

PAROXETINE SYNTHON

Paroxetine mesilate

Consumer Medicine Information

What is in this leaflet?

Please read this leaflet carefully before you take PAROXETINE SYNTHON tablets.

This leaflet answers some common questions about PAROXETINE SYNTHON.

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 PAROXETINE SYNTHON 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.

What is PAROXETINE SYNTHON used for?

The name of your medicine is PAROXETINE SYNTHON; it is also known as paroxetine. PAROXETINE SYNTHON 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. PAROXETINE SYNTHON corrects the chemical imbalance and so helps relieve the symptoms of depression.

PAROXETINE SYNTHON 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 SYNTHON may also be used to help prevent panic attacks.

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

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

Your doctor may have prescribed PAROXETINE SYNTHON for another use.

Ask your doctor if you have questions about why PAROXETINE SYNTHON has been prescribed for you.

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 PAROXETINE SYNTHON 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

Do not use it if you have ever had an allergic reaction to paroxetine mesilate or any of the ingredients listed toward the end of this leaflet. (See "Ingredients")

Do not use it if you have taken PAROXETINE SYNTHON before and became unwell
Tell your doctor or pharmacist before taking the first dose.

Do not use it if you are taking any other medications for the treatment of depression or have done so in the last 2 weeks.

Taking PAROXETINE SYNTHON with another antidepressant may cause a serious reaction. You must not take PAROXETINE SYNTHON 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 PAROXETINE SYNTHON with a MAOI may cause a serious reaction.

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

Do not use it if you are taking pimozide (Orap)

Do not use it if the expiry date (EXP) printed on the pack has passed.

Do not use it if the packaging is torn or shows signs of tampering

Before you start to take it

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 PAROXETINE SYNTHON during breastfeeding.

Tell your doctor if have any of the 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)

Taking other Medicines

Tell your doctor if 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)
- 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), non-steroidal 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.

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 PAROXETINE SYNTHON.

How to take it

Follow your doctors' instructions about how and when to take PAROXETINE SYNTHON.
Read the direction label carefully.

If you have any concerns about how to take PAROXETINE SYNTHON, talk to your doctor or pharmacist.

How much to take

The usual dose of PAROXETINE SYNTHON for depression, social anxiety disorder/social phobia, generalised anxiety disorder or post traumatic stress disorder is one 20mg 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 PAROXETINE SYNTHON 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 PAROXETINE SYNTHON with a full glass of water or another liquid.

PAROXETINE SYNTHON tablets can be broken in half, but should not be chewed.

When to take it

PAROXETINE SYNTHON should be taken in the morning, preferably with food.

How long to take it

Keep taking your PAROXETINE SYNTHON for as long as your doctor tells you.

Like other drugs of this type, PAROXETINE SYNTHON 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.

Do not stop taking PAROXETINE SYNTHON even if you begin to feel better.

Your doctor may decide that you should continue to use PAROXETINE SYNTHON for some time, even when you have overcome your problem. For best effect PAROXETINE SYNTHON must be taken regularly.

Your doctor will tell you when and how PAROXETINE SYNTHON 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 SYNTHON, 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 SYNTHON is not recommended for use in children and adolescents under 18 years.

The use of PAROXETINE SYNTHON 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 SYNTHON, 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.

If you take too much (Overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 131126) for advice, if you think you or anyone else may have taken too much PAROXETINE SYNTHON, even if there are no signs of discomfort or poisoning.

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

While you are taking PAROXETINE SYNTHON

WHILE YOU ARE TAKING IT

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 PAROXETINE SYNTHON to treat any other complaints unless your doctor says so.

Things to be careful of

Be careful driving or operating machinery until you know how PAROXETINE SYNTHON affects you.

Although drinking moderate amounts of alcohol is unlikely to affect your response to PAROXETINE SYNTHON, tests have shown that it is best to avoid alcohol while you are taking this medicine.

When your doctor decides that you should stop taking PAROXETINE SYNTHON 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 SYNTHON is stopped, particularly if stopped suddenly.

Although PAROXETINE SYNTHON 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

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

Like other medicines, PAROXETINE SYNTHON 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, diarrhoea
- drowsiness, dizziness, difficulty in getting to sleep

- impaired sexual function
- weakness
- feeling sweaty or shaky
- bruising
- weight gain

MORE SERIOUS EFFECTS

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

- muscle spasms or twitches

Stop taking PAROXETINE SYNTHON 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.**
- **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**

Other rare events that have been reported with PAROXETINE SYNTHON 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).

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 PAROXETINE SYNTHON 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 PAROXETINE SYNTHON 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.

After taking it

Storage

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. 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 PAROXETINE SYNTHON, ask your pharmacist what to do with any tablets that are left over.

Product description

What it looks like

PAROXETINE SYNTHON comes as a yellow to orange round shaped film-coated tablet, containing 20mg of paroxetine mesilate. The tablet is marked 'POT 20' on one side and has a break line on both sides.

Ingredients

PAROXETINE SYNTHON tablets contain the active ingredient paroxetine mesilate.

The tablets contain the following inactive ingredients: Calcium hydrogen phosphate anhydrous, sodium starch glycollate (potato starch), purified water, magnesium stearate, Macroglol 4000, hypromellose, titanium dioxide (E171), lactose, iron oxide yellow E172 and iron oxide red E172.

PAROXETINE SYNTHON tablets do not contain sucrose, gluten or tartrazine.

Supplier

PAROXETINE SYNTHON tablets are supplied by:

Synthon AU Pty Ltd
Suite 201, 6-12 Atchison St
St Leonards NSW 2065
Australia

AUST R Number
AUST R 152491

Where to go for further information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition.

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