

## Consumer Medicine Information

### What is in this leaflet

This leaflet answers some common questions about Fluotex. It does not contain all the available information. It does not take the place of talking with your doctor or pharmacist.

All medicines have risks and benefits.

Your doctor has weighed the risks of you taking Fluotex 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 this medicine.**

You may need to read it again.

### What Fluotex is used for

Fluotex is used to treat:

- depression
- obsessive compulsive disorder (OCD)
- premenstrual dysphoric disorder (PMDD)

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

Your doctor may have prescribed Fluotex for another reason.

Fluotex belongs to a group of medicines called selective serotonin reuptake inhibitors (SSRIs). SSRIs are thought to work by their action on brain chemicals called amines which are involved in controlling mood.

Fluotex is available only with a doctor's prescription.

Fluotex is not recommended for use in children and adolescents under 18 years of age.

### Before you take Fluotex

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

**Do not take Fluotex if you are allergic to**

- any medicines containing fluoxetine
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

**Do not take Fluotex if you are taking another medicine for depression called a monoamine oxidase inhibitor (MAOI) or have been taking a MAOI within the last 14 days. Check with your doctor or pharmacist if you are unsure as to whether or not you are taking a MAOI.**

If you do take Fluotex while you are taking a MAOI, you may experience shaking (tremor), shivering, muscle stiffness, fever, rapid pulse, rapid breathing or confusion.

**Do not take Fluotex if you are taking another medicine called pimozone to treat disturbances in thinking, feelings and behaviour.**

**Taking pimozone together with Fluotex may alter the rhythm of your heart.**

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

**Do not take Fluotex if the expiry date on the pack has passed.**

If it has expired or is damaged, return it to your pharmacist for disposal.

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

*Before you start to take it*

**Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.**

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

Your doctor will discuss the risks and benefits of taking Fluotex during pregnancy. If Fluotex is taken during pregnancy, you should be careful, particularly at the end of pregnancy. Transitory withdrawal symptoms have been reported rarely in the newborn after maternal use in the last 3 months of pregnancy.

**Tell your doctor if you are breastfeeding or wish to breastfeed.**

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

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

**Tell your doctor if you drink alcohol.**

Although drinking alcohol is unlikely to affect your response to Fluotex, your doctor may suggest avoiding alcohol while you are being treated for depression.

**If you have not told your doctor about any of the above, tell them before you start taking Fluotex.**

#### *Taking other medicines*

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

Some combinations of medicines may increase the risk of serious side effects and are potentially life threatening.

Some medicines may be affected by Fluotex, or may affect how well it works. These include:

- monoamine oxidase inhibitors (MAOIs), medicines used to treat some types of depression.  
**You should stop taking MAOIs at least two weeks before starting Fluotex**
- lithium, a medicine used to treat mood swings and some types of depression
- SNRIs, SSRIs and other medicines for depression, obsessive compulsive disorder or premenstrual dysphoric disorder (PMDD)
- sleeping tablets or sedatives
- medicines used to relieve anxiety
- medicines used to treat certain mental and emotional conditions, also called antipsychotics

- medicine used to treat disturbances in thinking, feelings and behaviour, such as pimozone
- medicines used to control fits
- medicines used to prevent blood clots, such as warfarin
- flecainide, a medicine used to treat some heart conditions
- Tryptophan
- St John's Wort
- medicines used to relieve pain, such as tramadol
- sumatriptan, a medicine used to treat migraine.

Your doctor can tell you what to do if you are taking any other medicines.

**If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.**

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

**Do not start taking other medicines for depression without checking with your doctor. Do this even if you have already stopped taking Fluotex.**

Monoamine oxidase inhibitors (MAOIs), which are other medicines used for depression, may interfere with Fluotex. You should not start a MAOI for at least 5 weeks after stopping Fluotex.

### How to take Fluotex

**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 much Fluotex you need to take each day.

The usual dose for Fluotex is one capsule taken once a day. Your doctor may increase or decrease your dose depending on your condition.

For premenstrual dysphoric disorder (PMDD), Fluotex may be prescribed to be taken every day or only during a certain part of the month. Your doctor will prescribe the dosing schedule that is right for you.

#### *How to take it*

**Swallow the capsules whole with a glass of water.**

#### *When to take it*

Fluotex is usually taken as a single morning dose.

**If your doctor tells you to take Fluotex twice a day, take a dose in the morning and at noon.**

**Take your medicine at about the same time each day.**

Taking it at the same time each day will help you remember when to take it.

