

CONSUMER MEDICINE INFORMATION

Arrow-Fluoxetine

Fluoxetine hydrochloride Capsules 20 mg

Fluoxetine hydrochloride Dispersible Tablets

What is in this leaflet

Please read this leaflet carefully before you start taking Arrow-Fluoxetine.

This leaflet answers some common questions about Arrow-Fluoxetine. 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 Arrow-Fluoxetine 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 Arrow-Fluoxetine is used for

Arrow-Fluoxetine is used to treat depression and the anxiety associated with depression, in adults. This affects 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 over nothing.

Arrow-Fluoxetine is also used to treat bulimia nervosa (eating disorder) and obsessive-compulsive disorder (OCD).

Arrow-Fluoxetine may also be used to treat premenstrual dysphoric disorder (PMDD), a severe form of premenstrual syndrome (PMS).

Your doctor may have prescribed Arrow-Fluoxetine for another reason.

Ask your doctor if you have any questions about why Arrow-Fluoxetine has been prescribed for you.

Your Arrow-Fluoxetine capsules or dispersible tablets contain fluoxetine hydrochloride. They belong 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.

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

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

Before you use Arrow-Fluoxetine

When you must not use it

Do not use Arrow-Fluoxetine if you are allergic to:

- any medicine containing fluoxetine
- any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can take this medicine.

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 use Arrow-Fluoxetine 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.
- another medicine that affects the level of a chemical in the brain called serotonin.

Ask your doctor or pharmacist if you are unsure if you are taking a MAOI or other medicine that affects serotonin in the brain.

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

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

Do not take Arrow-Fluoxetine 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 Arrow-Fluoxetine, talk to your doctor.

Before you start to use 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 Arrow-Fluoxetine during pregnancy.

When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like Arrow-Fluoxetine may affect your newborn baby and they may experience irritability, constant crying, feeding difficulties, vomiting, fluctuating

temperature, seizures or fits, tremors, jitteriness, bluish appearance (cyanosis), breathing interruptions, low blood sugar, muscle stiffness, muscle weakness, or over responsive reflexes, These symptoms are uncommon and may be due to the effect of Arrow-Fluoxetine or the discontinuation of Arrow-Fluoxetine.

When used during pregnancy, particularly in late pregnancy, medicines like Arrow-Fluoxetine may increase the risk of a serious condition in babies called persistent pulmonary hypertension (PPHN) which may cause the baby to breathe faster and appear bluish. If this happens to your baby, you should contact your doctor and/or go straight to the Emergency Department at your nearest hospital.

If you take Arrow-Fluoxetine near the end of your pregnancy, there may be an increased risk of heavy vaginal bleeding shortly after birth. Tell your doctor or midwife if you are taking Arrow-Fluoxetine so that they can advise you.

Talk to your doctor if you are breastfeeding or intend to breastfeed. Breastfeeding while on Arrow-Fluoxetine is not recommended.

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

- allergic reaction to any medicine that you have taken previously to treat your current condition
- heart conditions
- liver or kidney problems
- seizures or fits
- diabetes
- raised eye pressure
- a bleeding disorder or a tendency to bleed more than usual
- major depressive episodes or other mood disorders
- take any medicines for any other condition

Tell your doctor if you drink alcohol. It is not recommended to drink alcohol while you are taking Arrow-Fluoxetine.

If you have not told your doctor about any of the above, tell them before you start taking Arrow-Fluoxetine.

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.

You should also tell any health professional who is prescribing a new medication for you that you are taking Arrow-Fluoxetine.

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

Some medicines may be affected by Arrow-Fluoxetine, 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 Arrow-Fluoxetine. If you do take Arrow-Fluoxetine while you are taking a MAOI, you may experience elevated body temperature, muscle stiffness, involuntary muscle jerking, fluctuations of vital signs (blood pressure, heart rate, breathing rate) and mental state from extreme agitation progressing to confusion and coma (a condition called serotonin syndrome).**
- medicines used to relieve anxiety such as diazepam, alprazolam
- lithium, a medicine used to treat mood swings and some types of depression
- serotonin and noradrenaline reuptake inhibitors (SNRIs), SSRIs, tricyclic antidepressants and other medicines for depression, obsessive compulsive disorder or premenstrual dysphoric disorder (PMDD)
- sleeping tablets or sedatives
- medicines used to treat certain mental and emotional conditions, also called antipsychotics
- medicines used to control seizures, such as phenytoin and carbamazepine
- medicines used to prevent blood clots, such as warfarin
- flecainide, a medicine used to treat some heart conditions
- tryptophan
- St John's Wort
- opioids such as pethidine, tramadol, medicines used to relieve pain
- dextromethorphan, a cough suppressant
- triptan medicines used to treat migraine, such as sumatriptan
- tamoxifen, a medicine used to treat breast cancer
- oral antidiabetic medicines or insulin
- medicines that may increase risk of bleeding such as warfarin, aspirin and some anti-inflammatory medicines (NSAIDs)

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 Arrow-Fluoxetine.

