

PATIENT INFORMATION LEAFLET

FLUOVEX CAPSULE 20MG

Fluoxetine

In this leaflet:

1. What FLUOVEX is and what it is used for
2. Before you take FLUOVEX
3. How to take FLUOVEX
4. Possible side effects
5. Storing FLUOVEX
6. Further information

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

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

What is FLUOVEX and what is its use
--

FLUOVEX is one of a group of medicines called selective serotonin re-uptake inhibitor (SSRI) antidepressants. These medications work in the brain by interfering with one of the normal mechanisms of handling molecules that mediate communications between nerve cells.

This medicine is used to treat the following conditions:

Adults:

- Depression
- Obsessive-compulsive disorder
- Binge eating disorder in combination with psychotherapy

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. FLUOVEX should be offered to a child or young person with moderate to severe major depressive disorder only in combination with psychological therapy.

What you need to know before you take FLUOVEX
--

Do not take FLUOVEX and tell your doctor or pharmacist if the following apply:

- If you are allergic (hypersensitive) to fluoxetine or any of the other ingredients of FLUOVEX. An allergy may include rash, itching, swollen face or lips or shortness of breath.
- If you are taking or have recently been taking any medicines known as monoamine oxidase inhibitors (MAOI) which are used in the treatment of depression e.g. phenelzine, tranylcypromine, isocarboxazid and moclobemide.

Be cautious with FLUOVEX and tell your doctor or pharmacist 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.
- have epilepsy or have had a fit in the past; if you have a fit (seizure) or experience an increase in seizure frequency, contact your doctor immediately, the use of fluoxetine might need to be discontinued.
- have suffered from mania in the past; if you have a manic episode, contact your doctor immediately, the use of fluoxetine might need to be discontinued.
- have diabetes your doctor may need to adjust your dose of insulin or other antidiabetic treatment);
- have liver problems (your doctor may need to adjust your dosage)
- have heart problems
- are taking diuretics (water tablets), especially when you are elderly;
- are having ECT (electro-convulsive therapy) treatment;
- have a history of bleeding disorders or you develop bruises or unusual bleeding.
- are using medicinal products that effect the coagulation of blood (see ‘Taking other medicines’).
- start to experience fever, muscle stiffness or tremor, 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, the use of fluoxetine might need to be discontinued.
- have suicidal thoughts or want to harm your self. Depression is associated with an increased risk of suicidal thoughts, self harm and suicide (suicide related events). This risk persists until improvements of your illness occur. Since it can take 3 to 4 weeks before your illness improves following treatment with fluoxetine, your doctor will monitor you closely at the start of the treatment. Other psychiatric conditions for which FLUOVEX is prescribed can also be associated with an increased risk of suicide-related events. The same precautions should therefore be observed when treating patients with other psychiatric disorders.

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.

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.

Use in children and adolescents aged 8 to 18 years of age:

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. FLUOVEX 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 in other indications.

Additionally, only limited information concerning the long-term safety of FLUOVEX on growth, puberty, mental, emotional and behavioural development in this age group is available. Despite this, your doctor may prescribe FLUOVEX for patients under 18 for moderate to severe major depressive episode in combination with psychological therapy because he/she decides that this is in their best interests. If your doctor has prescribed FLUOVEX 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 FLUOVEX.

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

Withdrawal symptoms seen on discontinuation of FLUOVEX:

Abrupt discontinuation should be avoided. When stopping treatment with FLUOVEX the dose should be gradually reduced over a period of at least one to two weeks in order to reduce the risk of withdrawal reactions. If intolerable symptoms occur following a decrease in the dose or upon discontinuation of treatment, then resuming the previously prescribed dose may be considered. Subsequently, the physician may continue decreasing the dose, but at a more gradual rate.

Administration of FLUOVEX with food and drinks

- You can take FLUOVEX with or without food, whichever you prefer.
- You should avoid alcohol while you are taking this medicine.

Pregnancy

Ask your doctor or pharmacist for advice before taking any medicine.

Pregnancy

Information collected to date does not indicate a increased risk when used during pregnancy. However 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, difficulty in sucking or in sleeping.

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

In babies whose mothers took FLUOVEX 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 FLUOVEX. You and your doctor may decide that it is better for you to gradually stop taking FLUOVEX while you are pregnant. However, depending on your circumstances, your doctor may suggest that it is better for you to keep taking FLUOVEX .

For all SSRIs

Make sure your midwife and/or doctor know you are on FLUOVEX. When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like FLUOVEX 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.

For venlafaxine and mirtazapine

Make sure your midwife and/or doctor knows you are on FLUOVEX. When taken during pregnancy, similar drugs (SSRIs) 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.

Lactation

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

Driving or operating machinery

This medicine may affect your judgment or co-ordination. Do not drive or use machinery without advice from your physician or pharmacist.

