

## APX-PAROXETINE

paroxetine (as hydrochloride)

### Consumer Medicine Information

#### What is in this leaflet

This leaflet answers some common questions about APX-PAROXETINE.

It does not contain all of 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 APX-PAROXETINE against the benefits they expect it will have for you.

**Talk to your doctor or pharmacist if you have any concerns about taking this medicine.**

**Keep this leaflet with your medicine.** You may need to read it again.

#### What APX-PAROXETINE is used for

APX-PAROXETINE is used to:

- treat depression
- treat irrational fears or obsessional behaviour
- prevent panic attacks
- treat patients who avoid or are fearful of social situations
- treat patients with excessive anxiety and worry, and who feel irritable, restless, and/or tense in the muscles
- treat repetitive and distressing recollections of a past traumatic event.

Depression 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 wake up early, have low energy and feel guilty over nothing. APX-PAROXETINE corrects the chemical imbalance and so helps relieving the symptoms of depression.

APX-PAROXETINE 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.

Your doctor may have prescribed this medicine for another reason. **Ask your doctor if you have any questions about why it has been prescribed for you.**

It is not recommended to treat depression in children and adolescents under 18 (see *Use in children and adolescents*).

APX-PAROXETINE is available only with a doctor's prescription.

#### Before you take it

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. 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 APX-PAROXETINE if you are allergic to medicines containing paroxetine or any of the ingredients listed at the end of this leaflet.**

**Do not take this medicine if you are pregnant or intend to become pregnant.** Studies show that the 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 Effects that may occur on stopping treatment**).

**Do not take it if you have ever had an allergic reaction to paroxetine hydrochloride or any of the ingredients listed at the end of this leaflet.**

**Do not take it if you have taken paroxetine before and you became unwell. Tell your doctor or pharmacist before taking the first dose.**

**Do not take this medicine if you have taken any other medications for the treatment of depression in the last two weeks.**

Taking APX-PAROXETINE with another antidepressant may cause a serious reaction. You must not take it until 2 weeks after stopping monoamine oxidase inhibitor drugs (MAOIs). Examples of MAOIs are phenelzine (Nardil) and tranylcypromine (Parnate). Another MAOI includes antibiotic linezolid. There may be others, so please check with your doctor. Taking APX-PAROXETINE with a MAOI may cause a serious reaction.

**Do not take if you are taking or recently taken (within the last two weeks) a medicine called methylthioninium chloride (methylene blue).**

**Do not take it if you are taking thioridazine (Melleril, Aldazine) for the treatment of schizophrenia.**

**Do not take it if you are taking pimozide (Orap).**

**Do not take it if the expiry date (Exp.) printed on the pack has passed.**

**Do not take it if the packaging shows signs of tampering.**

Take special care with APX-PAROXETINE if you are over 65 years of age as APX-PAROXETINE 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 APX-PAROXETINE may affect your sperm. Fertility in some men may be reduced while taking APX-PAROXETINE.

#### 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 intend to become pregnant.**

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

Your doctor will discuss the risks and benefits of taking APX-PAROXETINE when breastfeeding.

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

- liver problems
- heart problems
- kidney problems
- epilepsy
- mania
- raised pressure in the eye
- blood clotting problems
- other psychiatric conditions (eg 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 APX-PAROXETINE.**

#### Taking other medicines

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

Some medicines may be affected by APX-PAROXETINE, or may affect how well it works. These include:

- any other medicines used to treat depression, anxiety, schizophrenia or attention-deficit hyperactivity disorder (ADHD) including medicines you buy without a doctor's prescription such as tryptophan or *Hypericum perforatum* (St John's wort), perphenazine, risperidone, lithium or atomoxetine.
- medicines used in anaesthesia or to treat pain or chronic pain, specifically tramadol or fentanyl
- medicines to lower blood pressure or treat heart conditions, such as metoprolol (Betaloc) or flecainide (Tambacor).
- medicines to control epilepsy (anti-convulsants), such as phenytoin (Dilantin), carbamazepine or phenobarbital.
- medicines to thin the blood such as warfarin (Coumadin, Marevan), aspirin

(Aspro) or non-steroidal anti-inflammatory drugs (NSAIDs).

