

## Fluvoxamine AN

Fluvoxamine maleate film coated tablets

### Consumer Medicine Information

#### What is in this leaflet

This leaflet answers some of the common questions about Fluvoxamine AN. It does not contain all of 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 Fluvoxamine AN against the benefits they expect it will have for you.

**If you have any concerns about using this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.**

You may need to read it again.

#### What is FLUVOXAMINE AN used for

Fluvoxamine AN belongs to a family of medicines known as selective serotonin reuptake inhibitors (SSRIs) and is approved for the conditions listed below.

##### Depression

Fluvoxamine AN is used to treat depression in adults only. It is not recommended for treatment of this condition in children and adolescents as the safety and effectiveness of this medicine, when used for depression in this age group, have not been established.

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. It can affect your whole body and can cause emotional and physical symptoms such as feeling low in spirit, loss of interest in activities, being unable to enjoy life, poor appetite or overeating, disturbed sleep, often waking up early, loss of sex drive, lack of energy and feeling guilty for no reason.

##### Obsessive compulsive disorder (OCD)

Fluvoxamine AN is also used to treat a condition known as obsessive compulsive disorder (OCD) in adults and children eight years of age or older.

People with OCD can have two types of symptoms – obsessions and compulsions. Obsessions are unwanted repeated thoughts or feelings, which are ongoing. Compulsions are the need to repeat actions over and over. The symptoms of OCD can vary from patient to patient.

Both of these conditions are thought to be caused by a chemical imbalance in parts of the brain. Fluvoxamine AN corrects this chemical imbalance and may help relieve the symptoms of depression and OCD.

**Ask your doctor if you have any questions about why Fluvoxamine AN has been prescribed for you.**

Your doctor may have prescribed it for another purpose.

There is no evidence that this medicine is addictive.

Fluvoxamine AN is only available with a doctor's prescription.

#### Before you start to take FLUVOXAMINE AN

*When you must not take it*

**Do not take Fluvoxamine AN if:**

- you have an allergy to fluvoxamine or any of the ingredients listed at the end of this leaflet
- you are taking medicines called monoamine oxidase inhibitors (MAOI) sometimes prescribed to treat depression or anxiety, including linezolid (an antibiotic which is also an MAOI). Taking Fluvoxamine AN with a MAOI may cause a serious reaction with a sudden increase in body temperature, extremely high blood pressure and severe convulsions. **Ask your doctor or pharmacist if you are not sure if you have been taking one of these medicines.**
- you are taking cisapride
- the packaging is torn or shows signs of tampering
- the tablets do not look right
- the expiry date (EXP) printed on the pack has passed. If you take this medicine after the expiry date has passed, it may not work (as well).

*Before you start to take it*

**Tell your doctor if:**

- you are allergic to any other medicines, foods, dyes or preservatives
- you have, or have had, any other medical conditions, including:
  - liver problems
  - kidney problems
  - epilepsy
  - high pressure in your eyes (glaucoma), or if you are at risk of acute narrow angle glaucoma
  - a history of bleeding disorders
  - diabetes
  - mania (a feeling of elation or over-excitement)
- you are having treatment with electroconvulsive therapy (ECT)
- you are pregnant or intend to become pregnant. Your doctor will discuss with you the risks and benefits of taking it when pregnant
- you are breastfeeding or wish to breastfeed. Like many other medicines, Fluvoxamine AN can pass into breast milk and may affect your baby
- you drink alcohol. **You should avoid drinking alcohol while taking Fluvoxamine AN.**

*Taking other medicines*

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

These include: aspirin, NSAID medicines, or any medications used to treat depression, obsessive compulsive disorder, anxiety disorders or other psychoses.

**Tell your doctor if you are taking tryptophan, sumatriptan, phentermine, tramadol, lithium, any herbal products containing St. John's Wort, warfarin, clomipramine, amitriptyline, imipramine, clozapine, olanzapine, tacrine, theophylline, methadone, mexiletine, thioridazine, propranolol, ropinirole, cisapride, alprazolam, triazolam,**

**midazolam, diazepam, haloperidol, terfenadine, astemizole, sildenafil, cyclosporin, carbamazepine or phenytoin.**

**These medicines may be affected by Fluvoxamine AN or may affect how well it works. You may need to take different amounts of your medicine or you may need to take different medicines. Some combinations of medicines (including herbal and other remedies) can interact with Fluvoxamine AN and increase the risk of side effects, some of which can be potentially life-threatening.**

Your doctor or pharmacist may have more information on medicines to avoid while taking Fluvoxamine AN.

