

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Paroxetine Sandoz.

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

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the benefits it is expected to have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

WHAT PAROXETINE SANDOZ IS USED FOR

The name of your medicine is Paroxetine Sandoz. It contains the active ingredient paroxetine hydrochloride.

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

Depression is longer lasting and/or more severe than the "low moods" that everyone has from time to time. It is thought to be caused by a chemical imbalance in parts of the brain. This imbalance affects your whole body and can cause emotional and physical symptoms. You may feel low in spirit, loss of interest in usual activities, being unable to enjoy life, have poor appetite or over eat, disturbed sleep, often waking up early, loss of sex drive, low energy and feeling guilty over nothing.

Paroxetine Sandoz may also be used to treat irrational fears or obsessional behaviour. These can also be due to chemical imbalance in parts of the brain.

Paroxetine Sandoz may also be used to help prevent panic attacks.

Paroxetine Sandoz may also be used to treat patients who may avoid and/or are fearful of social situations.

Paroxetine Sandoz may also be used to treat patients who have excessive anxiety and worry, and who feel irritable, restless, and/or tense in the muscles.

Paroxetine Sandoz may also be used to treat repetitive and distressing recollections of a past traumatic event.

Your doctor may decide that you should continue to use Paroxetine Sandoz for some time, even when you have overcome your problem. This should prevent the problem from returning.

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

Your doctor may have prescribed it for another reason.

BEFORE YOU TAKE PAROXETINE SANDOZ

Antidepressants can increase suicidal thoughts and actions in some children and adolescents younger than 18 years of age. But suicidal thoughts and actions can also be

caused by depression, a serious medical condition that is commonly treated with antidepressants. Thinking about killing yourself or trying to kill yourself is called suicidality or being suicidal.

Antidepressants are used to treat depression and other illnesses. Depression and other illnesses can lead to suicide. In some children and adolescents, treatment with an antidepressant increases suicidal thinking or actions. It is important to discuss all the risks of treating depression and also the risks of not treating it with your doctor. You should discuss all treatment choices with your doctor, not just the use of antidepressants.

Patients (and caregivers of patients) need to monitor for any worsening of their condition and/or the emergence of thoughts of suicide or suicidal behaviour or thoughts of harming themselves and to seek medical advice immediately if these symptoms present. (See Use In Children and Adolescents).

When you must not take it

Do not take this medicine if you have an allergy to:

- the active ingredient paroxetine hydrochloride or to any of the other ingredients listed at the end of this leaflet under Product Description
- any other similar medicines.

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 this medicine if you are pregnant or intend to become pregnant.

Studies show that use of paroxetine in early pregnancy (first 13 weeks) may be associated with an increased risk of some birth defects in babies. If you become pregnant or intend to become pregnant while taking paroxetine, you should make an appointment to see your doctor and have your treatment reviewed. It is important that you do not stop taking paroxetine suddenly. Paroxetine is a medicine that can have withdrawal side effects if stopped suddenly

(see Unwanted events that may occur on stopping treatment).

Do not take this medicine if:

- You are taking any other medication for the treatment of depression or have done so in the last two weeks.**

Taking Paroxetine Sandoz with another antidepressant may cause a serious reaction. You must not take Paroxetine Sandoz until two weeks after stopping monoamine oxidase inhibitor drugs (MAOIs). Examples of MAOIs are phenelzine and tranylcypromine. Another MAOI includes the antibiotic linezolid. There may be others so please check with your doctor. Taking Paroxetine Sandoz with a MAOI may cause a serious reaction.

- You are taking or have recently taken (within the last two weeks) a medicine called methylthionium chloride (methylene blue).**

- You are taking pimozide**
- You are taking thioridazine for the treatment of schizophrenia**
- You have taken Paroxetine Sandoz before and became unwell.**

Tell your doctor or pharmacist before taking the first dose.

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.

Take special care with Paroxetine Sandoz if you are over 65 years of age as Paroxetine Sandoz may cause a reduction in the amount of sodium within your blood which can lead to sleepiness and muscle weakness. If you experience these symptoms, please consult your doctor as soon as possible.

Medicines like Paroxetine Sandoz may affect your sperm. Fertility in some men may be reduced while taking Paroxetine Sandoz.

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 have allergies to:

- any other medicines, especially if they are in the same drug class as paroxetine (selective serotonin reuptake inhibitors)
- any other substances, including foods, preservatives or dyes.

