

AROPAX

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 taking AROPAX?

AROPAX contains the active ingredient paroxetine hydrochloride. AROPAX is used to help to relieve the symptoms of major depressive disorder. AROPAX may also be used to treat irrational fears, general anxiety and obsessive behaviour. For more information, see Section [1. Why am I taking AROPAX?](#) in the full CMI.

2. What should I know before I take AROPAX?

Do not use if you have ever had an allergic reaction to AROPAX 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 take AROPAX?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with AROPAX 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 AROPAX?

- To treat major depressive disorder, generalised or social anxiety disorder/social phobia, the usual dose is one 20 mg tablet per day
- To treat obsessions and compulsions or panic attacks, the usual dose is two 20 mg tablets per day
- To treat Post Traumatic Stress Disorder, the usual starting dose is one 20 mg per day

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

5. What should I know while taking AROPAX?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using AROPAX
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how AROPAX affects you
Drinking alcohol	<ul style="list-style-type: none">• Although drinking moderate amounts of alcohol is unlikely to affect your response to AROPAX, it is best to avoid alcohol while you are taking this medicine.
Looking after your medicine	<ul style="list-style-type: none">• Store below 30°C• Store in original packaging

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

6. Are there any side effects?

Like other medicines, AROPAX can cause some side effects. If they occur, they are most likely to be minor and temporary. Mild side effects can include feeling sick, dry mouth, constipation, decreased appetite, diarrhoea, vomiting, drowsiness, dizziness, difficulty in getting to sleep, impaired sexual function, weakness, feeling sweaty or shaky, yawning, bruising, abnormal dreams (including nightmares), weight gain and headache.

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.

AROPAX

Active ingredient(s): *paroxetine hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about using AROPAX. **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 AROPAX.**

Where to find information in this leaflet:

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

1. Why am I taking AROPAX?

AROPAX contains the active ingredient paroxetine hydrochloride. AROPAX belongs to a group of medicines called selective serotonin reuptake inhibitor (SSRI) antidepressants. They are thought to work by their action on brain chemicals called amines, which are involved in controlling mood.

Major depressive disorder is longer lasting 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, lose interest in usual activities, be unable to enjoy life, have poor appetite or over eat, have disturbed sleep, often waking up early, low energy and feel guilty over nothing. AROPAX corrects the chemical imbalance and so helps relieve the symptoms of major depressive disorder.

AROPAX may also be used to treat irrational fears, general anxiety and obsessive behaviour. These can also be due to chemical imbalances in parts of the brain.

AROPAX may also be used to treat the symptoms of panic attacks. When taken regularly it will help prevent the attacks.

AROPAX may also be used to treat patients who may avoid and/or are fearful of social situations (general and social anxiety).

AROPAX may also be used to treat patients who suffer from anxiety caused by re-experiencing an extremely traumatic event (Post Traumatic Stress Disorder).

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

2. What should I know before I take AROPAX?

Warnings

Do not take AROPAX if:

- you are allergic to paroxetine, 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:
 - itchy skin rash
 - shortness of breath and
 - swelling of the face or tongue
- you have taken AROPAX before and became unwell
- you are taking any other medications for the treatment of major depressive disorder or have done so in the last two weeks. Taking AROPAX with another antidepressant may cause a serious reaction. You must not take AROPAX until two weeks after stopping monoamine oxidase inhibitor drugs (MAOIs). Examples of MAOIs are phenelzine (Nardil) and tranylcypromine (Parnate). There may be others so please check with your doctor or pharmacist. Taking AROPAX with a MAOI may cause a serious reaction
- you are taking or have recently taken (within the last two weeks) a medicine called methylthioninium chloride (methylene blue)
- you are taking thioridazine (an antipsychotic medicine)
- you are taking pimozide

Check with your doctor if you:

- are under 18 years of age
- are over 65 years of age. AROPAX 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
- take any medicines for any other condition
- have or have had any other medical conditions including:
 - liver problems
 - heart problems
 - kidney problems
 - heart tracing (electrocardiogram/ECG) has an abnormality known as prolonged QT interval or you are taking medicines that may affect the QT interval in the ECG
 - epilepsy
 - mania (mood with excitement, over-activity and uninhibited behaviour) or a history of mania
 - raised pressure in the eye (glaucoma)
 - problems with blood clotting

- low blood potassium levels
- low blood magnesium levels
- diabetes
- allergic reaction to any medicine which you have taken previously to treat your current condition
- thoughts of suicide. Occasionally, the symptoms of major depressive disorder 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. Go to your doctor immediately and tell them if you have any distressing thoughts or experiences during this initial period or at any other time

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

Medicines like AROPAX may cause symptoms of sexual dysfunction (see Section [6. Are there any side effects?](#)). In some cases, these symptoms have continued after stopping treatment.

AROPAX should be used with caution in patients at risk of irregular heart beat (e.g. QTc prolongation and Torsades de Pointes). Your doctor may wish to perform tests on the electrical activity of your heart prior to starting or during your treatment.

