

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT  
**Fluoxetine 10, 30, 40 and 60 mg capsules, hard**

fluoxetine

**EIGHT IMPORTANT THINGS YOU NEED TO KNOW ABOUT FLUOXETINE**

**Fluoxetine treats 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 is not for use in children and adolescents under 8 years.** See section 2, *Children and adolescents*.

**Fluoxetine 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 think of harming 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** without talking to your doctor. If you stop taking Fluoxetine 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 may make these feelings worse. See section 4, *Possible side effects*.

**Taking some other medicines with Fluoxetine can cause problems.** You may need to talk to your doctor. 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 or pharmacist
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4

**What is in this leaflet**

1. What Fluoxetine capsules are and what they are used for
2. What you need to know before you take Fluoxetine capsules
3. How to take Fluoxetine capsules
4. Possible side effects
5. How to store Fluoxetine capsules
6. Contents of the pack and other information

**1. What Fluoxetine capsules are and what they are used for**

Fluoxetine capsules contain the active ingredient fluoxetine, which belongs to a group of medicines called selective serotonin re-uptake inhibitor (SSRI) antidepressants.

This medicine is used to treat the following conditions in:

*Adults:*

- Major depressive episodes
- Obsessive compulsive disorder (OCD)
- The eating disorder bulimia nervosa. Fluoxetine is used alongside psychotherapy for the reduction of binge-eating and purging

*Children and adolescents aged 8 years and above:*

- Moderate to severe major depressive disorder, if the depression does not respond to psychological therapy after 4-6 sessions. Fluoxetine should be offered to a child or young person with moderate to severe major depressive disorder only in combination with psychological therapy

*How fluoxetine works*

Everyone has a substance called serotonin in their brain. People who are depressed or have obsessive compulsive disorder or bulimia nervosa have lower levels of serotonin than others. It is not fully understood how fluoxetine and other SSRIs work but they may help by increasing the level of serotonin in the brain.

Treating these conditions is important to help you get better. If it's not treated, your condition may not go away and may become more serious and more difficult to treat.

You may need to be treated for a few weeks or months to ensure that you are free from symptoms.

**2. What you need to know before you take Fluoxetine capsules**

**Do not take Fluoxetine capsules**

- If you are allergic to fluoxetine hydrochloride or any of the other ingredients of this medicine (listed in section 6)

**If you develop a rash or other allergic reactions (like itching, swollen lips or face or shortness of breath), stop taking the capsules straight away and contact your doctor immediately.**

- If you are taking other medicines known as irreversible, non-selective monoamine oxidase inhibitors (MAOIs), since serious or even fatal reactions can occur (e.g. iproniazid used to treat depression)

Treatment with fluoxetine should only be started at least 2 weeks after discontinuation of an irreversible, non-selective MAOI.

**Do not** take any irreversible, non-selective MAOIs for at least 5 weeks after you stop taking fluoxetine. If fluoxetine has been prescribed for a long period and/or at a high dose, a longer interval needs to be considered by your doctor.

- If you are taking metoprolol (to treat heart failure) since there is an increased risk of your heartbeat becoming too slow

These capsules are available in different strengths from what you may be used to. This is to allow your doctor to more finely control your dose of fluoxetine so that you can take the smallest dose needed for you. Please make sure that you know exactly what strength and how many of each capsule you are to take and take care to ensure that you do not take more or less than the prescribed dose. If you are at all unsure please talk with your doctor or pharmacist, you might want to ask them to give you written instructions based on the sizes and markings of the capsule shells.