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

Your doctor will discuss with you the possible risks and benefits of using Paroxetine Sandoz during breastfeeding.

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

- epilepsy (fits)
- heart problems
- kidney problems
- liver problems
- raised pressure in the eye
- problems with blood clotting
- other psychiatric conditions (mania, bipolar disorder)
- diabetes
- history of bleeding disorders, such as after childbirth

If you have not told your doctor about any of the above, tell him/her before you start taking Paroxetine Sandoz.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get 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 and Paroxetine Sandoz may interfere with each other. These include:

- medicines used to treat depression, anxiety, schizophrenia or attention-deficit hyperactivity disorder (ADHD), including medicines you buy without a

doctor's prescription. Examples of these medicines include tryptophan, hypericum perforatum (St John's Wort), perphenazine, risperidone, lithium or atomoxetine.

- medicines used in anaesthesia or to treat chronic pain, specifically fentanyl and tramadol.
- medicines used to lower blood pressure or treat heart conditions such as metoprolol or flecainide
- phenytoin, carbamazepine, phenobarbital and other medicines used to control epilepsy (anti-convulsants)
- thin blood (anti-coagulants), such as warfarin, aspirin and non-steroidal anti-inflammatory drugs (NSAIDs)
- selegiline, procyclidine and other medicines used to treat Parkinson's disease
- cimetidine and other medicines used to treat stomach ulcers
- medicines used to treat migraine attacks, such as sumatriptan
- treat or prevent breast cancer, specifically tamoxifen
- fosamprenavir and ritonavir combination, medicines used to treat HIV infection
- used in anaesthesia, such as mivacurium and suxamethonium.

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

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

HOW TO TAKE PAROXETINE SANDOZ

Follow all directions given to you by your doctor or pharmacist carefully about how and when to take Paroxetine Sandoz.

They may differ from the information contained in this leaflet. Read the direction label carefully.

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

How much to take

The usual dose for depression or social anxiety disorder/social phobia is one Paroxetine Sandoz tablet (paroxetine 20mg) per day. Your doctor may increase the dose slowly over several weeks. This may require you to break the tablet in half.

To treat obsessions and compulsions or panic attacks, the usual dose of Paroxetine Sandoz is two 20mg tablets per day. Your doctor may start you on a lower dose (half a tablet) and increase the dose slowly over several weeks. This may require you to break the tablet in half.

Ask your doctor or pharmacist if you are unsure of the correct dose for you. They will tell you exactly how much to take.

Follow the instructions they give you.

If you take the wrong dose, Paroxetine Sandoz may not work as well and your problem may not improve.

How to take it

Take Paroxetine Sandoz with a full glass of water or another liquid. The tablets can be broken in half, but should not be chewed.

If you need to break Paroxetine Sandoz, place the tablet on a flat surface with the notch side facing up and press down on the scored side with the thumb.

Paroxetine Sandoz should be taken in the morning, preferably with food.

How long to take Paroxetine Sandoz

Keep taking Paroxetine Sandoz for as long as your doctor tells you.

Like other medications of this type, Paroxetine Sandoz will not relieve your symptoms straight away. People generally start feeling better in a few weeks or so. Occasionally, the symptoms of depression or other psychiatric conditions may include thoughts of harming yourself or committing suicide. It is possible that these symptoms may continue or increase until the full anti-depressant effect of your medicine becomes apparent. Tell your doctor immediately or go to the nearest hospital if you have any distressing thoughts or experiences during this initial period or at any other time. Also contact your doctor if you experience any worsening of your depression/other symptoms at any time during your treatment.

Stopping treatment

Do not stop taking Paroxetine Sandoz even if you begin to feel better. Your doctor may decide that you should continue to use Paroxetine Sandoz for some time, even when you have overcome your problem. This should prevent the problem from returning. For best effect Paroxetine Sandoz must be taken regularly. Your doctor will tell you when and how Paroxetine Sandoz should be discontinued.

Your doctor will usually recommend that you stop treatment by slowly reducing the dosage over a period of several weeks. When you stop treatment with Paroxetine Sandoz, especially if this is done suddenly, you may experience unwanted symptoms. Please see the section of this leaflet called "Unwanted Effects that may occur on stopping treatment".

Use in children and adolescents

Paroxetine Sandoz is not recommended for use in children and adolescents under 18 years.

