

ZACTIN TABS

contains the active ingredient fluoxetine (hydrochloride)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about ZACTIN TABS.

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 TABS 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 your medicine. You may need to read it again.

What ZACTIN TABS is used for

ZACTIN TABS is used to treat:

- Depression
- Obsessive compulsive disorder (OCD)
- Premenstrual dysphoric disorder (PMDD).

Your doctor may have prescribed ZACTIN TABS for another reason.

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

Zactin belongs to a group of medicines called selective serotonin reuptake inhibitors (SSRIs). They are thought to work by acting on chemicals in your brain called amines. These amines are involved in controlling mood.

ZACTIN TABS is not recommended for use in children, as the safety and effectiveness of fluoxetine in children have not been established.

ZACTIN TABS is available only with a doctor's prescription.

Before you take ZACTIN TABS

When you must not take it

Do not take ZACTIN TABS if you have an allergy to:

- 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 ZACTIN TABS 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.

Taking ZACTIN TABS with a MAOI may cause a serious reaction with a sudden increase in body temperature, shivering, rapid breathing, muscle stiffness and severe convulsions. Check with your doctor or pharmacist if you are unsure as to whether or not you have been taking a MAOI.

Do not take ZACTIN TABS if you are taking another medicine called pimozide

to treat disturbances in thinking, feelings and behaviour.

Taking pimozide together with ZACTIN TABS 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 our 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 TABS during pregnancy. If ZACTIN TABS 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 during the last 3 months of pregnancy. If you take ZACTIN TABS 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 TABS so they can advise you.

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

ZACTIN TABS passes into breast milk and may affect your baby. Your doctor will discuss the risks and benefits of taking ZACTIN TABS when breastfeeding.

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

- Liver problems
- Kidney problems
- Seizures (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 ZACTIN TABS, 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 him/her before you start taking ZACTIN TABS.

Taking other medicines

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

Some medicines may be affected by ZACTIN TABS, 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 ZACTIN TABS.

- 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 such as diazepam and alprazolam
- Medicines used to treat certain mental and emotional conditions, also called antipsychotics such as haloperidol, clozapine and pimozide
- Medicines used to control fits including phenytoin and carbamazepine
- Medicines used to prevent blood clots, such as warfarin
- Flecainide, a medicine used to treat some heart conditions
- Tryptophan, an amino acid found in certain supplements
- Other serotonergic drugs e.g., tramadol, sumatriptan
- St John's Wort (*Hypericum perforatum*), a herbal remedy.

These medicines may be affected by ZACTIN TABS 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 TABS.

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

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

How to take ZACTIN TABS

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 usual starting dose is one tablet (20 mg) each morning. Your doctor may change this dose depending on how you respond to this medicine.

Patients with kidney or liver problems, are elderly, or are on multiple medications may be given a lower or less frequent dose.

How to take it

Swallow the tablets whole with a glass of water or disperse the tablets in half a glass of water before swallowing.

To disperse ZACTIN TABS, remove the tablet from its foil packaging and drop it into about half a glass of water. Swirl the tablet in

the water until it disperses (falls apart), then drink it immediately.

ZACTIN TABS may be halved along the scoreline if your doctor has prescribed half a tablet.

When to take it

ZACTIN TABS can be taken with or without food.

ZACTIN TABS is usually taken as a single morning dose.

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

Take ZACTIN TABS at about the same time each day. This will help you remember when to take it.

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 tablets as you would normally.

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

If you have any questions about this, check with your doctor or pharmacist.

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.

How long to take it for

The length of treatment with ZACTIN TABS will depend on how quickly your symptoms improve. Most medicines of this type take time to work, so do not be discouraged if you do not feel better right away. While some symptoms will be relieved sooner than others, it can take up to 4 weeks or longer to feel the full benefits of ZACTIN TABS.

Keep taking ZACTIN TABS for as long as your doctor recommends.

If you do not start to feel better in about 4 weeks, check with your doctor.

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 that you or anyone else may have taken too much ZACTIN TABS. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

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

While you are taking ZACTIN TABS

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking ZACTIN TABS.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking ZACTIN TABS.

Tell your doctor if you feel that ZACTIN TABS is not helping your condition, or if, for any reason, you have not taken it exactly as prescribed.

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 become pregnant while taking ZACTIN TABS, tell your doctor immediately.

Your doctor will discuss the risks and benefits of taking ZACTIN TABS during pregnancy. If ZACTIN TABS 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 during 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 stop taking ZACTIN TABS, or lower the dose, without checking with your doctor.

Stopping ZACTIN TABS suddenly may cause nausea, headache, dizziness or anxiety. Your doctor may want you to gradually reduce the amount of ZACTIN TABS you are taking before stopping completely.

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

Do not use ZACTIN TABS to treat any other conditions unless your doctor tells you to.

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

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

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

Things to be careful of

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

ZACTIN TABS may cause drowsiness, dizziness or sleepiness in some people and affect alertness. Make sure you know how you react to ZACTIN TABS before you drive or operate machinery. If any of the above mentioned symptoms occur, 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 TABS.

Like all other medicines, ZACTIN TABS 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 patient to patient and often lessen 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 if you notice any of the following and they worry you:

- Nausea, vomiting
- Stomach upset, diarrhoea
- Loss of appetite, weight loss, changes in taste, dry mouth
- Trouble sleeping, unusual dreams
- Anxiety, nervousness
- Drowsiness, weakness
- Dizziness
- Headache
- 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 you notice any of the following:

- Itching, skin rash or hives
- Shortness of breath, wheezing or trouble breathing
- Swelling of the face, lips, tongue or other parts of the body
- Sudden switches of moods to one of excitement, overactivity and uninhibited behaviours
- Sudden fever
- Hallucinations
- Muscle spasms, tremors, twitches
- Convulsions or fits
- Fast, irregular heart beat
- Bleeding or bruising more easily than normal
- Loss of coordination, including uncontrolled movements of the eye, arms or legs
- Confusion
- Overactive reflexes

The above lists uncommon yet serious side effects. If any of these occur you may need urgent medical attention.

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 TABS 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 TABS

Storage

Keep ZACTIN TABS 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.

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

If you take the tablets out of their packaging they may not keep as well.

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

Do not store ZACTIN TABS or any other medicine in the bathroom or near a sink.

Do not leave ZACTIN TABS in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking ZACTIN TABS, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

ZACTIN TABS is an oval, convex, white tablet debossed "FL/20" on one side and "G" on the other.

Each blister pack contains 28 dispersible tablets.

Ingredients

The active ingredient in ZACTIN TABS is 20 mg fluoxetine (as hydrochloride).

The tablets also contain:

- Microcrystalline cellulose
- Colloidal anhydrous silica
- Maize starch
- Crospovidone
- Saccharin sodium
- Magnesium stearate
- Nat. Peppermint Micron TIM-11812

ZACTIN TABS contains sulfites and saccharin.

Manufacturer

ZACTIN TABS is made in Australia 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 numbers:

Blister pack - AUST R 90913

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