

ZACTIN

fluoxetine hydrochloride

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about ZACTIN.

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

All medicines have benefits and risks. Your doctor has weighed the risks of you taking ZACTIN against the benefits expected for you.

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

Keep this leaflet with your medicine.

You may need to read it again.

What ZACTIN is used for

ZACTIN is used to treat

- depression
- obsessive compulsive disorder (OCD)

ZACTIN 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.

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

Your doctor may have prescribed ZACTIN for another reason.

ZACTIN is available only with a doctor's prescription.

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

Before you take ZACTIN

When you must not take it

Do not take ZACTIN if you are allergic to:

- any other medicines containing fluoxetine (such as Prozac and Lovan)
- 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 ZACTIN if you are taking, or have taken within the last 14 days, another medicine for depression called a monoamine oxidase inhibitor (MAOI). Check with your doctor or pharmacist if you are unsure as to whether or not you are taking a MAOI.

If you do take ZACTIN while you are taking a MAOI, you may experience shaking (tremor), shivering, muscle stiffness, fever, rapid pulse, rapid breathing or confusion. Do not take ZACTIN if you are taking another medicine called pimozone to treat disturbances in thinking, feelings and behaviour.

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

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

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

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

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

Your doctor will discuss the risks and benefits of taking ZACTIN during pregnancy. If ZACTIN is taken during pregnancy, you should be careful, particularly at the end of your pregnancy. Transitory withdrawal symptoms have been reported rarely in the newborn baby after maternal use in the last 3 months of pregnancy. If you take ZACTIN near the end of your pregnancy there may be an increased risk of heavy vaginal bleeding shortly after birth, especially if you have a history of bleeding disorders. Your doctor or midwife should be aware that you are taking ZACTIN so they can advise you.

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

Like many other medicines, ZACTIN can pass into breast milk. Your doctor will discuss the risks and benefits of taking ZACTIN when breastfeeding.

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

- kidney problems
- liver problems
- diabetes
- fits (seizures)
- 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 ZACTIN, 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 ZACTIN.

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 medicines and ZACTIN may interfere with each other. 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 ZACTIN.

- 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
- pimozide, a medicine used to treat disturbances in thinking, feelings and behaviour

- medicines used to control fits
- medicines used to relieve pain, such as tramadol
- sumatriptan, a medicine used to treat migraine
- tryptophan, an amino acid available in food supplements and multivitamin preparations
- medicines used to prevent blood clots, such as warfarin
- flecainide, a medicine used to treat some heart conditions
- St John's Wort (*Hypericum perforatum*), a herbal remedy

These medicines may be affected by ZACTIN or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

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

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

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

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

How to take ZACTIN

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

They may differ from the information contained in this leaflet.

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

How much to take

The dose varies from person to person.

Your doctor will tell you how much ZACTIN you need to take each day.

The usual starting dose is one capsule taken once a day in the morning. Your doctor may change your dose depending on how you respond to the medicine.

How to take it

Swallow the capsules whole with a glass of water.

When to take it

ZACTIN is usually taken as a single dose in the morning. If your doctor tells you to take it 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 have the best effect. It will also help you remember when to take it.

ZACTIN can be taken with or without food.

How long to take it

Continue taking ZACTIN for as long as your doctor tells you to.

The length of treatment with ZACTIN 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, ZACTIN 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 the missed dose 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 you missed.

This may increase the chance of you getting an unwanted side effect.

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 the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much ZACTIN. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

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

While you are taking ZACTIN

Things you must do

Persons taking ZACTIN may be more likely to think about killing themselves or actually trying to do so, especially when ZACTIN is first started or the dose is changed. Tell your doctor immediately if you have any suicidal thoughts or other mental/mood changes.

Occasionally, the symptoms of depression or other psychiatric conditions may include thoughts of harming yourself or committing suicide. These symptoms may continue or get worse during the first one to two months of treatment until

the full antidepressant effect of the medicine becomes apparent. This is more likely to occur in children, adolescents and young adults under 25 years of age.

Contact your doctor or a mental health professional immediately or go to the nearest hospital for treatment if you or someone you know is demonstrating any of the following warning signs:

- worsening of your depression
- thoughts or talk about 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 mood or behaviour

All mentions of suicide or violence must be taken seriously.

If you are about to be started on any new medicine, tell your doctor or pharmacist that you are taking ZACTIN.

Tell any other doctors, dentists and pharmacists who are treating you that you are taking ZACTIN.

Tell your doctor immediately if you become pregnant while taking ZACTIN.

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

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

Things you must not do

Do not take ZACTIN to treat any other complaints unless your doctor tells you to.

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

Do not stop taking ZACTIN, or lower the dose, without checking with your doctor.

Stopping ZACTIN suddenly 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 ZACTIN you are taking before stopping completely.

Do not take the herbal remedy St John's Wort (*Hypericum perforatum*) while you are being treated with ZACTIN.

If you are already taking the herbal remedy, stop taking it and mention it to your doctor at your next visit.

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

Things to be careful of

Be careful driving or operating machinery until you know how ZACTIN affects you.

ZACTIN may cause drowsiness in some people. If you experience drowsiness, do not drive, operate machinery or do anything else that could be dangerous.

Side effects

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

Like all other medicines, ZACTIN may have unwanted side effects in some people. 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 person to person and often go away with continued use.

Do not be alarmed by the following list of possible 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

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

- 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
- convulsions or fits
- twitches
- 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 ZACTIN 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 taking ZACTIN

Storage

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

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

Keep your capsules in a cool dry place where the temperature stays below 30°C.

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

Heat and dampness can destroy some medicines.

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

Product description

What it looks like

ZACTIN capsules are light green opaque body with light purple opaque cap, marked "FL20" on the body and alpha symbol on cap.

Each pack contains 28 capsules.

Ingredients

The active ingredient in ZACTIN is fluoxetine (as fluoxetine hydrochloride). Each ZACTIN capsule contains 20 mg of fluoxetine.

The capsules also contain the following inactive ingredients:

- lactose monohydrate
- maize starch
- colloidal anhydrous silica
- purified talc
- magnesium stearate
- gelatin
- sodium lauryl sulfate
- shellac
- propylene glycol
- ammonium hydroxide
- potassium hydroxide
- titanium dioxide
- erythrosine CI45430
- indigo carmine CI73015
- quinoline yellow CI47005
- brilliant blue FCF CI42090
- iron oxide black (CI 77499)

ZACTIN contains sulfites and sugars (as lactose).

Manufacturer

ZACTIN is manufactured by:

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

Australian registration number:

AUST R 53773

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