- medicines used to relieve pain, swelling and other symptoms of inflammation, including arthritis (NSAIDs)
- medicines to treat Parkinson's disease such as selegiline (Eldepryl), procyclidine (Kemadrin)
- medicines to treat stomach ulcers, such as cimetidine (Tagamet)
- medicines to treat migraine attacks such as sumatriptan
- medicines used to treat or prevent breast cancer, specifically tamoxifen
- medicines to treat HIV infection, such as fosamprenavir (Telzir), ritonavir (Norvir)
- medicines used in anesthesia, such as mivacurium or suxamethonium.

Your doctor can tell you what to do if you are taking any of these medicines.

**Check with your doctor or pharmacist if you are not sure whether you are taking any of these medicines.**

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking APX-PAROXETINE.

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

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## How to take it

### *How much to take*

Your doctor will tell you how many tablets you need to take each day and when to take them. This depends on your condition and whether or not you are taking any other medicines.

The usual dose for depression, social anxiety disorder/social phobia, generalised anxiety disorder or post-traumatic stress disorder is one 20 mg tablet per day. Your doctor may increase the dose slowly over several weeks.

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 and increase the dose slowly over several weeks.

**Follow all directions given to you by your doctor and pharmacist carefully.**

### *How to take it*

**Swallow the tablets with a glass of water or other liquid. APX-PAROXETINE tablets can be broken in half, but should not be chewed.**

This medicine should be taken in the morning, preferably with food.

### *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 are not sure what to do, ask your doctor or pharmacist.**

### *How long to take it for*

**Keep taking APX-PAROXETINE for as long as your doctor tells you.**

Like other drugs of this type, it will not relieve your symptoms straight away. You should start to feel better after a week or two, although it may take longer.

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 (i.e. one to two months).

**You or anyone close to you or caring for you should watch for these symptoms and 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 or other symptoms at any time during your treatment.

### *Stopping treatment*

**Do not stop taking APX-PAROXETINE even if you begin to feel better.**

Your doctor may decide that you should continue to use this medicine for some time, even when you have overcome your problem. For best effect, the medicine must be taken regularly. Your doctor will tell you when and how it 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, especially if this is done suddenly, you may experience unwanted symptoms. Please see the section of this leaflet under "*Unwanted Effects that may occur on stopping treatment*".

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

**Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much APX-PAROXETINE. Do this even if there are no signs of discomfort or poisoning.**

If you are not sure what to do, contact your doctor or pharmacist.

### *Use in children and adolescents*

APX-PAROXETINE is not recommended to treat depression in children and adolescents under 18, as the medicine 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 APX-PAROXETINE 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 APX-PAROXETINE so they can advise you.

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## While you are taking it

### *Things you must do*

**Before starting any new medicine, tell your doctor or pharmacist that you are taking APX-PAROXETINE.**

**Tell all the doctors, dentists and pharmacists who are treating you that you are taking APX-PAROXETINE.**

**If you become pregnant while taking this medicine, tell your doctor.**

**People taking it may be more likely to think about killing themselves or actually try to do so, especially when APX-PAROXETINE is first started or the dose is changed. Tell your doctor immediately if you have thoughts about killing yourself or if you are close to or care for someone using it who talks about or shows signs of killing him or herself.**

All mentions of suicide or violence must be taken seriously.

Occasionally, the symptoms of depression may include thoughts of suicide or self-harm. It is possible that these symptoms continue or get worse during the first one to two months of taking APX-PAROXETINE until the medicine starts to work completely. This is more likely to occur if you are a young adult, i.e. 18 to 24 years of age, and you have not used antidepressant medicines before.

**If you or someone you know or care for demonstrates any of the following warning signs of suicide-related behaviour while taking APX-PAROXETINE, contact a doctor immediately, or even go to the nearest hospital for treatment:**

- thoughts or talk of death or suicide
- thoughts of talk of self-harm or harm to others
- any recent attempts of suicide or self-harm
- increase in aggressive behaviour, irritability or agitation
- worsening of depression.