**Warnings and precautions**

Talk to your doctor or pharmacist before taking Fluoxetine capsules if any of the following applies to you:

- Epilepsy or fits. If you have a fit (seizures) or experience an increase in the seizure frequency, contact your doctor immediately; Fluoxetine capsules might need to be discontinued
- Mania (overactive behaviour or thoughts) now or in the past; if you have a manic episode, contact your doctor immediately because Fluoxetine capsules might need to be discontinued
- Diabetes (your doctor may need to adjust your dose of insulin or other antidiabetic treatment)
- Liver problems (your doctor may need to adjust your dosage)
- Heart problems
- Low resting heart rate and/or if you know that you may have salt depletion as a result of prolonged severe diarrhoea and vomiting (being sick) or usage of diuretics (water tablets)
- Glaucoma (increased pressure in the eye)
- Ongoing treatment with diuretics (water tablets), especially if you are elderly
- Ongoing ECT (electroconvulsive therapy)
- History of bleeding disorders or appearance of bruises or unusual bleeding, or if you are pregnant (see *"Pregnancy, breast-feeding and fertility"*)
- Ongoing treatment with medicines that thin the blood (see *"Other medicines and Fluoxetine capsules"*)
- Ongoing treatment with tamoxifen (used to treat breast cancer) (see *"Other medicines and Fluoxetine capsules"*)
- Starting to feel restless and cannot sit or stand still (akathisia). Increasing your dose of Fluoxetine capsules may make this worse
- Appearance of fever, muscle stiffness or tremor or changes in your mental state like confusion, irritability and extreme agitation; you may suffer from

the so-called "serotonin syndrome" or "neuroleptic malignant syndrome". Although this syndrome occurs rarely it may result in potentially life threatening conditions; **contact your doctor immediately**, since Fluoxetine capsules might need to be discontinued

- Medicines like Fluoxetine capsules (so called SSRIs/SNRIs) may cause symptoms of sexual dysfunction (see section 4). In some cases, these symptoms have continued after stopping treatment

**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 all take time to work, usually about two weeks but sometimes longer.

You may be more likely to think like this:

- 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 adults aged 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 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 read this leaflet. You might 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.

**Children and adolescents**

Patients 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 this class of medicines. 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, mental, 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 if any of the symptoms listed above develop or worsen when patients under 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**

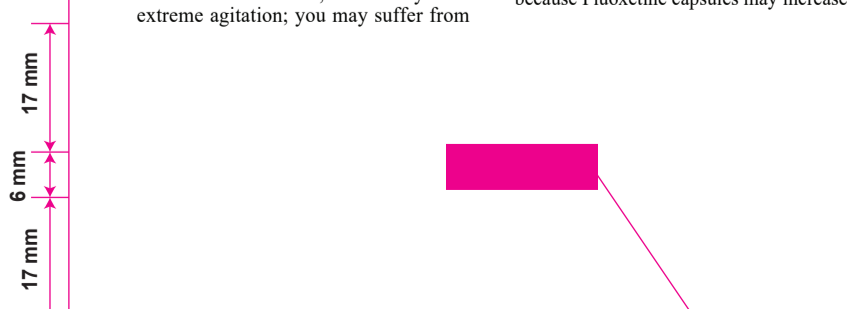
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

**Do not take Fluoxetine capsules with:**

- Certain **irreversible, non-selective monoamine oxidase inhibitors (MAOIs)**, some used to treat depression. Irreversible non-selective MAOIs must not be used with fluoxetine as serious or even fatal reactions (serotonin syndrome) can occur (see section *"Do not take Fluoxetine capsules"*). Treatment with fluoxetine should only be started at least 2 weeks after discontinuation of an irreversible, non-selective MAOI (for instance tranylcypromine). **Do not take** any irreversible, non-selective MAOIs for at least 5 weeks after you stop taking fluoxetine. If fluoxetine has been prescribed for a long period and/or at a high dose, a longer interval than 5 weeks may need to be considered by your doctor
- **Metoprolol** when used for heart failure; there is an increased risk of your heartbeat becoming too slow

Fluoxetine may affect the way some other medicines work (interaction), especially the following:

