

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using ZACTIN?

ZACTIN contains the active ingredient fluoxetine hydrochloride. ZACTIN is used to treat depression and obsessive compulsive disorder (OCD).

For more information, see Section [1. Why am I using ZACTIN?](#) in the full CMI.

2. What should I know before I use ZACTIN?

Do not use if you have ever had an allergic reaction to ZACTIN or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use ZACTIN?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ZACTIN and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use ZACTIN?

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

More instructions can be found in Section [4. How do I use ZACTIN?](#) in the full CMI.

5. What should I know while using ZACTIN?

Things you should do	- Remind any doctor, dentist or pharmacist you visit that you are using ZACTIN. - Tell your doctor immediately if you become pregnant while taking ZACTIN. - Tell your doctor immediately if you have thoughts about harming or killing yourself.
Things you should not do	- Do not stop using this medicine or lower the dosage without checking with your doctor. - Do not take the herbal remedy St. John's Wort while you are being treated with ZACTIN. - Do not give ZACTIN to anyone else, even if they have the same condition as you.
Driving or using machines	- Do not drive or operate machinery until you know how ZACTIN affects you. - ZACTIN may cause impaired judgement, reduced coordination, or drowsiness in some people.
Drinking alcohol	Tell your doctor if you drink alcohol.
Looking after your medicine	- Keep your capsules in the pack until it is time to take them. - Keep your capsules in a cool dry place where the temperature stays below 25°C.

For more information, see Section [5. What should I know while using ZACTIN?](#) in the full CMI.

6. Are there any side effects?

Common side effects include: fatigue, nausea, vomiting, upset stomach, diarrhoea, loss of appetite, headache, 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, joint aches, sexual problems, more frequent urination and changes in vision. Serious side effects may include: 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 heartbeat, abnormal bleeding or bruising, sudden mood swings, hallucinations, increased risk of breaking a bone, loss of coordination, confusion, overactive reflexes, Stevens-Johnson syndrome, erythema multiforme and serotonin syndrome.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Consumer Medicine Information (CMI)

This leaflet provides important information about using ZACTIN. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ZACTIN.**

Where to find information in this leaflet:

1. [Why am I using ZACTIN?](#)
2. [What should I know before I use ZACTIN?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use ZACTIN?](#)
5. [What should I know while using ZACTIN?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I using ZACTIN?

ZACTIN contains the active ingredient fluoxetine hydrochloride. 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.

ZACTIN is used to treat:

- depression
- obsessive compulsive disorder (OCD)

2. What should I know before I use ZACTIN?

Warnings

Do not use ZACTIN if:

- **you are allergic to fluoxetine hydrochloride, any other medicines containing fluoxetine (such as Prozac and Lovan), or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use 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.
- **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 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
- **you are taking another medicine called pimozide to treat disturbances in thinking, feelings and behaviour.**

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

- **you are taking another medicine called metoprolol to treat cardiac failure**

Check with your doctor if you:

- have any other medical conditions, such as:
 - o kidney problems
 - o liver problems
 - o heart conditions
 - o raised eye pressure
 - o diabetes
 - o fits (seizure)
 - o a bleeding disorder or a tendency to bleed more than usual
 - o any other mental condition
- have allergies to any other medicines, foods, preservatives or dyes
- had a recent bone fracture or were told you have, or have risk factors, for osteoporosis
- take any medicines for any other condition
- drink alcohol

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Your doctor will discuss the risks and benefits of taking ZACTIN during pregnancy.

When taken during pregnancy, particularly in the last 3 months, medicines like ZACTIN 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 either the effect or discontinuation of ZACTIN.

When used during pregnancy, particularly in late pregnancy, medicines like ZACTIN 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 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. Tell your doctor or midwife that you are taking ZACTIN so they can advise you.

Talk to your doctor if you are breastfeeding or intend 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.

Use in children

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

3. What if I am 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.

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

Some medicines may interfere with ZACTIN and affect how 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 ZACTIN.
If you do take ZACTIN 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). You should not start a MAOI for at least 5 weeks after stopping ZACTIN.
- tamoxifen, a medicine used to treat breast cancer.
- 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 relieve anxiety.
- medicines used to treat certain mental and emotional conditions, also called antipsychotics.
- medicines used to treat disturbances in thinking, feelings and behaviour, such as pimozide.
- medicines used to control fits (seizures), such as phenytoin and carbamazepine.
- medicines used to relieve pain, such as tramadol.
- triptan medicines used to treat migraine, such as sumatriptan.
- 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.
- metoprolol, a medicine used to treat cardiac failure

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.

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ZACTIN.

4. How do I use ZACTIN?

How much to take

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

When to take ZACTIN

- ZACTIN should be 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.

How to take ZACTIN

- Swallow the capsules whole with a glass of water.
- ZACTIN can be taken with or without food.

How long to take ZACTIN

- **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 ZACTIN

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 use too much ZACTIN

If you think that you have used too much ZACTIN, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

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

5. What should I know while using ZACTIN?

Things you should 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.

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

Things you should 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, sleep disturbance, anxiety, irritability, agitation, confusion, weakness, 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.**

Driving or using machines

Do not drive or use any machines or tools until you know how ZACTIN affects you.

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

Drinking alcohol

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.

Looking after your medicine

- **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 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it 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.

Getting rid of any unwanted medicine

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

If your doctor tells you to stop taking ZACTIN, or the expiry date has passed, take it to any pharmacy for safe disposal.

6. Are there any side effects?

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

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

Do not be alarmed by the following list of possible side effects.

You may not experience any of them.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Gastrointestinal: • nausea, vomiting • upset stomach, diarrhoea • loss of appetite, weight loss, changes in taste, dry mouth Nervous System: • drowsiness • flushing • nervousness, anxiety • dizziness • abnormal thoughts • headache Sleep: • trouble sleeping, unusual dreams Skin: • excessive sweating • lesions of skin and mucous membrane Eye: • changes in vision Muscle: • twitches General: • fatigue, weakness • yawning • chills • sexual problems (decreased sexual drive, problems with orgasm, ejaculation or erection).	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
In some cases, these symptoms have continued after stopping treatment • more frequent urination	

Serious side effects

Serious side effects	What to do
Allergic Reaction: • itching, skin rash or hives • shortness of breath, wheezing or trouble breathing • swelling of the face, lips, tongue or other parts of the body Nervous System: • muscle spasms • tremors • seizures or fits • loss of coordination • confusion • sudden switches of mood to one of overactivity and uninhibited behaviour • hallucinations • overactive reflexes Heart: • fast, irregular heartbeat • ECG changes Bone and Muscle: • increased risk of breaking a bone General: • abnormal bleeding or bruising • widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals, called Stevens-Johnson syndrome • severe skin rash which may blister and look like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge), called erythema multiforme	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

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 else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

Phone: 1800 274 276

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7. Product details

This medicine is only available with a doctor's prescription.

What ZACTIN contains

Active ingredient (main ingredient)	Fluoxetine hydrochloride
Other ingredients (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)
Potential allergens	Contains sulfites and sugars as lactose.

Do not take this medicine if you are allergic to any of these ingredients.

What ZACTIN looks like

ZACTIN are size 3 capsules with a light green opaque body and purple opaque cap, printed with "FL20" on the body and "α" symbol on the cap in black ink (AUST R 53773).

Each pack contains 28 capsules.

Who distributes ZACTIN

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au