The use of Paroxetine Sandoz is not recommended to treat depression in children and adolescents under 18, as the drug has not been shown to be effective in this age group and there are possible unwanted effects.

Information from clinical trials has suggested that young adults, particularly those with depression, may be at an increased risk of suicidal behaviour (including suicide attempts) when treated with paroxetine, especially during initial treatment (generally the first one to two months). The majority of attempted suicides in clinical trials in depression involved patients aged 18 to 30 years.

Family and caregivers of children and adolescents being treated with antidepressants for major depressive disorder or for any other condition (psychiatric or non-psychiatric) need to monitor them for the emergence of agitation, irritability, unusual changes in behaviour, as well as the

emergence of thoughts of suicide, and to report such symptoms immediately to their doctor. It is particularly important that monitoring be undertaken during the initial few months of antidepressant treatment or at times of dose increase or decrease.

Use in pregnancy

If you take Paroxetine Sandoz 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 Paroxetine Sandoz so they can advise you.

If you forget to take it

Do not take an extra dose. Take your dose as soon as you remember, and continue to take it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

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 when 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 or New Zealand 0800 POISON or 0800 764766) for advice, or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much Paroxetine Sandoz. 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, vomiting, dizziness, sedation, confusion, dilated pupils, dry mouth, fever, blood pressure changes, headache, involuntary muscle contractions, tremor, sweating, facial flush, agitation, anxiety, irritability and tachycardia.

WHILE YOU ARE TAKING PAROXETINE SANDOZ

Things you must do

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Tell your doctor if you feel the tablets are not helping your condition.

If you are being treated for depression, discuss with your doctor any problems you may have and how you feel, especially any feelings of severe sadness or bursts of unusual energy or anger.

This will help your doctor to determine the best treatment for you.

Persons taking Paroxetine Sandoz may be more likely to think about killing themselves or actually trying to do so, especially when Paroxetine Sandoz is first started or the dose

is changed. People close to persons taking Paroxetine Sandoz can help by paying attention to changes in user's moods or actions.

Contact your doctor right away if someone using Paroxetine Sandoz talks about or shows signs of killing him or herself. If you are taking Paroxetine Sandoz yourself and you start thinking about killing yourself, tell your doctor about this side effect right away.

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

Your doctor may want to do some blood tests and check your heart and blood pressure from time to time. This helps to prevent unwanted side effects.

Things you must not do

Do not stop taking Paroxetine Sandoz without your doctor's permission.

Suddenly stopping Paroxetine Sandoz may cause symptoms like dizziness, trouble sleeping, shaking, feeling anxious, nausea, sweating or tinnitus.

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

Do not give your medicine to anyone else, even if their symptoms seem similar to yours.

Things to be careful of

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

Tests have shown that Paroxetine Sandoz does not have a marked effect on driving ability. However, it may cause drowsiness, dizziness or light-headedness in some people. Make sure you know how you react to Paroxetine Sandoz before you drive a car, operate machinery or do anything else that could be dangerous.

Be careful when drinking alcohol while you are taking this medicine.

Although drinking moderate amounts of alcohol is unlikely to affect your response to Paroxetine Sandoz, it is best to avoid alcohol while you are taking this medicine.

There is an increased risk of breaking a bone in people taking medicines like Paroxetine Sandoz. This risk is greatest during the early stages of treatment.

When your doctor decides that you should stop taking Paroxetine Sandoz, the dose may be reduced slowly or the time between doses increased over one or two weeks. Some people may have symptoms such as dizziness, anxiety, sleep disturbances, pins and needles, electric shock sensations or feeling sick and sweating if Paroxetine Sandoz is stopped, particularly if stopped suddenly.

Although Paroxetine Sandoz is not recommended for children under 18 years of age, additional symptoms that have been experienced by children whilst stopping treatment are abdominal pain, nervousness and mood changes.

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well or experience an allergic reaction while you are taking Paroxetine Sandoz.

All medicines can have side effects.

Sometimes they are serious, most of the time

they are not. You may need medical attention if you get some of the side effects.

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.

MILD EFFECTS

Tell your doctor if you notice any of the following that are troublesome or ongoing:

- bruising
- drowsiness, dizziness, difficulty in getting to sleep
- feeling sick, dry mouth, constipation, decreased appetite, diarrhoea
- vomiting
- feeling sweaty or shaky
- impaired sexual function
- weakness
- abnormal dreams (including nightmares)
- weight gain

These are the more common side effects of Paroxetine Sandoz. Mostly, these are mild and short-lived, however, some may be serious and require medical attention.

