Fluoxetine capsules treat depression and anxiety disorders.

Like all medicines, it can have unwanted effects. It is therefore important that you and your doctor weigh up the benefits of treatment against the possible unwanted effects, before starting treatment.

**Fluoxetine capsules are not for use in children and adolescents under 18.** See section 2, Use in children and adolescents aged 8 to 18 years.

**Fluoxetine capsules 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 haven’t started feeling better. See section 3, How to take Fluoxetine capsules.

**Some people who are depressed or anxious may have a life threatening risk of harm or killing themselves, if you start to feel worse or think of harming or killing yourself, see your doctor or go to a hospital straight away.** See section 2.

**Don’t stop taking Fluoxetine capsules without talking to your doctor.** If you stop taking Fluoxetine capsules suddenly or miss a dose, you may get withdrawal effects. See section 3 for further information.

**If you feel restless and feel like you can’t sit or stand still, tell your doctor.** Increasing the dose of Fluoxetine capsules may make these feelings worse. See section 4, Possible side effects.

**Taking some other medicines with Fluoxetine capsules can cause problems.** See section 2, Other medicines and Fluoxetine capsules.

**If you are pregnant or planning to get pregnant, talk to your doctor.** See section 2, Pregnancy, breast-feeding and fertility.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Keep this leaflet. You may need to read it again.

- if you have any further questions, ask your doctor, pharmacist or nurse.
- 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. This includes any possible side effects not listed in the leaflet. See section 4.
Fluoxetine Capsules
20mg x 30's (UK)

Item number: BBBA5489

Dimensions: 296x210

Colours: 1. Black
2. 3. 4. 5. 6.

Non Printing Colours: 1. Profile

Fluoxetine 20mg Capsules PIL - UK

Fluoxetine Capsules approved for print/date 296x210 Leafl et Red Fed Bi Fold Profile (BST) page 2

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 treatment, or if, for any reason, you all take time to work, usually about two weeks but sometime longer.

You may find it helpful to think about:
- if you have previously had thoughts about killing or harming yourself.
- if you are a young adult. Information from clinical trials has shown an increased risk of suicidal behaviour in young adults (less than 25 years old) 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 go to a hospital straight away.
- 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 tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.

In children and adolescents aged 8 to 18 years:

Patients aged 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 this class of medicine. Fluoxetine should only be used in children and adolescents aged 8 to 18 years for the treatment of moderate to severe major depressive episodes (in combination with psychological therapy) and it should not be used to treat other conditions.

Additionally, only limited information concerning the long-term safety of Fluoxetine on growth, puberty, mood, emotional and behavioural development in this age group is available. Despite this, and if you are a patient under 18, your doctor may prescribe Fluoxetine for moderate to severe major depressive episodes, in combination with psychological therapy, because he/she decides that this is in your best interests. If your doctor has prescribed Fluoxetine for a patient under 18 and you want to discuss this, please go back to your doctor. You should inform your doctor of any symptoms listed above develop or worsen when patients aged 18 are taking Fluoxetine.

Fluoxetine should not be used in the treatment of children under the age of 8 years.

Other medicines and Fluoxetine Capsules

Do not take Fluoxetine capsules with:
- irreversible, non-selective monoamine oxidase inhibitors (MAOIs, e.g. tranylcypromine).
- Fluoxetine should only be started at least 2 weeks after stopping an irreversible non-selective MAOI. Do not take any irreversible non-selective MAOI for at least 5 weeks after you stop taking Fluoxetine.
- metoprolol (used to treat high blood pressure).
- propranolol, fenfluramine or phentermine (used to treat abnormal heart rhythms)
- fluoxetine, or other medications to treat attention deficit hyperactivity disorder (ADHD).
- risperidone (used to treat psychotic disorders)
- diuretics (water tablets).

- depresmepress (used to reduce amount urine produced by kidneys)
- ocxarbazepine (used to treat epilepsy)
- haloperidol, mirtazapine, venlafaxine, cyproheptadine, gabapentin (used to treat neuropathic pain, tic disorders, and fibromyalgia).
- gabapentin or phenytoin for epilepsy or other conditions.
- other medicines for depression e.g. tricyclic antidepressants, SSRIs (selective serotonin reuptake inhibitors).
- selegiline for Parkinson's disease.
- tramadol for pain relief.
- bupropion (used to stop smoking).
- triptans (e.g. sumatriptan) for migraine or cluster headaches.
- medicines to thin the blood (e.g. warfarin).
- non-steroïdal anti-inflammatory drugs (NSAIDs, e.g. ibuprofen).
- aspirin (for pain relief).
- cyproheptadine and mirtazapine (used to treat depression).
- the herbal St John's Wort and mention it to your doctor at your next visit.

Fluoxetine capsules with food, drink and alcohol

- You can take Fluoxetine capsules with or without food or with alcohol.
- You should avoid alcohol while you are taking this medicine.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor, pharmacist or nurse for advice before taking this medicine.

When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like Fluoxetine may increase the risk of a serious condition in babies, called persistent pulmonary hypertension of the newborn (PPHN), making the baby breathe faster and appear bluish. These symptoms usually begin during the first 24 hours after the baby is born. If this happens to your baby, you should contact a midwife and/or doctor immediately.

Fluoxetine capsules with food, drink and alcohol

- You can take Fluoxetine capsules with or without food or with alcohol.
- You should avoid alcohol while you are taking this medicine.

Breastfeeding

If you are breast feeding, think you may be breast feeding, or are planning to breast feed, ask your doctor, pharmacist or nurse for advice before taking Fluoxetine.

Antidepressants can affect your judgement or co-ordination. Do not drive or use machinery unless you are sure that you are not affected.

Driving and using machines

Antidepressants can affect your judgement or co-ordination. Do not drive or use machinery unless you are sure that you are not affected.

3 How to take Fluoxetine Capsules

Always read the leaflet that comes with your Fluoxetine capsules before taking the medicine. If you have any doubts about how to take your fluoxetine, ask your doctor, pharmacist or nurse if you are not sure.

You are advised not to drink alcohol with this medicine.

Swallow the capsule whole with a drink of water. Fluoxetine capsules may be taken as a single or separate doses, during or between meals.

Doses:

Adults:
- Depression: the recommended dose is one capsule a day. Maximum daily dose should not exceed 60mg (3 capsules) a day.
- Bulimia: the recommended dose is 60mg (3 capsules) a day.
- Obsessive-compulsive disorder: the recommended dose is one capsule a day. Maximum daily dose should not exceed 60mg (3 capsules) a day.
- If you suffer from kidney or liver problems or are elderly, your doctor may prescribe a different dose.

Children and adolescents aged 8 to 18 years with depression:

Treatment should be started and be supervised by a specialist. The recommended starting dose is 10mg a day (given as 2 x 5mg of Fluoxetine oral liquid). After 1 to 2 weeks, your doctor may increase the dose to 20mg a day. The dose should be increased carefully to ensure that you receive the lowest effective dose. Lower weight children may need lower doses. If there is no satisfactory response to treatment, your doctor will review the need for continuing treatment beyond 6 months. If you have not improved within 9 weeks, your doctor will reassess your treatment.

Fluoxetine may not make you feel any better for the first 2 weeks or more. It should be taken for as long as your doctor tells you to.

If you take more Fluoxetine Capsules than you should

- If you (or someone else) swallow a lot of capsules at the same time, or you think a child may have swallowed any, contact your nearest hospital casualty department or tell your doctor immediately. Signs of an overdose include feeling sick, being sick, diarrhoea, heart problems, lung problems, and signs of altered Central Nervous System status ranging from excitation to coma.