

# AROPAX

paroxetine tablets, 20 mg

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## Consumer Medicine Information Leaflet

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### What is in this leaflet

This leaflet answers some of the common questions about AROPAX. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

Please read this leaflet before you start taking AROPAX. If you are helping someone else take AROPAX, please read this leaflet before you give the first dose.

All medicines have risks and benefits. Your doctor has weighed the expected benefits of taking AROPAX against the possible risks. If you have any concerns, speak to your doctor.

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

**Keep this leaflet with the medication.**

You may want to read it again.

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### What AROPAX is used for

The name of your medicine is AROPAX; it is also known as paroxetine.

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.

Your doctor may have prescribed AROPAX for another use.

**Ask your doctor if you have questions about why AROPAX has been prescribed for you.**

AROPAX tablets are only available if prescribed by a doctor.

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### Before you take AROPAX

**When you must not take it**

**Do not take AROPAX if**

- You have had an allergic reaction to AROPAX or to any of the ingredients listed in the **Ingredients** section of this leaflet.

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. Tell your doctor or pharmacist before taking the first dose.
- 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 ( Melleril, Aldazine) ( an antipsychotic medicine)
- you are taking pimozone

**Do not take this medicine after the expiry date (EXP) printed on the pack or if the packaging is torn or shows signs of tampering, or the tablets look damaged or discoloured.**

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

Do not give this medicine to anyone else. Your doctor has prescribed it specifically for you and your condition.

### ***Before you start to take it***

**Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.**

Tell your doctor if you are under 18 years of age (see 'Use in Children under 18 years of age', below)

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

- You have had an allergic reaction to any medicine which you have taken previously to treat your current condition
- You have or have recently had 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.

- You 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.

- You have any of these medical conditions:

liver problems

heart problems

kidney problems

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

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 Side Effects section). 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.

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

Your doctor will discuss with you the possible risks and benefits of using AROPAX during pregnancy. 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 Effects on stopping AROPAX).

**Use in Children under 18 years of age**

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.

### **Taking other medicines**

Tell your doctor if you are taking any other medicines or have used other medicines until recently. This includes those that you buy without a prescription from a supermarket, pharmacy or health food shop. 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 (Tambacor), 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 (Eldepryl), procyclidine (Kemadrin)

- treat stomach ulcers, such as cimetidine (Tagamet).
- 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.

Some medicines may affect the way other medicines work. Your doctor or pharmacist will be able to tell you which medicines are safe to take with AROPAX.

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## **How to take AROPAX**

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### **Follow your doctor's instructions about how and when to take AROPAX.**

Read the label carefully. If you have any concerns about how to take AROPAX, talk to your doctor or pharmacist.

### **How much to take**

The usual dose of AROPAX for major depressive disorder, generalised or social anxiety disorder/social phobia 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. Aropax is not suitable for children under the age of 18 years.

To treat obsessions and compulsions or panic attacks, the usual dose of AROPAX 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 per day. The doctor may increase the dose slowly as well over several weeks. This may require you to break the tablet in half.

### **How and when to take it**

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

**AROPAX should be taken in the morning, preferably with food.**

### **How long to take it**

**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 take it**

Do not take an extra dose. Wait until the next day and take your normal dose then.

Do not try to make up for the dose that you missed by taking more than one dose at a time.

### ***If you take too much (overdose)***

**Immediately telephone your doctor or Poisons Information Centre (0800 POISON or 0800 764 766) for advice, or go to the nearest Accident and Emergency Department at your nearest hospital, if you think that you or anyone else may have taken too much AROPAX. Do this even if there are no signs of discomfort or poisoning.**

Keep phone numbers for these places handy. If you are unsure what to do, contact your doctor or pharmacist.

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## **While you are using AROPAX**

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### ***Things you must do:***

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

### ***Things to be careful of:***

**Be careful driving or operating machinery 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.

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.

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.

Do not take monoamine oxidase inhibitor antidepressants (MAOIs) until two weeks after you stop taking AROPAX. Examples of MAOIs include phenelzine (Nardil) and tranylcypromine (Parnate). There may be others so please check with your doctor.

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.

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## **Side effects**

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

Like other medicines, AROPAX can cause some side effects. If they occur, they are most likely to be mild, and may lessen after a few days. However, some may be serious and need medical attention.

### ***Mild effects***

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

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

- weight gain
- bruising
- headache

### ***More serious effects***

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

- muscle spasms or twitches
- irregular heartbeat or palpitations

These are serious side effects. You may need urgent medical attention. Serious side effects are rare.

If you think AROPAX is causing you to have an allergic reaction tell your doctor or go to the Accident and Emergency department of your nearest hospital if any of the following happens:

- raised and itchy rash (hives)
- 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)
- sudden onset of prolonged muscular spasm or twitches, affecting the eyes, head, neck and body.
- sudden increase in body temperature, severe convulsions
- fast heart beat, sweating, muscle spasm, racing thoughts, restlessness
- sudden eye pain and blurred vision, possibly with feeling ill and vomiting

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

Other side effects reported with AROPAX include:

- a feeling of restlessness or agitation which may be accompanied by the inability to sit or stand still
- irresistible urge to move the legs (Restless Legs Syndrome)
- abnormal liver function (sometimes jaundice)
- low levels of sodium in the blood, especially in older people
- high pressure inside the eye (acute glaucoma), blurred vision
- breast milk production when not breastfeeding
- abnormal bleeding
- menstrual period disorders (including heavy periods, bleeding between periods and absences of periods)
- reduced number of platelets in the blood
- changes in blood pressure which could make you feel faint and weak
- mood of excitement, over-activity and uninhibited behaviour (mania)
- hallucinations
- confusion, anxiety and agitation
- seizures
- rash caused by light or a sensitivity to light
- itchy rash, hives, swelling of the face, lips, mouth, tongue or throat
- increased levels of a hormone (ADH) that causes fluid or water retention.
- sensitivity of the skin to sunlight
- increases in cholesterol levels

- panic attacks or feeling as if your thoughts or actions are not your own (depersonalisation)
- skin irritation or itching
- painful persistent erection of the penis
- joint or muscle pain
- increase risk of bone fracture

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.

This is not a complete list of all possible events reported. Other events may occur in some people and there may be some unwanted effects not yet known. Remember to tell your doctor as soon as possible if you do not feel well when you are taking or soon after you have stopped taking AROPAX.

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## After using AROPAX

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### Storage

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

**Keep the pack in a cool dry place, in temperatures below 30°C. Do not leave it in the car on a hot day. Do not store medicines in the bathroom or near a sink. 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 advises you to stop taking AROPAX or the medicine has passed its expiry date, ask your pharmacist what to do with any tablets that are left over.**

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## Product description

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### What it looks like

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

AROPAX is available in packs of 30 tablets

**Ingredients**

AROPAX tablets also contain inactive ingredients, including the colouring agent titanium dioxide (white, E171), calcium hydrogen phosphate, hypromellose, sodium starch glycollate (potato starch), magnesium stearate, polysorbate 80 and macrogol 400.

AROPAX tablets do not contain sucrose, lactose, gluten or tartrazine.

**Distributor**

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