

# ROXTINE 20

*Paroxetine hydrochloride hemihydrate*

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## Consumer Medicine Information

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### What is in this leaflet

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Please read this leaflet carefully before you take ROXTINE tablets.

This leaflet answers some common questions about ROXTINE. 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 risks and benefits. Your doctor has weighed the expected benefits of you taking ROXTINE against the risks this medicine could 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.

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### What ROXTINE used for

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

ROXTINE 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.

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 waking up early, low energy and feel guilty over nothing.

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

ROXTINE may also be used to help prevent panic attacks.

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

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

ROXTINE 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 ROXTINE for some time, even when you have overcome your problem. This should prevent the problem from returning.

Your doctor may have prescribed ROXTINE for another use. Ask your doctor if you have questions about why ROXTINE has been prescribed for you.

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### Before you take ROXTINE

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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).

#### *Do not take if:*

You must not take ROXTINE 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 Effects that may occur on stopping treatment).
- you have ever had an allergic reaction to paroxetine hydrochloride or any of the ingredients listed toward the end of this leaflet. (See "Ingredients").
- you have taken ROXTINE before and became unwell, tell your doctor or pharmacist before taking the first dose.
- you are taking any other medications for the treatment of depression or have done so in the last 2 weeks. Taking ROXTINE with another antidepressant may cause a serious reaction. You must not take ROXTINE until 2 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. Taking ROXTINE 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) for the treatment of schizophrenia.
- you are taking pimozide (Orap).
- the expiry date printed on the pack has passed.

- the packaging is torn or shows signs of tampering.

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

### *Tell your doctor if:*

You must tell your doctor if:

- you are allergic to foods, dyes, preservatives or any other medicines.
- you are pregnant or intend to become pregnant.
- you are breastfeeding, or wish to breastfeed. Your doctor will discuss with you the possible risks and benefits of using ROXTINE during breastfeeding.
- you have any of these medical conditions:
  - liver problems
  - heart problems
  - kidney problems
  - epilepsy
  - mania
  - raised pressure in the eye
  - problems with blood clotting
  - other psychiatric conditions (Mania/Bipolar disorder)

- you are taking any other medicines, including medicines you buy without a prescription. In particular tell your doctor if you are taking any of the following medicines which:

- treat depression, anxiety, or schizophrenia including medicines you buy without a doctor's prescription such as tryptophan or *Hypericum perforatum* (St John's Wort).
- are used in anaesthesia or to treat chronic pain, specifically fentanyl.
- lower blood pressure or treat heart conditions, such as metoprolol (Betaloc), flecainide (Tambocor).
- control epilepsy, (anti-convulsants) such as phenytoin (Dilantin).
- thin blood (anti-coagulants), such as warfarin (Coumadin, Marevan), aspirin (Aspro), nonsteroidal anti-inflammatory drugs (NSAIDs).
- treat Parkinson's disease, such as selegiline (Eldepryl), procyclidine (Kemadrin).
- treat stomach ulcers, such as cimetidine (Tagamet).
- treat migraine attacks such as sumatriptan.
- treat breast cancer, specifically Tamoxifen.
- treat HIV infection such as a combination of fosamprenavir and ritonavir.

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 ROXTINE.

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## How do I take ROXTINE

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Follow your doctors' instructions about how and when to take ROXTINE.

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

### *How much to take*

The usual dose of ROXTINE 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. This may require you to break the tablet in half.

To treat obsessions and compulsions or panic attacks, the usual dose of ROXTINE 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.

### *How to take it*

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

ROXTINE should be taken in the morning, preferably with food.

### *How long to take it for*

Keep taking your ROXTINE for as long as your doctor tells you.

Like other drugs of this type, ROXTINE 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 ROXTINE even if you begin to feel better. Your doctor may decide that you should continue to use ROXTINE for some time, even when you have overcome your problem. For best effect ROXTINE must be taken regularly.

Your doctor will tell you when and how ROXTINE 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 ROXTINE, 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*

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

The use of ROXTINE 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 ROXTINE, 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.

### *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.

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

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**Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, if you think you or anyone else may have taken too much ROXTINE, even if there are no signs of discomfort or poisoning.**

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

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## While you are taking ROXTINE

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### *Things you must do*

**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.

### *Things you must not do*

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

**Do not use ROXTINE to treat any other complaints unless your doctor says to.**

### *Things to be careful of*

- Be careful driving or operating machinery until you know how ROXTINE affects you. Tests have shown that ROXTINE does not have a marked effect on driving ability. However, ROXTINE may cause drowsiness, dizziness or lightheadedness in some people. Make sure you know how you react to ROXTINE before you drive a car or operate machinery.
- Although drinking moderate amounts of alcohol is unlikely to affect your response to ROXTINE, 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 ROXTINE. This risk is greatest during the early stages of treatment.

- When your doctor decides that you should stop taking ROXTINE 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 ROXTINE is stopped, particularly if stopped suddenly.
- Although ROXTINE 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.
- **Tell your doctor immediately if you notice any of the following:**
  - muscle spasms or twitches
- **Stop taking ROXTINE and contact your doctor or go to the emergency department of your nearest hospital if any of the following happens:**
  - allergic reaction including swelling of limbs, face, lips, mouth or throat which may cause difficulty 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-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, affecting the eyes, head, neck and body
  - sudden increase in body temperature, severe convulsions
  - fast heart beat, sweating, muscle spasm, racing thoughts, restlessness.

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## Side Effects

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**Check with your doctor as soon as possible if you think you are experiencing any side effects or allergic reactions due to taking ROXTINE, even if the problem is not listed below.**

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

### **MORE SERIOUS EFFECTS**

**Other rare events that have been reported with ROXTINE 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
- 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).

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

Symptoms may include:

- dizziness
- sensory disturbances such as, 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 ROXTINE 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 ROXTINE is not recommended for children under 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, thoughts 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.

**Do not be alarmed by this list of possible side effects. You may not experience any of them.**

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## How do I store ROXTINE

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**Keep this medicine where children cannot reach it, such as in a locked cupboard.**

Keep your tablets in the blister pack until it is time to take them. Keep the pack in a cool dry place where it stays below 25°Celsius and is protected from light. Do not leave it in the car on a hot day. Do not store medicine in the bathroom or near a sink. Heat and dampness can destroy some medicines.

If your doctor tells you to stop taking ROXTINE, 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*

ROXTINE 20 is presented in pack size of 30 tablets in blister.

### **ROXTINE 20 (AUST R 176977)**

White to off-white coloured film-coated modified capsule shaped, biconvex tablets debossed with '56' on one side and 'C' with a deep break line on the other side.

### *Ingredients*

**Active Ingredient:**

Paroxetine (as hydrochloride hemihydrate).

Each tablet contains 20 mg of paroxetine as hydrochloride hemihydrate.

**Other Ingredients:**

- calcium hydrogen phosphate
- lactose
- sodium starch glycollate type A
- calcium hydrogen phosphate anhydrous
- magnesium stearate
- Opadry White 15B58810 (PIARTG No. 106602)

Please read this leaflet carefully before you start taking ROXTINE. You may wish to keep it to read again.

### *Name and Address of the Sponsor*

**Aurobindo Pharma Australia Pty Ltd**

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**Date of Approval**

21 December 2011