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

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

How to use Arrow-Fluoxetine

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 Arrow-Fluoxetine you need to take each day. The usual dose of Arrow-Fluoxetine is one capsule or one tablet taken once a day.

Your doctor may increase or decrease your dose depending on your condition.

For premenstrual dysphoric disorder (PMDD), Arrow-Fluoxetine 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.

Follow the instructions provided and use Arrow-Fluoxetine until your doctor tells you to stop.

How to take it

Swallow the capsules whole with a glass of water.

If you cannot swallow the tablets, disperse them in water. Swirl the tablet in half a glass of water until it disperses, then drink it immediately.

When to take it

Arrow-Fluoxetine is usually taken as a single morning dose. **If your doctor tells you to take Arrow-Fluoxetine 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 Arrow-Fluoxetine for as long as your doctor tells you. The length of treatment with Arrow-Fluoxetine 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, Arrow-Fluoxetine 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.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Information Centre (telephone 0800 POISON or 0800 764 766) or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much Arrow-Fluoxetine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of an overdose may include nausea (feeling sick), vomiting, seizures or fits, fast or slow heartbeat or change in heart rhythm, breathing difficulty, altered level of alertness from excitation to coma.

While you are using Arrow-Fluoxetine

Things you must do

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

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

Tell your doctor if you become pregnant or start breastfeeding while taking Arrow-Fluoxetine. Your doctor will discuss the risks and benefits of taking Arrow-Fluoxetine during pregnancy or breastfeeding. If Arrow-Fluoxetine 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 Arrow-Fluoxetine 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 you must NOT do

Do not stop taking your medicine or lower the dosage without checking with your doctor. Suddenly stopping Arrow-Fluoxetine may cause symptoms such as dizziness, sleep disturbance, headache, irritability, anxiety, agitation, nausea, confusion, weakness, and tingling or numbness in the hands or feet. Your doctor may want you to gradually reduce the amount of Arrow-Fluoxetine you are taking before stopping completely.

Do not take the herbal remedy St. John's Wort while you are being treated with Arrow-Fluoxetine. 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 give Arrow-Fluoxetine to anyone else, even if they have the same condition as you.

Do not let yourself run out of Arrow-Fluoxetine over the weekend or on holidays.

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

Things to be careful of

Do not drive or use any machines or tools until you know how Arrow-Fluoxetine affects you. Arrow-Fluoxetine may cause impaired judgement, reduced coordination, or drowsiness in some people.

Side effects

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

Arrow-Fluoxetine 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
- weight gain
- changes in taste, dry mouth
- trouble sleeping, unusual dreams
- nervousness, anxiety
- headache
- drowsiness
- fatigue, weakness
- dizziness
- yawning
- abnormal thoughts
- excessive sweating
- flushing
- allergic reactions
- chills
- rash
- itching
- twitches
- sexual disturbances (decreased sexual drive, problems with orgasm, ejaculation or erection). In some cases, these symptoms have continued after stopping treatment.
- more frequent urination
- changes in vision
- nose bleeds.

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

- Serious allergic reaction. 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, or rash, itching or hives on the skin.
- muscle spasms
- tremors
- sudden or severe headache (thunderclap headache)
- seizures or fits
- loss of coordination
- confusion
- sudden fever
- feeling confused, feeling restless, agitation, mood swings, sweating, shaking, diarrhoea, shivering, tremor, loss of coordination, overactive reflexes,

hallucinations, sudden jerks in your muscles or a fast heartbeat (these may be symptoms of a rare condition called serotonin syndrome)

- sudden switches of mood to one of overactivity and uninhibited behaviour
- fast, irregular heartbeat or palpitations
- ECG changes
- abnormal bleeding or bruising
- blood in stools or black, tarry bowel motions
- a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome)
- severe skin rash, which may blister and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge) (erythema multiforme)

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.

After using Arrow-Fluoxetine

Storage

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

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

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store Arrow-Fluoxetine or any other medicine in the bathroom or near a sink. Do not leave it on a windowsill 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 Arrow-Fluoxetine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

Your medicine is in the form of:

- Capsules in blister packs each containing 30 or 90 capsules; or
- Dispersible tablets in blister packs each containing 30 tablets.

What it looks like

Arrow-Fluoxetine capsules are coloured green and off white and are marked with “FLX” and “MIL”.

Arrow-Fluoxetine dispersible tablets are white round tablets, with a break line on one side.

Ingredients

Capsules

Arrow-Fluoxetine capsules contain 20 mg of fluoxetine as the active ingredient. They also contain:

- maize starch
- gelatin
- yellow iron oxide (E172)
- brilliant blue (E133)
- titanium dioxide (E171)
- edible black printing ink.

Tablets

Arrow-Fluoxetine dispersible tablets contain 20 mg of fluoxetine as the active ingredient. They also contain:

- microcrystalline cellulose
- croscarmellose sodium
- colloidal anhydrous silica
- magnesium stearate

Supplier

Arrow-Fluoxetine is distributed in New Zealand by:

Teva Pharma (New Zealand) Limited

PO Box 128 244

Remuera

Auckland 1541

Telephone: 0800 800 097

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09 July 2024 (based on data sheet dated 09 July 2024)