- **Lithium, selegiline, St John's Wort, tramadol** (a painkiller), **triptans** (for migraine) and **tryptophan**; there is an increased risk of mild serotonin syndrome when these drugs are taken with fluoxetine. Your doctor will carry out more frequent check-ups
- **Tramadol** (a painkiller) or **triptans** (for migraine); there is an increased risk of hypertension (raised blood pressure)
- You should not start to take the herbal remedy St John's wort while you are being treated with fluoxetine since this may result in an increase in side effects. If you are already taking **St John's wort** when you start on fluoxetine, stop taking St John's wort and tell your doctor at your next visit
- **Phenytoin** (for epilepsy); because Fluoxetine capsules may influence the blood levels of this drug, your doctor may need to introduce phenytoin more carefully and carry out check-ups when given with fluoxetine
- Medicines that may affect the heart's rhythm, e.g. **Class IA and III antiarrhythmics, antipsychotics** (e.g. phenothiazine derivatives, pimozide, haloperidol), **tricyclic antidepressants**, certain **antimicrobial agents** (e.g. sparfloxacin, moxifloxacin, erythromycin IV, pentamidine), **antimalaria treatment** particularly halofantrine or certain **antihistamines** (astemizole, mizolastine) because taking one or more of these drugs with Fluoxetine capsules may increase the risk of changes in the electrical activity of the heart
- **Flecainide, propafenone, nebivolol** or **encainide** (for heart problems), **carbamazepine** (for epilepsy), **atomoxetine or tricyclic antidepressants** (for example **imipramine, desipramine and amitriptyline**) or **risperidone** (for schizophrenia); because Fluoxetine capsules may possibly change the blood levels of these medicines, your doctor may need to lower their dose when administered with fluoxetine
- **Tamoxifen** (used to treat breast cancer), because Fluoxetine capsules may change the blood levels of this drug and a reduction of the effect of tamoxifen cannot be excluded, your doctor may need to consider different antidepressant treatments
- **Anticoagulants** (such as warfarin), **NSAIDs** (such as ibuprofen, diclofenac), **aspirin and other medicines which can thin the blood** (including clozapine, used to treat certain mental disorders); Fluoxetine capsules may alter the effect of these medicines on the blood. If Fluoxetine capsules treatment is started or stopped when you are taking warfarin, your doctor will need to perform certain tests, adjust your dose and check on you more frequently
- **Monoamine oxidase inhibitors A (MAOI-A)** including moclobemide, linezolid (an antibiotic) and methylthionium chloride (also called methylene blue, used for the treatment of medicinal or chemical product induced methemoglobinemia); due to the risk of serious or even fatal reactions (called serotonin syndrome). Treatment with Fluoxetine capsules can be started the day after stopping treatment with reversible MAOIs but the doctor may wish to monitor you carefully and use a lower dose of the MAOI-A drug
- **Mequitazine** (for allergies); because taking this drug with Fluoxetine capsules may increase the risk of changes in the electrical activity of the heart
- **Cyproheptadine** (for allergies); because it may reduce the effect of fluoxetine
- **Drugs that lower sodium levels in the blood** (including drugs that cause an increase in urination, desmopressin, carbamazepine and oxcarbazepine); because these drugs may increase the risk of sodium levels in the blood becoming too low when taken with fluoxetine
- **Antidepressants such as serotonergic antidepressants**, other selective serotonin reuptake inhibitors (SSRIs) or bupropion, **mefloquine chloroquine** (used to treat malaria), **tramadol** (used to treat severe pain) or antipsychotics such as phenothiazines or butyrophenones; because Fluoxetine capsules may increase



**Fluoxetine Capsules 10/30/40/60 mg - PIL - Cutterguide**  
**Dim: 110 x 640 mm (Open size)**  
**Auto-cartonator PIL Layout No.: PGB092198960/61/62 LF**

the risk of seizures when taken with these medicines

#### **Fluoxetine capsules with food, drink and alcohol**

- You can take fluoxetine with or without food, whatever you prefer
- 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 or pharmacist for advice before taking this medicine.