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

Otherwise, your doctor may think that it was not working as it should and change your treatment unnecessarily.

**Visit your doctor regularly so he/she can check on your progress.**

### *Things you must not do*

**Do not stop taking APX-PAROXETINE, or lower the dose, without checking with your doctor.**

When your doctor decides that you should stop taking it, the dose may be reduced slowly over a period of several weeks. When you stop treatment with paroxetine, 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*'.

**Do not use your medicine to treat any other conditions unless your doctor tells you to.**

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

*Things to be careful of*

**Be careful of driving or operating machinery until you know how it affects you.**

This medicine may cause drowsiness, dizziness or lightheadedness in some people. If any of these occur, do not drive, operate machinery or do anything else that could be dangerous.

Although drinking moderate amounts of alcohol is unlikely to affect your response to APX-PAROXETINE, 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. This risk is greatest during the early stages of treatment.

When your doctor decides that you should stop taking paroxetine the dose may be reduced slowly or the time between doses increased over 1 or 2 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 is stopped, particularly if stopped suddenly.

Although paroxetine 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.

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## Side effects

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

Like all other medicines, it 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.

**Do not be alarmed by this list of possible 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 and they worry you:**

- feeling sick
- dry mouth
- decreased appetite
- diarrhoea, constipation
- vomiting
- drowsiness or dizziness
- difficulty falling asleep
- impaired sexual function
- weakness
- feeling sweaty or shaky
- bruising
- abnormal dream (including nightmares)
- weight gain.

### MORE SERIOUS EFFECTS

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

- muscle spasm or twitches.

**Stop taking APX-PAROXETINE and tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following soon after taking this medicine:**

- allergic reactions including swelling of limbs, face, lips, mouth or throat which may cause difficulty in swallowing or breathing. Hayfever, lumpy rash (hives) or fainting are also symptoms of an allergic reaction
- 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 muscle spasm, affecting the eyes, head neck and body
- sudden increase in body temperature, severe convulsions
- fast heart beat, sweating, muscle spasm, racing thoughts, restlessness.

### Other rare events that may occur are:

- 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 exposure to light
- itchy 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.
- Heavy vaginal bleeding shortly after birth.
- severe allergic reactions.

### Unwanted Effects that may occur on stopping treatment:

Symptoms may include:

- dizziness
- sensory disturbances such as tinnitus, pins and needles, burning sensations and 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 APX-PAROXETINE 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 whilst stopping treatment are 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.

Although APX-PAROXETINE is not recommended for children under the age of 18 years of age, the most common unwanted effects in children under 18 are:

- decreased appetite
- tremor (uncontrollable trembling)
- sweating
- hyperactivity
- hostile/unfriendly behaviour
- agitation
- changing emotions, including crying, changes in mood, trying to harm themselves, thought of suicide and attempting suicide.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

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## After using APX-PAROXETINE

### Storage

**Keep your medicine 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.**

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

**Do not store it, or any other medicine in the bathroom or near a sink.**

**Do not leave it in the car or on window sills.**

Heat and dampness can destroy some medicines.

### Disposal

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

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## Product description

### What it looks like

APX-PAROXETINE 20 is an oval white tablet marked "X|T" on one side.

Each blister pack contains 30 tablets.

### ***Ingredients***

The active ingredient in APX-PAROXETINE is paroxetine hydrochloride. Each APX-PAROXETINE 20 tablet contains 20 mg of paroxetine.

The tablets also contain:

- magnesium stearate
- sodium starch glycollate
- mannitol
- microcrystalline cellulose
- Eudragit E100
- Opadry White 200 -203A180008 (ARTG No.111778).

*The tablets do not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.*

### ***Manufacturer***

Arrow Pharma Pty Ltd  
15-17 Chapel Street  
Cremorne VIC 3121

Australian registration numbers:

Blister pack  
APX-PAROXETINE 20 - AUST R 328841

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