#### How to take FLUVOXAMINE AN

**Follow your doctor's instructions about how and when to take this medicine.**

These directions may differ from the information contained in this leaflet.

*How much to take*

Your doctor or pharmacist will tell you how many Fluvoxamine AN tablets to take each day. These will be printed on the pharmacy label on the container.

**To treat depression:**

Adults: The usual starting dose is 50 mg each day, but your doctor may adjust the number of tablets or the strength of the tablets you are taking until the desired response is achieved.

**To treat OCD:**

Adults: The usual starting dose is 50 mg each day, but your doctor may adjust the number of tablets or the strength of the tablets you are taking until the desired response is achieved.

Children & Adolescents: The usual starting dose is 25 mg each day. The doctor will probably adjust the dose until the desired response is achieved.

*How to take it*

**Swallow the tablet with a full glass of water. Do not chew the tablets.**

**Take Fluvoxamine AN with or without food.**

**If you have any concerns about how to take this medicine, ask your doctor or pharmacist.**

*How long to take it*

**Even if you feel better, continue taking your medicine until your doctor tells you to stop.**

The length of treatment will depend on how quickly your symptoms improve. Most antidepressants take time to work, so don't be discouraged if you don't feel better right away. Some of your symptoms may improve in 1 or 2 weeks but it can take up to 4 or 6 weeks to feel any real improvement. Even when you feel well, you will usually have to take Fluvoxamine AN for several months or even longer to make sure the benefits are maintained.

**This medicine should not be stopped abruptly, especially if you are taking 200 mg or more per day.**

The dose should be reduced by 100 mg every three days.

*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, then go back to taking it as you would normally.

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

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

*If you take too much (Overdose)*

**Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26 Australia or 0800 764 766 New Zealand), or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too much Fluvoxamine AN.**

**Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention. The most common symptoms are nausea (feeling sick), vomiting and diarrhoea. You could also experience drowsiness and dizziness, or feel faint.

If possible, show the doctor the pack of tablets.

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While you are taking  
FLUVOXAMINE AN

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*Things you must do*

**If you are about to start or stop any medicine, including any that you buy without a prescription from your pharmacy, supermarket or health food shop, tell your doctor and pharmacist that you are taking Fluvoxamine AN.**

**Tell all doctors, dentists and pharmacists who are treating you that you are taking Fluvoxamine AN.**

**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 tablets are not helping your condition.**

**If you are being treated for depression, be sure to discuss with your doctor any problems you may have and how you feel, especially any feelings of severe sadness or bursts of unusual energy or anger.**

This will help your doctor to determine the best treatment for you.

**Tell your doctor immediately if you become pregnant while taking Fluvoxamine AN.**

**Be sure to keep all of your appointments with your doctor so that your progress can be checked.**

Your doctor may want to take some blood tests and check your heart and blood pressure from time to time. This helps prevent unwanted side effects.

*Things to be careful of*

**Tell your doctor immediately if you have any suicidal thoughts or other mental/mood changes.**

All mentions of suicide or violence must be taken seriously.

**Immediately contact your doctor or go to the nearest hospital for help if you or**

**someone you know are being treated for depression (or for any other condition) and are demonstrating any of the warning signs of suicide.**

Families and caregivers of children and adolescents who are taking Fluvoxamine AN should be especially watchful of the warning signs associated with suicide listed below.

The warning signs include:

- Thoughts or talk of death or suicide
- Thoughts or talk of self-harm or harm to others
- Any recent attempts of self-harm
- Mood changes such as an increase in aggressive or unusual behaviour, irritability, agitation or worsening of depressive symptoms.

**Be especially careful of any suicidal thoughts or other mental/mood changes in the first few months of taking Fluvoxamine AN or when the dose is changed.**

These effects are more likely to occur in people aged less than 24 years including those not being treated for depression.

**Be careful driving or operating machinery until you know how Fluvoxamine AN affects you.**

It may cause drowsiness, dizziness or sleepiness in some people and affect alertness.