#### *Pregnancy*

Talk to your doctor as soon as possible if you are pregnant, if you might be pregnant, or if you are planning to become pregnant.

In babies whose mothers took fluoxetine during the first few months of pregnancy, there have been some reports showing an increased risk of birth defects, in particular those affecting the heart. In the general population, about 1 in 100 babies are born with a heart defect. This increased to about 2 in 100 babies in mothers who took fluoxetine. You and your doctor may decide that it is better for you to gradually stop taking fluoxetine while you are pregnant.

If you take Fluoxetine capsules near the end of your pregnancy there may be an increased risk of heavy vaginal bleeding shortly after birth, especially if you have a history of bleeding disorders. Your doctor or midwife should be aware that you are taking Fluoxetine capsules so they can advise you.

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 your midwife and/or doctor immediately.

It is preferable not to use this treatment during pregnancy unless the potential benefit outweighs the potential risk. Thus, you and your doctor may decide that it is better for you to gradually stop taking fluoxetine while you are pregnant. However, depending on your circumstances, your doctor may suggest that it is better for you to keep taking fluoxetine.

Caution should be exercised when used during pregnancy, especially during late pregnancy or just before giving birth since the following effects have been reported in new born children: irritability, tremor, muscle weakness, persistent crying, and difficulty in sucking or in sleeping.

#### *Breast-feeding*

Fluoxetine is excreted in breast milk and can cause side effects in babies. You should only breast-feed if it is clearly necessary. If breast-feeding is continued, your doctor may prescribe a lower dose of fluoxetine.

#### *Fertility*

Fluoxetine has been shown to reduce the quality of sperm in animal studies. Theoretically, this could affect fertility, but impact on human fertility has not been observed as yet.

#### **Driving and using machines**

Fluoxetine capsules may affect your judgment or co-ordination. Do not drive or use machinery until you know how fluoxetine affects you.

**Fluoxetine 10 mg capsules contain sodium**  
This medicine contains less than 1 mmol sodium (23 mg) per 10mg capsule, that is to say fluoxetine 10mg capsules are essentially 'sodium-free'.

### **3.How to take Fluoxetine capsules**

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. The instructions will also be on the label on the pack. Do not take more capsules than your doctor tells you.

#### **Taking Fluoxetine capsules**

Swallow the capsules with a drink of water. Do not chew the capsules.

#### **Dose**

##### **Adults:**

The recommended dose is:

- **Depression:** The recommended dose is 20 mg daily. Your doctor will review and adjust your dosage if necessary within 3 to 4 weeks of the start of treatment. If required, the dosage can be gradually increased up to a maximum of 60 mg daily. The dose should be increased carefully to ensure that you receive the lowest effective dose. You may not feel better immediately when you first start taking your medicine for depression. This is usual because an improvement in depressive symptoms may not occur until after the first few weeks. Patients with depression should be treated for at least 6 months
- **Bulimia nervosa:** The recommended dose is 60 mg daily
- **Obsessive compulsive disorder:** The recommended dose is 20 mg daily. Your doctor will review and adjust your dosage if necessary after 2 weeks of treatment. If required, the dosage can be gradually increased up to a maximum of 60 mg daily. If no improvement is noted within 10 weeks, your doctor will reconsider your treatment

##### **Use in children and adolescents:**

Aged 8 to 18 years with depression: Treatment should be started and be supervised by a specialist. The starting dose is 10mg/day (given as 2.5 ml of fluoxetine 20mg/5ml oral solution). After 1 to 2 weeks, your doctor may increase the dose to 20 mg/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 a 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.

##### **Elderly:**

Your doctor will increase the dose with more caution and the daily dose should generally not exceed 40 mg. The maximum dose is 60 mg daily.

##### **Liver impairment:**

If you have a liver problem or are using other medication that might affect fluoxetine, your doctor may decide to prescribe a lower dose or tell you to use fluoxetine every other day.