MORE SERIOUS EFFECTS

Tell your doctor immediately if you notice any of the following:

- muscle spasms or twitches

These may be serious side effects of Paroxetine Sandoz. You may need urgent medical attention. Serious side effects are rare.

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

- allergic reaction including swelling of the limbs, face, lips, mouth or throat which may cause difficulty in swallowing or breathing
- skin rash which may blister, and looks like small targets (central dark spots surround by a paler area, with a dark ring around the edge) called erythema multiforme
- a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens-John syndrome)
- a widespread rash with blisters and skin peeling on much of the body surface (toxic epidermal)
- sudden onset of prolonged muscular spasm, affecting the eyes, head, neck and body
- sudden increase in body temperature, severe convulsions
- fast heartbeat, sweating, muscle spasm, racing thoughts, restlessness

These are very serious side effects. You may need urgent medical attention or hospitalisation. All of these side effects are very rare.

Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects.

Other rare events that have been reported with paroxetine include:

- blurred vision
- abnormal liver function

- low levels of sodium in the blood, especially in older people
- bleeding disorders, including nose bleeds and gastrointestinal bleeding which occurs very rarely
- hormone disturbances
- mood of excitement, over-activity and uninhibited behaviour
- confusion
- seizures
- rash caused by light
- itch rash, hives, swelling of the face, lips, mouth, tongue or throat
- akathisia (restlessness or difficulty keeping still, caused by medicines to treat mental disorders)
- irresistible urge to move the legs (Restless Legs Syndrome)
- menstrual period disorder (including heavy periods, bleeding between periods and absence of periods).
- severe allergic reaction
- heavy vaginal bleeding shortly after birth.

Unwanted events that may occur on stopping treatment:

- dizziness
- sensory disturbances such as, pins and needles, burning sensations, electric shock like sensations
- sleep disturbances, including intense dreams
- agitation or anxiety
- feeling sick
- shaking or tremors
- confusion
- sweating
- headache
- diarrhoea.

These are likely to occur in the first few days of stopping treatment or very rarely if you miss a dose. However, they are more likely to occur if you stop taking Paroxetine Sandoz too quickly. Therefore, always consult your doctor before stopping your medicine. For the majority of patients, symptoms go away on their own within a few weeks. However, if you feel that the unwanted symptoms are too severe, see your doctor who will suggest how to manage stopping treatment more slowly.

Additional symptoms that have been experienced by children and adolescents when stopping treatment include changing emotions (including thoughts of suicide, attempting suicide, mood changes and feeling tearful), abdominal pain and nervousness.

Tell your doctor immediately if you notice any of the following:

Wheezing, swelling of the lips/mouth, difficulty in breathing, hayfever, lumpy rash (hives) or fainting. These could be a symptom of an allergic reaction.

Unwanted events in children and adolescents under the age of 18 years:

Although Paroxetine Sandoz is not recommended for children and adolescents under the age of 18 years, the most common unwanted effects in this age group are:

- decreased appetite
- tremor (uncontrollable trembling)

- sweating
- hyperactivity
- hostile/unfriendly behaviour
- agitation
- changing emotions including crying, changes in mood, trying to harm themselves, thoughts of suicide and attempting suicide.

20mg film-coated tablets: AUST R 82551 (blisters)

20mg film-coated tablets: AUST R 82550 (bottles)#

#Not registered in New Zealand

AFTER TAKING PAROXETINE SANDOZ

Storage

Keep your medicine in the original container.

If you take it out of its original container it may not keep well.

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

Do not store Paroxetine Sandoz 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 this medicine 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

Paroxetine Sandoz 20mg - round white tablets with a score notch on one side and embossed with 'PX 20' on the other side.

Available in blisters and bottles# of 30 tablets.

Ingredients

Active ingredient:

- Paroxetine Sandoz 20mg - 20mg paroxetine (as hydrochloride).

Inactive ingredients:

- colloidal anhydrous silica
- copovidone
- hypromellose
- mannitol
- microcrystalline cellulose
- purified talc
- sodium starch glycollate
- magnesium stearate
- titanium dioxide.

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

Supplier

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Australian Registration Numbers