

## FLUOXETINE-GA

fluoxetine hydrochloride 20 mg

### Consumer Medicine Information

#### What is in this leaflet

This leaflet answers some common questions about Fluoxetine-GA.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Fluoxetine-GA against the benefits they expect it will have for you.

**If you have any concerns about taking this medicine, talk to your doctor or pharmacist.**

**Keep this leaflet with the medicine.** You may need to read it again.

#### What Fluoxetine-GA is used for

The name of your medicine is Fluoxetine-GA. It contains the active ingredient fluoxetine hydrochloride.

Fluoxetine-GA is used to treat depression.

Depression is longer lasting and/or more severe than the "low moods" everyone has from time to time due to the stress of everyday life.

Depression is thought to be caused by a chemical imbalance in parts of the brain. This imbalance affects your whole body and can cause emotional and physical symptoms such as feeling low in spirit, being unable to enjoy life, poor appetite or overeating, disturbed sleep, loss of sex drive, lack of energy and feelings of guilt.

Fluoxetine-GA belongs to a group of medicines called selective serotonin reuptake inhibitors (SSRIs). These medicines work by acting on certain brain chemicals and may help to relieve the physical and emotional symptoms of depression.

Fluoxetine-GA is also used to treat a condition known as obsessive compulsive disorder (OCD). The symptoms of OCD vary from patient to patient. Check with your doctor if you need more information.

Your doctor may have prescribed Fluoxetine-GA for another reason. Ask your doctor if you have any questions about why Fluoxetine-GA has been prescribed for you.

Fluoxetine-GA is available only with a doctor's prescription.

Fluoxetine-GA is not recommended for use in children and adolescents under 18 years of age.

#### Before you take Fluoxetine-GA

##### *When you must not take it*

**Do not take Fluoxetine-GA if you are allergic to any medicine containing fluoxetine or any of the ingredients listed at the end of this leaflet.**

Signs of an allergic reaction may include asthma, wheezing, shortness of breath, swelling of the face, lips or tongue or other parts of the body which may cause difficulty in swallowing or breathing, hives, itching or skin rash or fainting.

**Do not take Fluoxetine-GA if you are taking another medicine called a monoamine oxidase inhibitor (MAOI) such as moclobemide (e.g. Aurorix), phenelzine (e.g. Nardil), selegiline (e.g.**

**Eldepryl) or tranlycypromine (e.g. Parnate), or have been taking a monoamine oxidase inhibitor medicine within the last 14 days.**

Taking Fluoxetine-GA with a MAOI may cause a serious reaction with a sudden increase in body temperature, shivering, shaking (tremor) muscle stiffness, extremely high blood pressure and rapid breathing or confusion.

**Do not take Fluoxetine-GA if you are taking pimozide (e.g. Orap). Taking pimozide together with Fluoxetine-GA may alter the rhythm of your heart.**

**Ask your doctor or pharmacist if you are not sure if you have been taking one of these medicines.**

**Do not take Fluoxetine-GA after the expiry date printed on the pack.**

**Do not take Fluoxetine-GA if the packaging is torn or shows signs of tampering or if the capsules do not look quite right.**

**If you are not sure whether you should start taking Fluoxetine-GA, talk to your doctor.**

##### *Before you start to take it*

**Tell your doctor if you have any allergies to:**

- any other medicines, including any other antidepressant medicines
- any other substances, such as foods, preservatives or dyes

**Tell your doctor if you are pregnant or intend to become pregnant.**

Fluoxetine-GA may affect your developing baby if you take it during pregnancy. Your doctor will discuss the risks and benefits of using Fluoxetine-GA during pregnancy.

**Tell your doctor if you are breast-feeding or intend to breast-feed.**

The use of Fluoxetine-GA is not recommended during breast-feeding. Fluoxetine-GA passes into breast milk and may affect the breast-fed baby.

**Tell your doctor if you have or have had any medical conditions, especially the following:**

- kidney problems
- liver problems
- diabetes
- fits
- a bleeding disorder or a tendency to bleed more than usual.

**If you have not told your doctor about any of the above, tell them before you use Fluoxetine-GA.**

**Tell your doctor if you drink alcohol. Your doctor may suggest avoiding alcohol while you are being treated for depression.**

**Use in children and adolescents (<18 years)**

The safety and effectiveness of Fluoxetine-GA for the treatment of children and adolescents less than 18 years of age has not been established. Fluoxetine-GA is not recommended for use in children and adolescents less than 18 years of age.