##### **If you take more Fluoxetine capsules than you should**

- If you take too many capsules, go to your nearest hospital emergency department (or casualty) or tell your doctor straight away
- Take the pack of fluoxetine with you if you can

Symptoms of overdose include: nausea, vomiting, seizures, heart problems (like irregular heart beat and cardiac arrest), lung problems and change in mental condition ranging from agitation to coma.

##### **If you forget to take Fluoxetine capsules**

- If you miss a dose, do not worry. Take your next dose the next day at the usual time. Do not take a double dose to make up for a forgotten dose
- Taking your medicine at the same time each day may help you to remember to take it regularly

##### **If you stop taking Fluoxetine capsules**

- **Do not** stop taking fluoxetine without asking your doctor first, even when you start to feel better. It is important that you keep taking your medicine
- Make sure you do not run out of capsules

You may notice the following effects (withdrawal effects) when you stop taking fluoxetine: dizziness; tingling feelings like pins and needles; sleep disturbances (vivid dreams, nightmares, inability to sleep); feeling restless or agitated; unusual tiredness or weakness; feeling anxious; nausea/vomiting (feeling sick or being sick); tremor (shakiness); headaches.

Most people find that any symptoms appear within a few weeks. If you experience symptoms when you stop treatment, contact your doctor.

When stopping fluoxetine, your doctor will help you to reduce your dose slowly over one or two weeks - this should help reduce the chance of withdrawal effects.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

### **4.Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

- If you have thoughts of harming or killing yourself at any time, **contact your doctor or go to a hospital straight away** (see section 2)
- If you get a rash or allergic reaction such as itching, swollen lips/tongue or wheezing/shortness of breath, **stop taking the capsules straight away and tell your doctor immediately**
- If you feel restless and cannot sit or stand still, you may have akathisia; increasing your dose of fluoxetine may make you feel

worse. If you feel like this, **contact your doctor**

- **Tell your doctor immediately** if your skin starts to turn red or you develop a varied skin reaction or your skin starts to blister or peel. This is very rare

#### **Some patients have had:**

- A combination of symptoms (known as "serotonin syndrome") including unexplained fever with faster breathing or heart rate, sweating, muscle stiffness or tremor, confusion, extreme agitation or sleepiness (only rarely)
- Feelings of weakness, drowsiness or confusion mostly in elderly people and in (elderly) people taking diuretics (water tablets)
- Prolonged and painful erection
- Irritability and extreme agitation
- Heart problems, such as fast or irregular heart rate, fainting, collapsing or dizziness upon standing which may indicate abnormal functioning of the heart rate

#### **If you have any of the above side effects, you should tell your doctor immediately.**

The following side effects have also been reported in patients taking fluoxetine:

**Very common** (may affect more than 1 in 10 people)

- Insomnia
- Headache
- Diarrhoea, feeling sick (nausea)
- Fatigue

**Common** (may affect up to 1 in 10 people)

- Not feeling hungry, weight loss
- Nervousness, anxiety
- Restlessness, poor concentration
- Feeling tense
- Dizziness
- Change in taste
- Uncontrollable shaking movements
- Blurred vision
- Yawning
- Rash, urticaria, itching
- Excessive sweating
- Joint pain
- Dry mouth
- Indigestion, vomiting
- Passing urine more frequently
- Unexplained vaginal bleeding
- Feeling shaky or chills
- Sleep problems, unusual dreams, tiredness or sleepiness
- Flushing
- Rapid and irregular heartbeat sensations
- Decreased sex drive or sexual problems (including difficulty maintaining an erection for sexual activity)

**Uncommon** (may affect up to 1 in 100 people)

- Feeling detached from yourself
- Strange thinking
- Abnormally high mood
- Orgasm problems
- Teeth grinding
- Enlarged (dilated) pupils
- Low blood pressure
- Shortness of breath
- Difficulty swallowing
- Hair loss
- Increased tendency to bruising
- Cold sweat
- Discomfort or pain when passing urine
- Feeling hot or cold
- Muscle twitching, involuntary movements or problems with balance or co-ordination
- Memory impairment
- Ringing in the ears
- Nose bleeds
- Abnormal liver test results
- Sexual dysfunction
- Malaise
- Feeling abnormal

