Paroxetine 20mg and 30mg tablets
(paroxetine hydrochloride anhydrous)

Please read all of the leaflet and keep it. You may need to read it again. It contains a lot of important information about this medicine. This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

Eight important things you need to know about paroxetine:

• Like all medicines, Paroxetine can have unwanted effects.
• It is therefore important that you and your doctor weigh up the benefits against the possible side effects before starting treatment.
• Paroxetine is not for use in children and adolescents under 18.
• Paroxetine won’t work straight away. Some people taking antidepressants feel worse before feeling better. Your doctor should ask to see you again a couple of weeks after you first start treatment. Tell your doctor if you have not started feeling better. See section 3, How to take.
• Some people who are depressed or anxious think of harming or killing themselves. If you start to feel worse and think of harming or killing yourself, see your doctor or go to a hospital straight away. See section 2, Thoughts of suicide.
• Can’t stop taking paroxetine without talking to your doctor. If you stop taking paroxetine suddenly or miss a dose, you may get withdrawal effects. See section 3, If you stop taking the tablets.
• If you feel restless and feel like you can’t sit or stand still, tell your doctor. Increasing the dose of paroxetine may make these feelings worse. See section 4, Possible side effects.
• Taking some other medicines with paroxetine can have a bigger effect than taking other medicines.
• If you are pregnant or planning to get pregnant, talk to your doctor. See section 2, Pregnancy and breastfeeding.

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1. What Paroxetine tablets are and what they are used for

Paroxetine is one of a type of antidepressants known as Selective Serotonin Re-uptake Inhibitors (SSRIs). Low levels of the hormone serotonin may be a cause of depression and other related conditions. Paroxetine works by bringing the levels of serotonin back to normal. Paroxetine is used in adults to treat:

• depression
• panic disorder with or without agoraphobia (fear of open spaces or new situations)
• obsessive compulsive disorder
• generalized anxiety disorder
• premenstrual tension disorder
• anxiety disorders.

2. Before you take

Do not take Paroxetine tablets and tell your doctor if you are:

• allergic (hypersensitive) to paroxetine or any of the other ingredients (see section 6).
• taking medicines called monoamine oxidase inhibitors (MAOIs), or have taken them at any time within the last two weeks.
• have had epilepsy (or a tendency to have seizures).

Check with your doctor or pharmacist before taking Paroxetine tablets if:

• you are depressed or have an anxiety disorder, and ask them to talk to you or more about treatment options
• you have a history of fits (epilepsy) or have had a convulsion while you were asleep
• you have a history of mood disorders
• you smoke
• you have abnormal bleeding
• you have glaucoma (pressure in the eye).

Take special care with Paroxetine

- patients with a history of symptoms such as confusion, restlessness, sweating, shaking, shivering, hallucinations or tetany (stiffness of the muscles); sudden jerks of the muscles or a fast heartbeat, since these symptoms could be a sign of ‘serotonin syndrome’.

Thoughts of suicide and worsening of your depression or anxiety disorder

If you are depressed and/or have anxiety disorders, you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting antidepressants, since these medicines take time to work, usually 2–4 weeks but sometimes longer.

You may be more likely to think like this if you:

• have previously had thoughts about harming or killing yourself
• are a young adult. Information from clinical trials has shown an increased risk of suicidal behaviour in young adults (less than 25 years) with psychiatric conditions who were treated with an antidepressant

If you have thoughts of harming or killing yourself at any time, contact your doctor or get to a hospital straight away.

Children and adolescents under 18

Paroxetine should not be used in children and adolescents under 18 years. Histories under 18 have an increased risk of side effects such as suicide attempt, suicidal thoughts and hostility (predominantly aggression, oppositional behaviour and anger) when they take Paroxetine. If your doctor has prescribed Paroxetine for you or your child and you want to discuss this, please go back to your doctor. You should inform your doctor if any of the symptoms listed below develop in you or your child while you are taking Paroxetine. Your doctor may want to check your symptoms against a list of possible side effects.

In children and adolescents under 18, common side effects that affected less than 1 in 10 children/adolescents were:
• an increase in suicidal thoughts and suicide attempts, deliberately self-harming themselves, being hostile, aggressive or violent,
• lack of appetite, shaking, abnormal sweating, hyperactivity (having too much energy), agitation, changes in mood (including crying and changes in mood) and unusual bruising or bleeding (such as nose bleeds). These studies also showed that the same symptoms affected children and adolescents taking sugar pills (placebo) instead of Paroxetine, although these were seen in fewer children. These patients in those studies under 18 had withdrawal effects when they stopped taking Paroxetine. These effects were mostly similar to those seen in adults after stopping Paroxetine (see Section 3, How to take, inside this leaflet). Children and adolescents under 18 are a young adult. Information from clinical trials has shown an increased risk of suicidal behaviour in young adults (less than 25 years) with psychiatric conditions who were treated with an antidepressant.

