Eight important things you need to know about paroxetine

- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. They will advise you if any possible side effects listed in this leaflet.
- It is therefore if you are taking, have recently taken or talk to your doctor. See section 2, Thoughts of suicide.
- Paroxetine isn’t for use in children and adolescents under 18.
- Paroxetine won’t work straight away. Some people taking antidepressants feel worse before they feel better. Your doctor should ask to see you again after a few weeks to check whether paroxetine is helping. See section 2, Before you start taking paroxetine.
- Some people who are depressed or anxious think of harming or killing themselves. If you start to feel worse, think of harming or killing yourself, see your doctor or go to a hospital straight away. See section 2, Thoughts of suicide.
- Don’t stop taking paroxetine without talking to your doctor. If you stop taking paroxetine suddenly, especially if you have been taking it for a while, you may get withdrawal effects. See section 3, If you stop taking paroxetine.
- If you’re pregnant or planning to get pregnant, talk to your doctor. See section 3, Pregnancy, breast-feeding and fertility.
- Paroxetine is not for use in children and adolescents under 18. It is therefore if you are taking, have recently taken or talk to your doctor. See section 2, If you stop taking the tablets.
- Some symptoms of sexual dysfunction (see section 4). In some cases, these symptoms could be a sign of “serotonin syndrome”.
- Contact your doctor if you develop any of the symptoms listed above or worsen when you (or your child) are taking Paroxetine. Also, the long term safety effects concerning sexual drive and function and behaviour of Paroxetine in the age group have not yet been demonstrated. In studies of Paroxetine in under 18, common side effects that affected up to 1 in 10 children/adults were: an increase in suicidal thoughts and suicide attempts, delusional beliefs about having acquired superhuman powers, aggressive or unruly, lack of appetite, sleeping, abnormal sweating, hyperactivity, low mood (very much), appetite loss, changing emotions (including crying and changes in mood) and unusual crying or bleading (such as nose bleed). These studies also showed that some children and adolescents taking paroxetine pills (placebo) instead of Paroxetine, although these were less seen in some patients. In these studies of up to 1 in 10 children/adults severe an increase in suicidal thoughts and suicide attempts, delusional beliefs about having acquired superhuman powers, aggressive or unruly, lack of appetite, sleeping, abnormal sweating, hyperactivity, low mood (very much), appetite loss, changing emotions (including crying and changes in mood) and unusual crying or bleeding (such as nose bleed). You or your family may notice a change in the way you feel or think. You might take any other medicines, including medicines obtained without a prescription, such as:
- monamine oxidase inhibitors (MAOIs, see medicinal product information) or have taken them at any time within the last two weeks.
- thiobendazole (a tranquiliser)
- ketamine or ketamine-like (a tranquiliser)
- tramadol (a painkiller)
- haloperidol or pimozide (a tranquiliser)
- linezolid (an antibiotic)

Paroxetine tablets have a number of side effects, and this leaflet contains important information for you. In addition, patients under 18 also commonly (affecting up to 1 in 10 children) have thoughts of harming or killing themselves or have thoughts of harming or killing themselves at any time, 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 ideation in those under 25 years old with psychiatric conditions who were treated with an antipsychotic.
- Paroxetine should not be used for children and adolescents under 18 years. Also, patients under 18 have an increased risk of side effects such as: oxidation attempts, suicidal thoughts and hostility (predominantly aggressiveness, oppositional behaviour and anger) when they take Paroxetine. Your doctor has prescribed Paroxetine for you or your child. If you want to discuss this, please go back to your doctor. You should inform your doctor if any of the symptoms listed above develop or worsen when you (or your child) are taking Paroxetine. Also, the long term safety effects concerning sexual drive and function and behaviour of Paroxetine in the age group have not yet been demonstrated. In studies of Paroxetine in under 18, common side effects that affected up to 1 in 10 children/adults were: an increase in suicidal thoughts and suicide attempts, delusional beliefs about having acquired superhuman powers, aggressive or unruly, lack of appetite, sleeping, abnormal sweating, hyperactivity, low mood (very much), appetite loss, changing emotions (including crying and changes in mood) and unusual crying or bleeding (such as nose bleed). These studies also showed that some children and adolescents taking paroxetine pills (placebo) instead of Paroxetine, although these were less seen in some patients. In these studies of up to 1 in 10 children/adults severe an increase in suicidal thoughts and suicide attempts, delusional beliefs about having acquired superhuman powers, aggressive or unruly, lack of appetite, sleeping, abnormal sweating, hyperactivity, low mood (very much), appetite loss, changing emotions (including crying and changes in mood) and unusual crying or bleeding (such as nose bleed). You or your family may notice a change in the way you feel or think. You might take any other medicines, including medicines obtained without a prescription, such as:
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you to gradually stop taking paroxetine while you are pregnant. However, depending on your circumstances, your doctor may suggest that it is better for you to keep taking paroxetine.

When taken during pregnancy, particularly in the last 3 months of pregnancy, paroxetine can increase the risk of problems in the condition in babies, called persistent pulmonary hypertension of the newborn. This can increase blood pressure in the blood vessels in the lung. This may result in abnormal flow to the lung and heart and babies cannot get enough oxygen into their bloodstream. These symptoms usually begin during the first 24 hours after birth and include not being able to sleep or feel properly, breathing problems, a blue skin or bluish hands or feet, or cold, blue skin, crying, a stiff or floppy muscles, breathing difficulty, and a blue or tinted face. If your baby has any of these symptoms when it is born and you are concerned, contact your doctor or midwife who will be able to help.

Medicines like paroxetine may reduce the quality of your sperm. Although the impact of this on fertility is unknown, fertility may be affected in some men whilst taking paroxetine.

Driving and using machines

Paroxetine may affect your concentration, coordination or changes in your ability to drive or use machines. If affected, do not drive or use machinery.

Paroxetine tablets with Alcohol

Do not drink alcohol while taking paroxetine. Alcohol may make you feel worse while you are taking paroxetine.

If you forget to take Paroxetine tablets

Do not take a double dose to make up for a forgotten dose.

If you only remember during the morning with food

Swallow them with a drink of water. The tablets may be broken in half, but do not chew.

Dosage:

- Do not exceed these doses in a day.
- If you are uncertain about which dose to take, your doctor may advise you what dose to take when you first start taking paroxetine.

If you have to take more than Paroxetine tablets than prescribed

If you are an adult, you should be prescribed no more than 20mg a day.

Patients with liver or kidney disease

If you have liver or kidney problems, your doctor may decide that you should have a lower dose. If you have severe liver or kidney disease, the maximum dose is 10mg a day.

Elderly

Do not exceed these doses in old people 0 to 10mg a day per.

Children and adolescents

Not recommended for use in children aged up to 18 years.

• Patients with liver or kidney disease

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If you forget to take Paroxetine tablets

Do not double up to make up the missed dose.

Do you feel any side effects?

Contact your doctor if you feel any side effects (may affect up to 1 in 10 people):

• Nausea

• constipation

• sexual interest disturbance

• headache

• dry mouth

• cough

• tremors

• dizziness

• tiredness

• diarrhoea

• sweating

• stomach discomfort

• insomnia

• skin rash

• itching

• dry mouth

• constipation

• stomach discomfort

• headache

• tremors

• dizziness

• tiredness

• diarrhoea

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