**Rare** (may affect up to 1 in 1,000 people)

- Low levels of salt in the blood
- Untypical wild behaviour
- Hallucinations
- Agitation
- Panic attacks
- Fits (epileptic)
- Widening of blood vessels
- Sensitivity to sunlight
- Producing breast milk
- Difficulty in passing urine
- Raised prolactin levels in the blood
- Vasculitis (inflammation of a blood vessel)
- Unusual bleeding or bruising
- Reduction in white blood cell count
- Rapid swelling of the tissues around the neck, face, mouth and/or throat
- Pain in the tube that takes food or water to your stomach
- Reduction in blood platelets, which increase risk of bleeding or bruising
- Confusion
- Stuttering
- Aggression
- Hepatitis
- Lung problems
- Muscle pain
- Problems urinating
- Gastrointestinal bleeding

**Not known** (frequency cannot be estimated from the available data)

- Heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see 'Pregnancy, breast-feeding and fertility' in section 2 for more information

**Bone fractures** - an increased risk of bone fractures has been observed in patients taking this type of medicine.

If you have any of the symptoms listed and they bother you, or last for some time, tell your doctor or a pharmacist.

Most of these side effects are likely to disappear with continued treatment.

#### **Additional side effects in children and adolescents**

In addition to the possible side effects listed above, fluoxetine may slow growth or possibly delay sexual maturity. Suicide-related behaviours (suicide attempt and suicidal thoughts), hostility, mania and nose bleeds were also commonly reported in children.

#### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

#### **5.How to store Fluoxetine capsules**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

#### **6.Contents of the pack and other information**

##### **What Fluoxetine capsules contain**

- The active substance is fluoxetine. Each capsule contains fluoxetine hydrochloride equivalent to 10, 30, 40 or 60 mg of fluoxetine
- The other ingredient is pregelatinised starch. The capsule shell contains gelatin and is coloured with iron oxide yellow (E172), patent blue V (E131) and titanium dioxide (E171). The 10mg strength capsules shell also contains sodium lauryl sulfate
- The black ink contains shellac (E904), dehydrated alcohol, isopropyl alcohol, butyl alcohol, propylene glycol, strong ammonia solution, black iron oxide and potassium hydroxide

##### **What Fluoxetine capsules look like and contents of the pack**

Fluoxetine capsules are hard gelatin capsules. The 10 mg capsules have a white body marked 'F10' and a dark green opaque cap marked 'F 10' containing a white to off-white powder.

The 30 mg capsules have an off-white opaque body marked 'F30' and a green opaque cap marked 'F 30' containing a white to off-white powder.

The 40 mg capsules have an off-white opaque body marked 'F40' and a green opaque cap marked 'F 40' containing a white to off-white powder.

The 60 mg capsules have an off-white opaque body marked 'F60' and a green opaque cap marked 'F 60' containing a white to off-white powder.

Fluoxetine capsules are available in aluminium/PVC blister packs of 30 capsules.

##### **Marketing Authorisation Holder**

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##### **Manufacturer**

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##### **Other sources of information**

To request a copy of this leaflet in large print or audio, please contact us via our website: [www.keypharma.co.uk](http://www.keypharma.co.uk).

This leaflet was last revised in March 2021.

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Pictograms	NA	

Approved by: Key Pharma	Technical approval by: Manufacturer



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	PRODUCT: <b>Fluoxetine Capsules 10, 30, 40, 60 mg -PIL</b>			
DIMENSIONS (mm) <b>110x640</b>	COLOURS: <span style="background-color: black; color: white; border-radius: 10px; padding: 2px 10px; font-weight: bold;">Black</span>			