them if any new medicines are about to be started.
- If you/your child become pregnant while taking this medicine, tell your doctor immediately.
- If you/your child have a gastrointestinal illness that leads to vomiting, tell your doctor. This can be like missing doses which could lead to an increase in blood pressure or heart rate.
- All thoughts of suicide must be taken seriously. Talk to your doctor or mental health professional if you/your child have thoughts or talk about death or suicide; or thoughts or talk about self-harm or doing harm to others.
- Keep all of your/your child's doctor's appointments so that your/your child's progress can be checked. Your doctor will want to check your/your child's height and weight, and blood pressure and heart rate at least once a year or when your/your child's dose is changed or stopped to make sure the medicine is working and to prevent unwanted side effects.

Things you/your child should not do

- Do not stop using this medicine suddenly or lower the dosage without checking with your doctor. If GUANFACINE VIATRIS is stopped suddenly, your/your child's condition may worsen or your/your child's blood pressure and heart rate may increase.
- Do not take GUANFACINE VIATRIS to treat any other complaints unless your doctor tells you to.
- Do not give GUANFACINE VIATRIS to anyone else, even if they have the same condition as you/your child.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how GUANFACINE VIATRIS affects you.

This medicine may cause dizziness, light-headedness, tiredness, drowsiness in some people. If you/your child have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous. Children should be careful when riding bicycles or climbing trees.

Drinking alcohol

Tell your doctor if you drink alcohol.

Be careful when drinking alcohol while taking GUANFACINE VIATRIS because it could make you sleepy and drowsy.

Looking after your medicine

Keep GUANFACINE VIATRIS tablets in the pack until it is time to take them. Store GUANFACINE VIATRIS in a cool dry place where the temperature stays below 25°C.

Do not store it in the bathroom or near a sink, or in the car or on windowsill.

Do not use this medicine after the expiry date.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• feeling sleepy or very drowsy • feeling tired or weary • headache • stomach pain • feeling restless or irritable • trouble sleeping or broken sleep or nightmares • feeling depressed, worried or having mood swings • new or worse aggressive behaviour, hostility • weight gain • loss of appetite • have a dry mouth • wetting yourself • feeling or being sick • diarrhoea, indigestion (upset stomach) or constipation • slow heartbeat	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
• asthma • rash • feeling dizzy or faint	

Serious side effects

Serious side effects	What to do
• allergic reaction which may result in a rash or more rarely to a sharp drop in blood pressure, difficulty breathing, and hives/itching (anaphylactic reaction) • chest pain • seizures (fits) or convulsions • fainting • trouble breathing • low blood pressure or feeling dizzy when standing up • pale skin colour • high blood pressure or an unusual heart rhythm • fast heartbeat	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Serious side effects	What to do
• itchy skin • need to urinate frequently • feeling agitated • hallucinations • sleeping more than normal • changes in liver blood test results • loss of strength • suicidal thoughts or behaviour	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you/your child experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What GUANFACINE VIATRIS contains

Active ingredient (main ingredient)	Guanfacine hydrochloride
Other ingredients (inactive ingredients)	Methacrylic acid - ethyl acrylate copolymer (1:1) hypromellose lactose monohydrate povidone crospovidone microcrystalline cellulose glycerol dibehenate macrogol 6000 silica colloidal anhydrous magnesium stearate indigo carmine aluminium lake & iron oxide yellow (in 3 mg and 4 mg tablets)

Do not take this medicine if you are allergic to any of these ingredients.

What GUANFACINE VIATRIS looks like

GUANFACINE VIATRIS 1 mg tablet: White to off white colour, round shaped, biconvex tablet debossed with 'G1' on one side and plain on the other side.

GUANFACINE VIATRIS 2 mg tablet: White to off white colour, oval shaped, biconvex tablet debossed with 'G2' on one side and plain on the other side.

GUANFACINE VIATRIS 3 mg tablet: Light green to green colour, round shaped, biconvex tablet debossed with 'G3' on one side and plain on the other side.

GUANFACINE VIATRIS 4 mg tablet: Light green to green colour, oval shaped, biconvex tablet debossed with 'G4' on one side and plain on the other side.

GUANFACINE VIATRIS is supplied as a 28 tablet blister pack and 28 tablet bottle pack sizes.

Who distributes GUANFACINE VIATRIS

Sponsor

Maple Healthcare Pty Ltd

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Melbourne VIC 3000 Australia

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