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

**You should minimise your intake of caffeine-containing beverages (eg, coffee, tea) while taking Fluvoxamine AN.**

Large amounts of caffeine may result in side effects such as tremor (shaking), palpitations (fast or irregular heart beat), nausea, restlessness and trouble or inability to sleep.

Older people may become confused when taking Fluvoxamine AN. Families and carers should be aware of this. Special care may be needed.

You should be careful for 1 or 2 weeks after stopping this medicine, because it will still be in your blood stream.

*Things you must not do*

**Do not stop taking Fluvoxamine AN or lower the dose, without first checking with your doctor. Do not let yourself run out of medicine over the weekend or on holidays.**

Suddenly stopping it may cause headache, nausea, dizziness and anxious feelings.

**Do not give this medicine to anyone else, even if their symptoms seem similar to yours or if they have the same condition as you.**

**Do not use Fluvoxamine AN to treat any other complaints unless your doctor tells you to.**

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Side effects

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**Check with your doctor as soon as possible if you do not feel well while you are taking Fluvoxamine AN, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.**

Like other medicines, Fluvoxamine AN can cause some side effects. If they occur, most are likely to be minor and temporary.

However, some may be serious and need medical attention.

**Do not be alarmed by this list of possible side effects.**

You may not experience any of them.

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

Nausea, vomiting, drowsiness, difficulty sleeping, dizziness, nervousness, feeling anxious or agitated, tremor, dry mouth, stomach pain, constipation, diarrhoea, heart burn, loss of appetite, muscle weakness, pins and needles, abnormal taste, headache, faster heart beat, sweating, weight gain, weight loss or unusual bruising.

**Tell your doctor immediately if you notice any of the following:**

- Muscle spasms or twitches

**Stop taking Fluvoxamine AN and tell your doctor immediately, or go to Accident and Emergency at your nearest hospital if any of the following happens:**

- Allergic reaction including swelling of limbs, face, lips, mouth or throat which may cause difficulty swallowing or breathing
- Sudden onset of prolonged muscular spasm, affecting the eyes, head, neck and body
- Sudden increase in body temperature, severe convulsions
- Fast heart beat, sweating, racing thoughts and restlessness.

These are very serious, though rare, side effects.

Other side effects observed more frequently in children are: abnormal thoughts or behaviour, cough, increased period pain, nose bleeds, increased restlessness, infection and sinusitis.

**Tell your doctor if you notice anything else that is making you feel unwell including any suicidal thoughts or other mental/mood changes (see *'Things to be careful of'*).**

Other side effects not listed above may occur in some patients.

**Ask your doctor or pharmacist to answer any questions you may have.**

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After taking FLUVOXAMINE AN

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*Storage*

**Keep your tablets in their original pack until it is time to take them.**

**Keep the pack in a cool, dry place (below 25°C). Do not store Fluvoxamine AN in the bathroom, near a sink or leave it in the car on hot days.**

Heat and dampness can destroy some medicines.

**Keep Fluvoxamine AN where young 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 Fluvoxamine AN, or the tablets have passed their expiry date, ask your pharmacist what to do with any left over tablets.**

**Return any unused medicine to your pharmacist.**

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## Product description

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### *What it looks like*

FLUVOXAMINE AN (fluvoxamine maleate) 50mg: round, biconvex, scored white film-coated tablets inscribed with '291' on one side, on either side of the score line and other side plain. Available in packs of 30 tablets.

FLUVOXAMINE AN (fluvoxamine maleate) 100mg: oval, biconvex, scored, white film-coated tablet, inscribed with '313' on one side, on either side of the score line and other side plain. Available in packs of 30 tablets.

### *Ingredients*

#### **Active ingredient:**

- Fluvoxamine AN 50 mg tablets – fluvoxamine maleate 50 mg
- Fluvoxamine AN 100 mg tablets – fluvoxamine maleate 100 mg

#### **Inactive ingredients:**

- mannitol
- maize starch
- pregelatinised potato starch
- sodium stearyl fumarate
- colloidal anhydrous silica
- hypromellose
- macrogol 6000
- purified talc
- titanium dioxide.

Fluvoxamine AN does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

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## Distributor

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

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