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.

It is important that you do not stop taking paroxetine suddenly. Paroxetine is a medicine that can have withdrawal side effects if stopped suddenly.

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

Children

AROPAX is not recommended in children under the age of 18 years.

When AROPAX was tested in children under 18 years with major depressive disorder, obsessive compulsive disorder or social anxiety, there were additional unwanted effects to those seen in adults, such as suicidal thoughts, hostile and unfriendly behaviour and changing moods. The use of AROPAX is not recommended to treat major depressive disorder in children under 18, as the drug has not been shown to be effective in this age group. The long-term safety effects of paroxetine in this age group have not yet been demonstrated.

Information from clinical trials has suggested that young adults, particularly those with major depressive disorder, may be at an increased risk of suicidal behaviour (including suicide attempts) when treated with AROPAX. The

majority of attempted suicides in clinical trials in major depressive disorder 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.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, or have used other medicines until recently including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with AROPAX and affect how it works. In particular tell your doctor if you are taking any medicines that:

- treat major depressive disorder such as tricyclic antidepressants (amitriptyline, nortriptyline, imipramine and desipramine), monoamine oxidase inhibitors (MAOI's), anxiety, or schizophrenia. This includes medicines you buy without a doctor's prescription such as tryptophan or *hypericum perforatum* (St John's Wort)
- treat manic major depressive disorder or bipolar disorder, such as lithium
- are used in anaesthesia or to treat chronic pain, specifically mivacurium, suxamethonium, fentanyl or tramadol
- lower blood pressure or treat heart conditions, such as metoprolol (Betaloc)
- make the heartbeat regular such as flecainide (Tambocor), propafenone (Rytmonorm)
- control epilepsy, (anti-convulsants) such as phenytoin (Dilantin), carbamazepine (Tegretol), sodium valproate (Epilim)
- thin blood (anti-coagulants), such as warfarin (Coumadin, Marevan), aspirin, non-steroidal anti-inflammatory drugs (NSAIDs)
- treat Parkinson's disease, such as selegiline, procyclidine (Kemadrin)
- treat stomach ulcers, such as cimetidine
- treat or prevent breast cancer, specifically Tamoxifen
- treat migraines or cluster headaches, such as triptans
- treat HIV, such as fosamprenavir or ritonavir
- treat schizophrenia, such as perphenazine or risperidone
- treat attention-deficit hyperactivity disorder (ADHD), such as atomoxetine
- treat high blood pressure or heart disease, such as metoprolol
- treat tuberculosis, such as rifampicin

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

4. How do I take AROPAX?

How much to take

- to treat major depressive disorder, generalised or social anxiety disorder/social phobia, the usual dose is one 20 mg tablet 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 is two 20 mg 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.
- to treat Post Traumatic Stress Disorder, the usual starting dose is one 20 mg tablet per day. The doctor may increase the dose slowly as well over several weeks. This may require you break the tablet in half.

How to take AROPAX

- take AROPAX with a full glass of water or another liquid. AROPAX tablets can be broken in half, but should not be chewed

When to take AROPAX

- AROPAX should be taken in the morning, preferably with food
- keep taking your AROPAX for as long as your doctor tells you. It may take a number of weeks for AROPAX to work
- do not stop taking AROPAX even if you begin to feel better. Your doctor may decide that you should continue to use AROPAX for some time, even when you have overcome your problem. For best effect AROPAX must be taken regularly
- your doctor will tell you when and how AROPAX should be stopped. Usually the dose is gradually reduced before you would stop taking it. Like some other similar medicines, if AROPAX is stopped suddenly you may experience some discontinuation side effects

If you forget to use AROPAX

AROPAX should be used regularly at the same time each day. If you miss your dose at the usual time, do not take an extra dose. Wait until the next day and take your normal dose then.

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

If you use too much AROPAX

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

You should immediately:

- phone the Poisons Information Centre (by calling 0800 POISON or 0800 764 766), 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.

5. What should I know while taking AROPAX?

Things you should do

Check with your doctor, pharmacist or dentist before taking any other medicines. This includes medicines that you buy without a prescription as well as other medicines that a doctor prescribes for you.

Remind any doctor, dentist or pharmacist you visit that you are using AROPAX.

Things you should not do

- Do not stop using this medicine suddenly. When your doctor decides that you should stop taking AROPAX, 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 ringing in the ears if AROPAX is stopped suddenly

Things to be aware of

- there is an increased risk of breaking a bone in people taking medicines like AROPAX. This risk is greatest during the early stages of treatment

Driving or using machines

Be careful before you drive or use any machines or tools until you know how AROPAX affects you.

Tests have shown that AROPAX does not have a marked effect on driving ability. However, AROPAX may cause drowsiness, dizziness or light-headedness in some people. Make sure you know how you react to AROPAX before you drive a car or operate machinery.

