PAXIL

Patient Information Leaflet

SCHEDULING STATUS:

S5

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

PAXIL 20 Tablets

Read all of this leaflet carefully before you start taking PAXIL.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- PAXIL has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

WHAT PAXIL CONTAINS:

Each tablet contains paroxetine hydrochloride equivalent to paroxetine 20 mg free base.

The inactive ingredients include dibasic calcium phosphate (dihydrate), sodium starch glycollate and magnesium stearate.

The film-coat contains hypromellose, titanium dioxide (EEC No. 171), macrogol 400 and polysorbate 80.

Sugar-free.

WHAT PAXIL IS USED FOR:

PAXIL may be prescribed for ADULTS who suffer from any of the following:

- depression
- obsessive or compulsive (uncontrollable) behaviour

- panic attacks, including that caused by a fear of open spaces (agoraphobia)
- feeling generally very anxious or nervous
- feeling very anxious or nervous in situations in which you have to socialise or perform.

BEFORE YOU TAKE PAXIL:

Do not use PAXIL if:

- you are allergic (hypersensitive) to, or have ever had a bad reaction to any of the ingredients of PAXIL
- you are taking or have recently taken (within the last two weeks) other anti-depressant medicines called Monoamine Oxidase Inhibitors e.g. tranylcypromine, meclobemide
- you are taking a medicine called thioridazine
- you are taking a medicine called pimozide
- PAXIL should not be used to treat children under 18 years of age
- you are pregnant.

Take special care with PAXIL:

Get a doctor's/healthcare professional's advice before you use PAXIL if:

- you have kidney, liver or heart problems
- you have ever had a "manic" episode (uncontrollable excitement and overactivity)
- you suffer from epilepsy or have a history of fits (seizures)
- you suffer from glaucoma (high pressure in the eye)
- you bruise or bleed easily, or are taking a medicine that may increase bleeding (such as aspirin)
- you are pregnant, may be pregnant or breastfeeding
- you are having/taking any other form of antidepressant treatment
- you are diagnosed with schizophrenia and are taking medicines to treat this condition
- there is an increased risk of fractures (breaking a bone) in people whilst on treatment with PAXIL.

Take special care with PAXIL if you are over 65 years of age, as PAXIL 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.

Taking PAXIL with food and drink:

It is not advisable to drink alcohol whilst taking PAXIL.

PAXIL tablets should be administered as a single daily dose, usually in the morning, preferably with food.

PAXIL tablets should not be chewed or crushed and should be swallowed whole.

Pregnancy and Breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice, before taking this medicine.

Pregnancy: You should not use PAXIL when you are pregnant. Ask your doctor or pharmacist for advice before taking PAXIL. If you are already taking/using PAXIL and have just found out that you are pregnant, or if you are planning to become pregnant, you should talk to your doctor immediately.

There is an increase in the risk of birth defects, particularly heart defects, in babies whose mothers take PAXIL during pregnancy.

Breastfeeding: Tell the doctor if you are breastfeeding your baby. You should not be treated with PAXIL when breastfeeding your baby.

Driving and using machinery:

Before driving or operating machinery, see whether PAXIL makes you feel tired or sleepy. If it does, these activities should be avoided.

Taking other medicines with PAXIL:

Always tell your healthcare professional if you are taking any other medicine (this includes complementary or traditional medicines). Medicines known to interact with PAXIL are:

- other antidepressants

- other medicines that affect serotonin such as, lithium, linezolid, tramadol, tryptophan, St. John's Wort, certain migraine preparations
- certain medicines used to treat patients with irregular heartbeats (dysrhythmias)
- certain medicines used to treat schizophrenia
- procyclidine, which is used to treat Parkinson's Disease or other movement disorders
- metoprolol, which is used to treat high blood pressure, irregular heartbeats (dysrhythmias) and angina
- certain medicines which may affect blood clotting and increase bleeding, such as warfarin, aspirin and other non-steroidal anti-inflammatory medicines (e.g. ibuprofen)
- certain medicines used to treat epilepsy.

HOW TO TAKE PAXIL:

Follow the doctor's instructions about how and when to take PAXIL. Your doctor will decide how many tablets you need to take each day.

Once you have started using PAXIL:

You may be at an increased risk of suicidal behaviour (including suicide attempts) when treated with PAXIL. The majority of attempted suicides in clinical trials in depression involved patients aged 18 to 30 years.

➔ **Tell your doctor immediately or go to the nearest hospital if you have any distressing thoughts or experiences.**

PAXIL will not relieve your symptoms straight away. People generally start feeling better in a few weeks or so. Also contact your doctor if you experience any worsening of your depression/other symptoms at any time during your treatment.

You may have feelings of restlessness or agitation combined with an inability to sit or stand, particularly during the first few weeks of treatment. If you experience these symptoms, tell your doctor as soon as possible.

