Package leaflet: Information for the user

Guanfacine 1 mg prolonged-release tablets
Guanfacine 2 mg prolonged-release tablets
Guanfacine 3 mg prolonged-release tablets
Guanfacine 4 mg prolonged-release tablets
Guanfacine 5 mg prolonged-release tablets
Guanfacine 6 mg prolonged-release tablets
Guanfacine 7 mg prolonged-release tablets

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- This leaflet has been written as though the person taking the medicine is reading it. If you are giving this medicine to your child, please replace "you" with "your child" throughout.

What is in this leaflet:

1. What Guanfacine is and what it is used for
2. What you need to know before you take Guanfacine
3. How to take Guanfacine
4. Possible side effects
5. How to store Guanfacine
6. Contents of the pack and other information

1. What Guanfacine is and what it is used for

What Guanfacine is

Guanfacine contains the active substance guanfacine. This medicine belongs to a group of medicines which affects brain activity. This medicine can help improve your attention, concentration and make you less impulsive and hyperactive.

What Guanfacine is used for

This medicine is used to treat 'attention deficit hyperactivity disorder' (ADHD) in children and adolescents 6-17 years old for whom current stimulant medication is not appropriate and/or current medication does not adequately control ADHD symptoms.

The medicine is given as part of a treatment programme, which usually includes the following:
- psychological therapy
- educational therapy
- social therapy

About ADHD

People with ADHD find it hard to:
- sit still
- concentrate.

ADHD can cause problems with everyday life. Children and young people with ADHD may have

difficulty learning and doing homework. They can find it hard to behave well at home, at school or in other places.

2. What you need to know before you take Guanfacine

Do not take Guanfacine if:

- you are allergic to guanfacine or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine if:

- you have low or high blood pressure, heart problems or have a family history of heart problems
- you have fainted recently
- you have thoughts or feelings of suicide
- you suffer from any other psychiatric conditions

Talk to your doctor or pharmacist if you are taking this medicine and:

- experience aggressive feelings or behaviour, or
- have suicidal thoughts or feelings

Guanfacine may affect your weight and height if taking for long periods, your doctor will therefore monitor your growth.

Do not stop taking Guanfacine without talking to your doctor. If you suddenly stop taking Guanfacine, you may develop withdrawal symptoms of increased heart rate and high blood pressure (see section 4).

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking this medicine. This is because this medicine can make these problems worse. Your doctor will routinely monitor you to see how this medicine affects you.

Children (under 6 years old) and adults (18 years and over)

This medicine should not be used in children under 6 years of age and adults 18 years and over because it is not known if it works or is safe.

Checks your doctor will do when you take Guanfacine

Before you start taking this medicine your doctor will check to make sure this medicine is safe for you and that it will help you. While you are taking this medicine your doctor will repeat these checks weekly during initial dosing, after dose adjustments, at least every 3 months for the first year and then at least twice a year. These checks may include:

- your blood pressure and heart rate and other checks on your heart if appropriate
- your response to treatment, in particular if it makes you sleepy or drowsy
- your height and weight

You should talk to your doctor if you do not feel better or if you feel worse and very sleepy or drowsy after taking this medicine for around 6 weeks. Your doctor may want to review your treatment.

Other medicines and Guanfacine

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because Guanfacine and some other medicines can affect each other.

In particular, tell your doctor or pharmacist if you are taking any of the following types of medicines:

- medicines that lower your blood pressure (antihypertensives)
- medicines for epilepsy such as valproic acid

- medicines that make you sleepy (sedatives)
- medicines for mental health problems (benzodiazepines, barbiturates and antipsychotics)
- medicines that can affect the way Guanfacine is eliminated by the liver (please see table below)

Medicines	**Used to treat**
Aprepitant	Nausea and vertigo.
Atazanavir, efavirenz, etravirine, fosamprenavir, indinavir, nevirapine, ritonavir, saquinavir	HIV infection.
Ciprofloxacin, chloramphenicol, clarithromycin, erythromycin, rifabutin, rifampicin, telithromycin	Bacterial infections.
Fluconazole, itraconazole, posaconazole, ketoconazole	Fungal infections.
Crizotinib, imatinib	Cancer.
Diltiazem, verapamil	Cardiovascular conditions.
Boceprevir, telaprevir	Viral hepatitis.
Suboxone	Substance dependence.
Bosentan	Cardiovascular conditions (e.g. constriction of blood vessels in the lung).
Carbamazepine, oxcarbazepine, phenobarbital, phenytoin, primidone	Used to control epilepsy.
Modafinil	Is a medicine that promotes alertness and is used to treat sleep disorders.
St. John's Wort	Is a herbal preparation that is used to treat depression.