##### *Taking other medicines*

**Tell your doctor if you are taking any other medicines, including any medicines**

**you buy without a prescription from a pharmacy, supermarket or health food shop.**

Some medicines may interfere with Fluoxetine-GA. These include:

- other medicines for depression or OCD
- selegiline (e.g. Eldepryl, Selgene). **You should stop taking selegiline or any antidepressant medication such as monoamine oxidase inhibitor medicines at least two weeks before starting Fluoxetine-GA.**
- flecainide, a medicine used to treat irregular heart beat
- tramadol, a medicine used for pain relief
- sumatriptan, a medicine used to treat migraine
- sleeping tablets or sedatives
- medicines for anxiety
- medicines used to control fits
- antipsychotics, e.g. pimozide
- medicines used to prevent blood clots e.g. warfarin
- lithium, a medicine used to treat mood swings and some kinds of mental conditions
- tryptophan
- St John's Wort (*Hypericum perforatum*), a herbal remedy

These medicines may be affected by Fluoxetine-GA or may affect how well it works. You may need to use different amounts of your medicine or you may need to take different medicines. Your doctor will advise you.

**Do not take any monoamine oxidase inhibitor medicines for at least 5 weeks after you have stopped Fluoxetine-GA.**

**Do not start taking any other medicines for depression without first checking with your doctor. Do this even if you have already stopped taking Fluoxetine-GA.**

After you have stopped taking Fluoxetine-GA, you should be careful taking other medicines for at least 5 weeks because some of the medicine will still be in your blood stream.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Fluoxetine-GA.

#### How to take Fluoxetine-GA

**Follow all directions given to you by your doctor or pharmacist carefully.**

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

##### *How much to take*

Your doctor will tell you how many capsules you will need to take each day. This depends on your condition and whether you are taking any other medicines.

The usual dose is one capsule each morning. Your doctor may change your dose depending on how you respond to this medicine.

### *How to take it*

Swallow the prescribed dose of Fluoxetine-GA capsules with a full glass of water.

### *When to take it*

It does not matter if you take Fluoxetine-GA before or after food.

Take each dose of Fluoxetine-GA at about the same time each day.

Taking each dose of Fluoxetine-GA at the same time each day will have the best effect. It will also help you to remember when to take the capsules.

### *How long to take it*

The length of treatment with Fluoxetine-GA will depend on how quickly your symptoms improve. Most medicines of this type take time to work so don't be discouraged if you do not feel better right away.

While some symptoms will be relieved sooner than others it may take up to four weeks before improvement is apparent. You may need to take Fluoxetine-GA for several months or longer.

Continue taking Fluoxetine-GA for as long as your doctor recommends.

If you do not start to feel better in about four weeks, check with your doctor.

### *If you forget to take it*

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking it as you would normally.

Do not take a double dose to make up for the dose you have missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

### *If you take too much (overdose)*

Immediately telephone your doctor or the Poisons Information Centre (13 11 26), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else has taken too much Fluoxetine-GA. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you have taken too much Fluoxetine-GA, you may experience symptoms such as, vomiting, feeling sick in the stomach, restlessness, agitation, or excitation.

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### *While you are taking Fluoxetine-GA*

#### *Things you must do*

Tell all doctors, dentists and pharmacists who are treating you that you are taking Fluoxetine-GA.

If you are about to start taking any new medicine, including any medicine that you buy without a prescription, tell your doctor and pharmacist that you are taking Fluoxetine-GA.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed. Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Tell your doctor if you feel the medicine is not helping your condition.

The symptoms of depression or other psychiatric conditions may include thoughts of harming yourself or suicide. These symptoms may continue or get worse during the first one or two months of treatment until the full antidepressant effect of Fluoxetine-GA becomes apparent. This is more likely to occur in young adults under 25 years of age.

If you or someone you know is demonstrating any of the following warning signs, contact your doctor or a mental health professional right away or go to your nearest hospital for treatment:

- Worsening of your depression
- Thoughts or talk of death or suicide
- Thoughts or talk of self-harm or harm to others
- Any recent attempts at self-harm
- Increase in aggressive behaviour, irritability or any other unusual changes in behaviour or mood.