You may find it helpful to tell a relative or close friend that you are depressed or have an anxiety disorder, and ask them to talk to you or more about treatment options.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including:

• monoamine oxidase inhibitors (MAOIs), including moclobemide, or have taken them at any time within the last two weeks.
• thioridazine or other antipsychotics
• other antidepressants including Selective Serotonin Re-uptake Inhibitors (SSRIs)
• other medicines known to affect the nervous system (e.g. st John’s wort, a herbal remedy for depression)
• certain medicines that thin the blood (e.g. aspirin, ibuprofen or other medicines called NSAIDs (non-steroidal anti-inflammatory drugs) such as celecoxib, etodolac, etodolac etopropionate)
• other medicines that can increase the effect of paroxetine.

Concomitant use of above-mentioned medicinal products may lead to serotonin syndrome (see “Take special care with paroxetine”).

Oral drugs taken with Paroxetine that may cause unwanted effects include:

• aspirin, diphtheria or other medicines called NSAIDS (non-steroidal anti-inflammatory drugs) such as ibuprofen, etodolac, meloxicam and felbinoxate (for pain and inflammation)
• other antidepressants including tricyclic and other antidepressants like trimipramine, doxepin and imipramine
• other medicines that can increase the effect of paroxetine.

Other drugs taken with Paroxetine that may cause unwanted effects include:

• clozapine, haloperidol or other medicines called neuroleptics (antipsychotics) such as risperidone, olanzapine, risperidone or quetiapine
• theophylline (as an anti-convulsant)
• benzodiazepines or barbiturates (to treat anxiety or insomnia) or used in anaesthetics
• drugs to treat certain psychiatric conditions such as lithium, perphenazine
• St John’s wort (as a herbal remedy for depression)
• antidepressants such as fluoxetine, citalopram or paroxetine
• tricyclic antidepressants such as desipramine, nortriptyline or protriptyline
• other medicines that can increase the effect of paroxetine.

• clozapine (to treat schizophrenia, particularly when resistance to treatment has developed)
• warfarin or other anticoagulants (to thin the blood)
• clopidogrel, ticlopidine (to treat irregular heart rhythms)
• tamoxifen (used in breast cancer)
• losartan or irbesartan (used in hypertension)
• metoprolol (used in high blood pressure and heart problems)
• tramadol (used in tuberculosis (TB) and leprosy)
Pregnancy and breast-feeding

If you are planning to become pregnant or are breast-feeding ask your doctor, midwife or pharmacist for advice before taking this medicine. If you have already taken Paroxetine and have just found out that you are pregnant you should talk to your doctor immediately.

It is believed that some studies have suggested there is an increase in the risk of heart defects in babies whose mothers received paroxetine in the first few months of pregnancy. These studies found that less than 2 in 100 babies (2%) whose mothers received paroxetine in early pregnancy had a heart defect, compared with the normal rate of 1 in 100 babies (1%) seen in the general population. You and your doctor may decide that it is better for you to gradually stop taking paroxetine while you are pregnant. However, depending on your circumstances, your doctor may decide that you should continue to take it. If you are planning to become pregnant or are breast-feeding, talk to your doctor or midwife who will be able to advise you.

Paroxetine may help to reduce the quality of sleep in animal studies. Theoretically, this could affect fertility, but in practice fertility has not been observed as a problem.

Driving and using machines
Paroxetine may cause dizziness, confusion or changes in vision. If any of these occur by themselves or in combination, do not drive or use machinery.

Alcohol
Do not drink alcohol while you are taking paroxetine. Alcohol may make the side effects worse.

Important information about some of the ingredients of Paroxetine
Paroxetine tablets contain soya lecithin. If you are allergic to peanut or soya, do not take this medicine.

How to take
Always follow your doctor's instructions. Your doctor has told you to take your tablets along with a drink of water. Please wash them with a drink of water. The tablets can be cut in half. Do not chew.

How to take
Adults
Your doctor will advise you what dose to take when you first start taking paroxetine.

Doses:
- Obsessive-compulsive disorder: 20mg a day to a maximum of 60mg
- Panic disorder: 10mg a day to a maximum of 60mg
- Social anxiety disorder: 20mg a day to a maximum of 50mg
- Anorexia nervosa: 20mg a day to a maximum of 50mg
- Elsa: The maximum dose for people over 65 is 40mg per day.

Children and adolescents
Not recommended for use in children aged under 10 years.

Patients with liver or kidney disease
If you have trouble with your liver or kidney, your doctor may decide that you should have a lower dose. If you have severe liver or kidney disease, the maximum dose is 20mg per day.