If any of the above apply to you or you are not sure, talk to your doctor or pharmacist before taking this medicine.

Guanfacine with food, drinks and alcohol

- Do not take this medicine with fatty foods (e.g., high fat breakfast), as it may affect the way this medicine works.
- Do not take grapefruit juice with this medicine as it can have an effect on the way this medicine works.
- Do not drink alcohol when taking this medicine as it may make you sleepy or drowsy.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

- Do not take this medicine if you are pregnant or you are not using contraception. It is not known if Guanfacine will affect your unborn baby.
- Do not breast-feed while taking Guanfacine unless told to do so by your doctor.

Driving and using machines

You may feel dizzy and drowsy when taking this medicine, especially at the start of treatment and this may last for 2 to 3 weeks possibly longer. If this happens, do not drive, cycle, use any tools or machines or participate in activities that could cause injury until you know how this medicine affects you. Fainting has also been reported but is not a common effect.

Guanfacine contains lactose

Lactose is a type of sugar. If you have been told by your doctor that you have an intolerance to some

sugars, contact your doctor before taking this medicine.

Guanfacine contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Guanfacine

Your treatment will start under the supervision of an appropriate specialist in childhood and/or adolescent behavioural disorders.

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

As part of your treatment your doctor will closely monitor how Guanfacine is affecting you during initial dosing and/or dose adjustments.

How much to take

- Your doctor will start you on 1 mg per day. Your doctor may increase your dose based on your body weight and how Guanfacine is working for you but not by more than 1 mg per week. Depending on how you respond to treatment your doctor may increase your dose more slowly. The recommended maintenance dose is between 0.05 up to 0.12 mg per kg of bodyweight per day.
- You may not notice an immediate effect upon starting treatment, some patients may notice an improvement after the first week but it could take longer.
- Your daily dose will be between 1 and 7 mg depending on your age and how you respond to Guanfacine, but not more that 7 mg.

How to take Guanfacine

- This medicine should be taken once a day either in the morning or evening.
- It can be taken with or without food, but do not take it with fatty foods (e.g., high fat breakfast).
- Swallow the tablet whole with a drink of water or other liquid (but not grapefruit juice).
- Do not break, crush or chew the tablet; this will affect how the tablet works. Tell your doctor if you cannot swallow the tablet whole.

Duration of treatment

If you need to take Guanfacine for more than a year your doctor will monitor your response to treatment and your doctor may stop the medicine for a short time; this may happen during a school holiday. This will show if you still need to take the medicine.

If you take more Guanfacine than you should

If you take more Guanfacine than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you and tell them how much you have taken.

The following effects may happen: low or high blood pressure, slow heart rate, slow breathing rate, feeling tired or exhausted.

If you forget to take Guanfacine

If you forget a dose, wait until the next day and take your usual dose.

- If you have missed two or more doses talk to your doctor as you may need to restart

Guanfacine with a lower dose.
- Do not take a double dose to make up for a forgotten dose.

If you stop taking Guanfacine

Do not stop taking this medicine without first talking to your doctor.
- If you stop taking this medicine your blood pressure and heart rate may increase (see section 4 below).
- To stop the medicine, your doctor will slowly reduce your Guanfacine dose to minimise any side effects.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. If you are worried, speak to your doctor.

If you feel unwell in any way while you are taking your medicine please tell an adult straight away.

Serious side effects

The following serious side effects have been reported: feeling drowsy (sedation), feeling dizzy (hypotension), slow heart beat (bradycardia), feeling faint or loss of conciousness (syncope), a serious withdrawal side effect of high blood pressure after suddenly stopping Guanfacine; symptoms may include headaches, feeling confused, nervousness, agitation, and tremors (hypertensive encephalopathy).

Some of these side effects are more likely to occur at the start of treatment and may disappear as you continue with your treatment, if you experience any of these side effects contact your doctor straight away.