Drinking alcohol

Tell your doctor if you drink alcohol.

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

Looking after your medicine

- store below 30°C
- store in original packaging

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

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

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.

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
<p>General disorders:</p> <ul style="list-style-type: none"> • dry mouth • yawning <p>Skin and subcutaneous tissue disorders:</p> <ul style="list-style-type: none"> • rash caused by light or a sensitivity to light • skin irritation or itching <p>Nervous system disorders:</p> <ul style="list-style-type: none"> • drowsiness, dizziness, difficulty in getting to sleep • headache • feeling sweaty or shaky • impaired sexual function <p>Musculoskeletal connective tissue disorders:</p> <ul style="list-style-type: none"> • weakness • irresistible urge to move the legs (Restless Legs Syndrome) • joint or muscle pain • increase risk of bone fracture <p>Psychiatric disorders:</p> <ul style="list-style-type: none"> • abnormal dreams (including nightmares) • mood of excitement, over-activity and uninhibited behaviour (mania) • a feeling of restlessness or agitation which may be accompanied by the inability to sit or stand still • confusion, anxiety and agitation <p>Metabolism and nutrition disorders:</p> <ul style="list-style-type: none"> • abnormal liver function (sometimes jaundice) • increases in cholesterol levels 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

<ul style="list-style-type: none"> • weight gain <p>Gastrointestinal disorders:</p> <ul style="list-style-type: none"> • feeling sick (nausea) • constipation • decreased appetite • diarrhoea • vomiting <p>Blood and lymphatic system disorders:</p> <ul style="list-style-type: none"> • bruising • low levels of sodium in the blood, especially in older people • reduced number of platelets in the blood • menstrual period disorders (including heavy periods, bleeding between periods and absences of periods) • breast milk production when not breastfeeding • increased levels of a hormone (ADH) that causes fluid or water retention 	
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Serious side effects

Serious side effects	What to do
<p>Cardiovascular disorders:</p> <ul style="list-style-type: none"> • irregular heartbeat or palpitations • changes in blood pressure which could make you feel faint and weak <p>Musculoskeletal connective tissue disorders:</p> <ul style="list-style-type: none"> • muscle spasms or twitches • sudden increase in body temperature, severe convulsions • sudden onset of prolonged muscular spasm or twitches, affecting the eyes, head, neck and body • painful persistent erection of the penis <p>Skin and subcutaneous tissue disorders:</p> <ul style="list-style-type: none"> • raised and itchy rash (hives) • swelling of the face, lips, mouth, tongue or throat • sensitivity of the skin to sunlight <p>Eye disorders:</p> <ul style="list-style-type: none"> • sudden eye pain and blurred vision, possibly with feeling ill and vomiting 	<p>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.</p>

- high pressure inside the eye (acute glaucoma), blurred vision

Blood and lymphatic system disorders:

- abnormal bleeding

Psychiatric disorders:

- hallucinations
- panic attacks or feeling as if your thoughts or actions are not your own (depersonalisation)

Nervous system disorders:

- seizures

Immune system disorders and allergic reactions:

- swelling, sometimes of the face and mouth (angioedema), causing difficulty in breathing
- collapse or loss of consciousness
- 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-Johnson syndrome)
- a widespread rash with blisters and skin peeling on much of the body surface (toxic epidermal necrolysis)
- fast heartbeat, sweating, muscle spasm, racing thoughts, restlessness

Effects on stopping AROPAX:

Studies show that 3 in 10 people notice some symptoms on stopping AROPAX compared to 2 in 10 patients after stopping sugar pills. However, this is not the same as the medicine being addictive or becoming dependent on it, as is seen with drugs such as heroin. Symptoms may include:

- dizziness
- sensory disturbances such as ‘pins and needles’, burning sensations, electric shock-like sensations or ringing in the ears
- sleep disturbances, including intense dreams
- feeling anxious or agitated
- nausea (feeling sick)
- shaking or tremors
- confusion
- sweating
- headache
- diarrhoea
- visual disturbances
- heart palpitations

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 AROPAX 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.

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 via <https://pophealth.my.site.com/carmreportnz/s/>

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.

7. Product details

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

What AROPAX contains

Active ingredient (main ingredient)	paroxetine hydrochloride
Other ingredients (inactive ingredients)	Sodium Starch Glycollate Magnesium Stearate Calcium hydrogen phosphate dihydrate Titanium dioxide Hypromellose Macrogol 400 Polysorbate 80

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

What AROPAX looks like

AROPAX tablets are white, film-coated, oval shaped biconvex tablets, de-bossed with “20” on one side and a break bar on the other, containing 20 mg of paroxetine. (TT50-4923).

AROPAX is available in packs of 30 tablets.

Who distributes AROPAX

GlaxoSmithKline NZ Ltd
Private Bag 106600
Downtown
Auckland 1143
New Zealand

Phone: (09) 367 2900
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