All mentions of suicide or violence must be taken seriously.

Tell your doctor immediately if you become pregnant while taking Fluoxetine-GA. Visit your doctor regularly so that your progress can be checked.

#### *Things you must not do*

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not take the herbal remedy St. John's Wort while you are being treated with Fluoxetine-GA. If you are already taking the herbal remedy, stop taking it and mention it to your doctor at your next visit.

Do not use Fluoxetine-GA to treat any other complaints unless your doctor tells you to.

Do not stop taking Fluoxetine-GA, or lower the dose, without first checking with your doctor.

Your doctor may want you to gradually reduce the amount of Fluoxetine-GA you are using before stopping completely. This may help reduce the possibility of any withdrawal symptoms occurring.

Do not let yourself run out of medicine over the weekend or on holidays.

#### *Things to be careful of*

Be careful driving or operating machinery until you know how Fluoxetine-GA affects you.

Fluoxetine-GA may cause drowsiness or light-headedness in some people and affect mental alertness. Make sure you know how you react to Fluoxetine-GA before you drive a car, operate machinery, or do anything else that could be dangerous if you are affected.

Speak to your doctor before drinking alcohol while you are taking Fluoxetine-GA.

Although drinking moderate amounts of alcohol is unlikely to affect your response to Fluoxetine-GA your doctor may suggest avoiding alcohol while you are being treated for depression.

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### *Side effects*

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Fluoxetine-GA.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist any questions you may have.

### *Adults*

Tell your doctor if you notice any of the following and they worry you:

- difficulty in sleeping
- excessive sweating
- feeling sick, vomiting
- diarrhoea
- loss of appetite, weight loss
- anxiety and nervousness
- drowsiness, tiredness, weakness
- dizziness, light-headedness
- sexual problems
- visual disturbances
- dry mouth, change in sense of taste
- chills and joint aches
- more frequent urination
- erythema multiforme

These side effects are usually mild.

Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following:

- sudden switch of mood to excitement, overactivity, talkativeness and uninhibited behaviour
- fast, irregular or pounding heart beat, chest pain
- fits, seizures
- cramps, lethargy, confusion
- abnormal bleeding or bruising
- skin rash, hives, itching, peeling or blistering of skin
- shortness of breath or difficulty breathing, swelling of the face, lips or tongue or other parts of the body which may cause difficulty in swallowing or breathing
- muscle spasm, twitches, tremor, muscle stiffness
- fever
- yellowing of the skin or eyes
- shakiness

These side effects are serious. You may need urgent medical attention. These side effects are rare.

### *Children and Adolescents*

Common: Headaches

Less Common: Weight loss & decreased height gain have been observed. This is similar to the group of medicines called selective serotonin reuptake inhibitors (SSRIs).

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

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## After taking Fluoxetine-GA

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### *Storage*

**Keep your capsules in the blister pack until it is time to take them.**

If you take the capsules out of the box or the blister pack they will not keep well.

**Keep your Fluoxetine-GA in a cool dry place where it stays below 25°C.**

**Do not store it, or any other medicine, in the bathroom or near a sink.**

**Do not leave it in the car or on a windowsill.**

Heat and dampness can destroy some medicines.

**Keep this medicine where children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

### *Disposal*

**If your doctor tells you to stop taking Fluoxetine-GA or you find that they have passed their expiry date, ask your pharmacist what to do with any capsules that are left over.**

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## Product description

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### *What it looks like*

Fluoxetine-GA capsules are available in packs of 28. The capsules are a size 3 gelatin capsule with an opaque light green cap and an opaque ivory body containing a white odourless powder.

### *Ingredients*

Active ingredient:

Each Fluoxetine-GA capsule contains 20 mg fluoxetine (as fluoxetine hydrochloride).

Inactive ingredients:

Each Fluoxetine-GA capsule also contains:

- lactose
- cellulose - microcrystalline
- magnesium stearate
- silica - colloidal anhydrous
- gelatin
- titanium dioxide CI77891
- iron oxide yellow CI77492
- quinoline yellow CI47005
- indigo carmine CI73015

### *Supplier*

Amneal Pharma Australia Pty Ltd  
12 River Street  
South Yarra VIC 3141

### *Australian Registration Number*

Fluoxetine-GA Capsules:  
AUST R 148090

This leaflet was amended in July 2015