Other side effects

The following side effects have been reported.

Very common (may affect more than 1 in 10 people)
- feeling sleepy (somnolence)
- feeling tired (fatigue)
- headache
- tummy pain (abdominal pain).

Common (may affect up to 1 in 10 people)
- low heart rate
- blood pressure decreased
- feeling restless or irritable
- trouble sleeping (insomnia) or broken sleep (middle insomnia) or nightmares
- feeling depressed, worried (anxiety) or having mood swings (affect lability)
- lack of energy (lethargy)
- weight gain
- loss of appetite
- have a dry mouth
- wetting yourself (enuresis)
- feeling (nausea) or being sick (vomiting)
- diarrhoea, abdominal discomfort or constipation
- low blood pressure when standing up (orthostatic hypotension)

- rash.

Uncommon (may affect up to 1 in 100 people)
- allergic reaction (hypersensitivity)
- chest pain
- indigestion (dyspepsia)
- trouble breathing (asthma)
- feeling weak (asthenia)
- pale skin colour (pallor)
- fits or convulsions
- need to urinate frequently (pollakiuria)
- feeling agitated
- aggression
- changes in liver blood test results (increased alanine aminotransferase)
- increase in blood pressure
- unusual heart rhythm (sinus arrhythmia and first-degree arterioventricular block)
- fast heart beat (tachycardia)
- reduced heart rate
- feeling dizzy when standing up (postural dizziness)
- itchy skin (pruritus)
- seeing or hearing things that are not there (hallucination).

Rare (may affect up to 1 in 1,000 people)
- sleeping more than normal (hypersomnia)
- high blood pressure (hypertension)
- feeling unwell (malaise).

Very rare (may affect up to 1 in 10,000 people)
- a serious withdrawal side effect of high blood pressure after suddenly stopping Guanfacine; symptoms may include headaches, feeling confused, nervousness, agitation, and tremors (hypertensive encephalopathy).

Not known (frequency cannot be estimated from the available data)
- difficulty to get or keep an erection (erectile dysfunction).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Guanfacine

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister pack after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Do not use this medicine if the tablets or blister pack look damaged.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to

throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Guanfacine contains

- Each 1 mg tablet contains guanfacine hydrochloride equivalent to 1 mg of guanfacine
- Each 2 mg tablet contains guanfacine hydrochloride equivalent to 2 mg of guanfacine
- Each 3 mg tablet contains guanfacine hydrochloride equivalent to 3 mg of guanfacine
- Each 4 mg tablet contains guanfacine hydrochloride equivalent to 4 mg of guanfacine
- Each 5 mg tablet contains guanfacine hydrochloride equivalent to 5 mg of guanfacine
- Each 6 mg tablet contains guanfacine hydrochloride equivalent to 6 mg of guanfacine
- Each 7 mg tablet contains guanfacine hydrochloride equivalent to 7 mg of guanfacine

The other ingredients are Hypromellose (2208), methacrylic acid-ethyl acrylate copolymer (Type A), lactose monohydrate, povidone K-30, crospovidone (Type A), microcrystalline cellulose, silica colloidal anhydrous, sodium laurilsulfate, polysorbate 80, fumaric acid, glycerol dibehenate.

What Guanfacine looks like and contents of the pack

Guanfacine is a prolonged-release tablet which means that the active substance is released from the tablet over a period of time. The tablets come in pack sizes of 28.

- The 1 mg prolonged-release tablets are white, 8 mm diameter round, biconvex tablets with the inscription “1” on one side.
- The 2 mg prolonged-release tablets are white, 14 x 6 mm oblong, biconvex tablets with the inscription “II” on one side.
- The 3 mg prolonged-release tablets are white, 6 mm diameter round, biconvex tablets with the inscription “3” on one side.
- The 4 mg prolonged-release tablets are white, 7 mm diameter round, biconvex tablets with the inscription “IV” on one side.
- The 5 mg prolonged-release tablets are white, 8 mm diameter round, biconvex tablets with the inscription “V” on one side.
- The 6 mg prolonged-release tablets are white, 9 mm diameter round, biconvex tablets with the inscription “VI” on one side.
- The 7 mg prolonged-release tablets are white, 12.5 x 6.5 mm oblong, biconvex tablets with the inscription “7” on one side.

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