Even after you start to feel better it is important to keep taking the medicine for as long as the doctor recommends, in order to help prevent symptoms from returning. This will probably be at least several months after recovery from depression and may be even longer for panic disorder or obsessions and compulsions. Your doctor will advise you on how long you should take PAXIL.

If you take more PAXIL than you should:

If you take more PAXIL than you should, you may notice the following side effects: vomiting, your pupils are enlarged (dilated), fever, changes in your blood pressure, headache, muscle contractions, feeling agitated and anxious and a rapid heart beat. If overdosage is severe, you could go into a coma.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take/missed a dose of PAXIL:

Wait and take PAXIL at the normal time the next morning. If you forget your medicine for a whole day, do NOT take/administer double the dose the next day, to make up for any missed dose.

Effects when treatment with PAXIL is stopped:

DO NOT stop treatment with PAXIL until told to do so by the doctor. 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 PAXIL, especially if this is done suddenly, you may experience unwanted symptoms.

Symptoms on stopping PAXIL treatment 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 tremours
- confusion
- sweating
- headache
- diarrhoea.

These are likely to occur in the first few days of stopping treatment or if you miss a dose. However, they are more likely to occur if you stop taking PAXIL too quickly. Therefore always consult your doctor before stopping your medicine. If you feel that the unwanted symptoms are too severe, see your doctor who will suggest how to manage stopping treatment more slowly.

POSSIBLE SIDE EFFECTS:

PAXIL can have side effects.

Not all side effects reported for PAXIL are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist, or other healthcare professional.

Some people may be hypersensitive (allergic) to medicines. If any of the following happens, stop taking PAXIL and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the eyelids, face, lips, mouth or tongue, or throat with difficulty breathing or swallowing
- lumpy skin rash or 'hives' anywhere on the body
- itching.

➔ **These are all very serious side effects. If you have them, you may have had a serious allergic reaction to PAXIL. You may need urgent medical attention or hospitalisation.**

Tell your doctor if you notice any of the following:

Frequent side effects with PAXIL are:

- feeling nauseous (taking your medicine in the morning with food may help to reduce the chance of this happening)
- a change in normal sexual functioning e.g. impotence, premature ejaculation
- decreased appetite
- sleepiness
- inability to sleep
- dizziness
- tremor (uncontrollable trembling)
- blurred vision
- yawning
- constipation
- diarrhoea
- dry mouth
- sweating
- weakness.

Less frequent side effects that might occur when taking PAXIL include:

- bruising easily or unusual bleeding especially from the skin or mucous membranes
- confusion
- hallucinations
- uncontrolled movements of the body, including the face
- rapid heartbeat
- a temporary increase or decrease in blood pressure (usually seen in patients with existing anxiety or high blood pressure)
- skin rashes

- inability to urinate (pass water).

Other side effects experienced include:

- fits (seizures)
- a feeling of restlessness or agitation which may be accompanied by the inability to sit or stand still
- uncontrollable excitement, behaviour and overactivity (manic episodes)
- low sodium levels in the blood (especially in elderly people)
- high pressure inside the eye (acute glaucoma)
- a change in liver enzyme test results or symptoms of liver disorder which may appear as nausea, vomiting, loss of appetite, generally feeling unwell, fever, itching, yellowing of the skin and eyes, and dark coloured urine
- producing breast milk when not breastfeeding
- swelling of the arms/legs
- bleeding in the stomach
- reduced number of platelets in the blood
- sensitivity of the skin to sunlight
- 'serotonin syndrome' (a collection of symptoms which can include restlessness, confusion, sweating, hallucinations, increased reflexes, muscle spasms, shivering, increased heart beat and shaking)
- increased levels of a hormone (ADH) that causes fluid or water retention.

If you notice these or any other unwanted effects not mentioned here, you should tell your doctor or healthcare professional.

STORING AND DISPOSING OF PAXIL:

Store all medicines out of reach of children.

Store in a cool, dry place in the original packaging, at or below 30 °C.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

PRESENTATION OF PAXIL:

Child-resistant blisters comprised of white, opaque polyvinyl chloride (PVC) backed with aluminium foil laminated with paper, packed in a cardboard carton.

OR

Blisters comprised of transparent polyvinyl chloride (PVC) coated with polyvinylidene chloride (PVdC) backed with aluminium (AL) foil, packed in a cardboard carton.

Cartons containing 28 blister packed tablets in strips of 14.

IDENTIFICATION OF PAXIL:

A white, film-coated, oval shaped, biconvex tablet, engraved 20 on one side and a break bar on the other.

REGISTRATION NUMBER:

A39/1.2/0078

THE NAME AND ADDRESS OF REGISTRATION HOLDER:

GlaxoSmithKline South Africa (Pty) Ltd

39 Hawkins Avenue

Epping Industria 1, 7460

DATE OF PUBLICATION:

Date of registration: 29 July 2005

Date of most recent revision: 6 June 2014

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