If you take more than you should
If you (or someone else) accidentally take a tablet or tablets at the time, or your child may have swallowed any, contact your nearest hospital casualty department or your local doctor immediately. Signs of overdose include being unable to sleep or to feel or to talk, convulsions, rash, difficulty breathing, changes in vision.

If you forget to take the tablets
Do not take a double dose to make up for a forgotten dose. If you do not take your paroxetine on time before you go to bed, take it straight away, then take the next dose at the right time. If you only remember during the night, or the next day, leave out the missed dose.

If you stop the tablets
Do not stop treatment early because your doctor will help you to reduce your dose slowly over a number of weeks or months. This should help reduce the chance of withdrawal effects such as incontinence, feeling of unreality, tingling, electric shock sensations, burning sensations, sleep disturbances, intense dreams, restlessness, anxiety feeling sick, shaking, confusion, sweating, headache, diarrhoea, irregular menstrual periods, irritability or changes in vision.

Talk to your doctor before you stop taking the tablets and follow the advice that you are given.

What to do if you're feeling no better
Paroxetine will not relieve your symptoms straight away - all antidepressants take time to work. Some people will start to feel better within a couple of weeks, but for others it may take a little longer. Some people taking antidepressants feel worse before feeling better. If you don't start to feel better after a couple of weeks consult your doctor who will advise you. Your doctor should advise you to have a couple of weeks after you start treatment. Tell your doctor if you haven't started to feel better within:

- 6 weeks, if you are taking paroxetine.
- 8 weeks, if you are taking sertraline.

Possible side effects
As with all other medicines paroxetine can cause some side effects but not everybody gets them.

Contact your doctor at once if you experience any of the following:

- an allergic reaction and lump skin rash, severe skin rash with flushing, hives, blisters, ulcers, swelling of the face, lips, mouth or tongue, itching or difficult breathing or swelling
- unusual bruising or bleeding, including vomiting blood or passing blood in your stools.
- not being able to pass water
- seizures (fits)
- akathisia (restlessness, and feeling like you can't sit or stand still), low blood sodium (causing tiredness, weakness, confusion and acetyl, stiff or uncoordinated muscles)
- serotonin syndrome (confusion, restlessness, shaking, shivering, hallucinations (strange images or sounds), sudden jolts of the muscles or a fast heartbeat).

Tell your doctor if you notice any of the following side effects or any other effects not listed:

- Very common (occurs in more than 1 in 10 users):
- changes in sex drive or function (lack of orgasm, abnormal ejaculation and ejaculation in men), impaired concentration.
- Common (occurs in less than 1 in 10 users):
- dry mouth, diarrhoea, constipation, being sick
- lack of appetite, weight gain, in more than 1 in 100 users:
- drying of the mucous membranes of the mouth and tongue
- abnormal dialpted pupils
- increase in the need to pass urine
- Rare (occurs in less than 1 in 1,000 users):
- abnormal reduction of blood in the brain and muscles
- slow heartbeat
- slow effects on the liver showing up in liver function tests
- pain attacks, irritable behaviour (including anger), feeling detached from yourself (detachment), feeling distant, restless leg syndrome (RLS)
- very rare (occurs in less than 1 in 10,000 users):
- loss of feeling in the skin or of the edges
- fluid and water retention which may cause swelling of the ankles or legs
- sensitivity to sunlight
- acute glaucoma (eye pain and blurred vision)
- partial perforation of the penis that won't go away
- Other possible side effects (rare):
- joint or muscle pain.
- bone fractures, ringing in the ears, suicidal ideation and suicidal behaviour (see section 2).

How to store
Keep out of the reach of children and of sight. No special precautions for storage.

Do not use Paroxetine after the expiry date stated on the label. The expiry date refers to the last day of that month. Ask your pharmacist how to dispose of medicines no longer required.

Further information
How much Paroxetine tablets contain
The active substance in this medicine is paroxetine hydrochloride. Each tablet contains 20mg of the active ingredient (equivalent to 20mg of paroxetine).

How much of the other ingredients are there?
The other ingredients are magnesium stearate, sodium starch glycollate (Type A), microcrystalline cellulose, talc, lecithin soya (E322), and xanthan gum (E415). 20mg tablets also contain opadry AMB white (polyvinyl alcohol part hydrolysed, titanium dioxide (E171), talc, lactose (E901), microcrystalline cellulose (E301), sodium starch glycollate (E415), talc, FDC blue #2/4 and red lake (E120), sucrose (E960),EDDA yellow (#6), sunset yellow (E110) and quinoline yellow (E104).

How Paroxetine tablets look and contents of the tablets
Paroxetine tablets are white and Paroxetine tablets are blue, circular, film-coated tablets. Pack size is 30 tablets.

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