**It does not matter if you take this medicine before or after food.**

### *How long to take it*

**Continue taking Fluotex for as long as your doctor recommends.**

The length of treatment with Fluotex 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, Fluotex commonly takes two to four weeks before improvement is really apparent.

**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 your medicine as you would normally.**

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

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

**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 (13 11 26) for advice or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Fluotex. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.**

If you have taken too much Fluotex, you may feel sick in the stomach, vomit; feel restless, agitated or excited.

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### While you are taking Fluotex

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#### *Things you must do*

**If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Fluotex.**

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

**Tell your doctor if you become pregnant while taking Fluotex.**

Your doctor will discuss the risks and benefits of taking Fluotex during pregnancy. If Fluotex is used during pregnancy, you should be careful, particularly at the end of pregnancy. Transitory withdrawal symptoms have been reported rarely in the newborn after maternal use in the last 3 months of pregnancy.

**Keep all of your doctor's appointments so that your progress can be checked.**

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 Fluotex 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 the 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.

#### *Things to be careful of*

**If you experience drowsiness, do not drive, operate machinery or do anything else that could be dangerous.**

#### *Things you must NOT do*

**Do not stop taking your medicine or lower the dosage without checking with your doctor.**

Suddenly stopping Fluotex may cause symptoms such as dizziness, anxiety, headache, feeling sick or tingling or numbness of the hands or feet. Your doctor may want you to gradually reduce the amount of Fluotex you are taking before stopping completely.

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

**Do not drive or operate machinery until you know how Fluotex affects you.**

Fluotex may cause drowsiness in some people.

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

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

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

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### Side effects

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Fluotex.**

Fluotex may have unwanted side effects in some people. 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.

Side effects vary from patient to patient and often lessen with continued use.

**Do not be alarmed by the following lists of side effects. You may not experience any of them.**

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

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

- nausea, vomiting
- upset stomach, diarrhoea
- loss of appetite, weight loss, changes in taste, dry mouth
- trouble sleeping, unusual dreams
- nervousness, anxiety
- drowsiness, weakness
- dizziness
- excessive sweating, flushing, chills

- lesions of skin and mucous membrane
- fever and joint aches
- sexual problems
- more frequent urination
- changes in vision.

**If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:**

- itching, skin rash or hives
- shortness of breath, wheezing or trouble breathing
- swelling of the face, lips, tongue or other parts of the body
- muscle spasms
- tremors
- twitches
- convulsions or fits
- fast, irregular heart beat
- abnormal bleeding or bruising
- sudden switches of mood to one of overactivity and uninhibited behaviour.
- sudden fever
- hallucinations
- loss of coordination
- confusion
- overactive reflexes

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

### *Children and Adolescents*

Headaches are very common side effects.

Weight loss and decreased height gain have been observed in association with the use of fluoxetine in children and adolescent patients. This is similar to other medicines that belong to the group of medicines called selective serotonin reuptake inhibitors (SSRIs).

**Tell your doctor or pharmacist if you notice anything that is making you feel unwell.**

Other side effects not listed above may also occur in some people.

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### After taking Fluotex

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#### *Storage*

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

If you take your capsules out of the blister pack they may not keep as well.

**Keep your capsules in a cool dry place where the temperature stays below 30 degrees C. Protect from light.**

**Do not store Fluotex or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.**

Heat and dampness can destroy some medicines.

**Keep it 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 Fluotex or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.**

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## Product description

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### *What it looks like*

Fluotex capsules are available in packs of 28. The capsules are Green/Off-white hard gelatin self locked capsules of size '2' imprinted with 'FLX' and 'MIL' on cap/body.

### *Ingredients*

#### **Capsules**

Fluotex capsules contain 20 mg of fluoxetine (as the hydrochloride) as the active ingredient.

They also contain:

- pregelatinised maize starch
- Gelatin\*
- brilliant blue FCF
- iron oxide yellow
- titanium dioxide
- sodium lauryl sulfate
- black edible ink

In addition, the black printing ink contains the following ingredients:

- shellac,
- ethanol absolute,
- isopropyl alcohol,
- butan-1-ol,
- propylene glycol,
- iron oxide black
- purified water

\*May contain trace amounts of phenylalanine and sulfites.

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

### *Sponsored by*

Arrotex Pharmaceuticals Pty Ltd  
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[www.arrotex.com.au](http://www.arrotex.com.au)

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### *Australian Registration Number:*

Fluotex capsules: AUST R 273925 (blister packs)