Administration of other medication

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, (up to five weeks ago) including medicines obtained without prescription. This medicine may affect the way some other medicines work (interaction). An interaction could occur with:

- MAO-inhibitors (used to treat depression). Non-selective MAO-inhibitors and MAO-inhibitors type A (moclobemide) should not be used with FLUOVEX as serious or even fatal reactions (serotonin syndrome) can occur (see section “Do not take FLUOVEX”). MAO-inhibitors type B (selegeline) can be used with FLUOVEX provided that your doctor monitors you closely.
- lithium, tryptophan; there is an increased risk of serotonin syndrome when these drugs are co-administered with FLUOVEX. When fluoxetine is used in combination with lithium your doctor will carry out more frequent check-ups.
- phenytoin (for epilepsy); because FLUOVEX 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 FLUOVEX.
- clozapine, (used to treat certain mental disorders), tramadol (a painkiller) or triptans (for migraine); there is an increased risk of serotonin syndrome. Use with triptans carries the additional risk of coronary vasoconstriction and hypertension.
- flecainide or encainide (for heart problems), carbamazepine (for epilepsy), tricyclic antidepressants (for example imipramine, desipramine and amitriptyline); because FLUOVEX may possibly change the blood levels of these medicines, your doctor may need to lower their dose when administered with FLUOVEX.
- warfarin or other medicines used to thin the blood; FLUOVEX may alter the effect of these medicines on the blood. If FLUOVEX treatment is started or stopped when you are taking warfarin, your doctor will need to perform certain tests.
- You should not start to take the herbal remedy St John’s wort while you are being treated with FLUOVEX since this may result in an increase of undesirable effects. If you are already taking St John’s wort when you start on FLUOVEX, stop taking the St John’s wort and tell your doctor at your next visit.
- Electroconvulsive Therapy (ECT): There have been rare reports of prolonged seizures in patients on fluoxetine receiving ECT treatment, therefore caution is advisable.

How to take FLUOVEX

Always take FLUOVEX exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The usual 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. When appropriate the dosage can be gradually increased up to a maximum of 60 mg. 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 a period of at least 6 months.
- **Bulimia nervosa:** The recommended dose is 60 mg daily.
- **OCD:** The recommended dose is 20 mg daily. Your doctor will review and adjust your dosage if necessary after 2 weeks of treatment. When appropriate the dosage can be gradually increases up to a maximum of 60 mg. If no improvement is noted within 10 weeks, treatment with FLUOVEX should be reconsidered.
- **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. After one to two weeks, your doctor may increase the dose to 20mg/day. The dose should be increased carefully to ensure that you receive the lowest effective dose. Lower weight children may need lower doses. Your doctor should review the need for continuing treatment beyond 6 months. If you have not improved, your treatment should be reassessed.

If you are 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 per day.

If you have a liver problem or are using other medication that might have an influence on fluoxetine, your doctor may decide to prescribe a lower dose or instruct you to use FLUOVEX every other day.

Method of administration:

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

If you take larger dose of FLUOVEX

- 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 FLUOVEX 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 forgot to take FLUOVEX

- 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.

Possible side effects

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

- 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 feel like you cannot sit or stand still, you may have something called akathisia; increasing your dose of FLUOVEX may make you feel worse. If you feel like this, **contact your doctor.**
- **Tell your doctor immediately** if your skin starts to turn red and then 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 on diuretics (water tablets);
- prolonged and painful erection;
- irritability and extreme agitation.

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

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

Whole body - chills, sensitivity to sunlight, weight loss.

Digestive system - diarrhoea and stomach upsets, vomiting, indigestion, difficulty swallowing or a change in taste, or a dry mouth. Abnormal liver function has been reported rarely, with very rare cases of hepatitis.

Nervous system - headache, sleep problems or unusual dreams, dizziness, poor appetite, tiredness, abnormally high mood, uncontrollable movements, fits, extreme restlessness, hallucinations, untypical wild behaviour, confusion, agitation, anxiety, nervousness, not being able to concentrate or think properly, panic attacks; or thoughts of suicide or harming yourself.

Urogenital system and reproductive disorders - difficulty passing urine or passing urine too frequently, poor sexual performance, prolonged erections, and producing breastmilk.

Respiratory System - sore throat, shortness of breath. Lung problems (including inflammatory processes of varying histopathology and/or fibrosis) have been reported rarely.

Other - hair loss, yawning, blurred vision, unexplained bruising or bleeding, sweating, hot flushes, feeling dizzy when you stand up, or joint or muscle pain, low levels of sodium in the blood.

An increased risk of bone fractures has been observed in patients taking this type of medicines.

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

Additionally in Children and Adolescents (8-18 years) – fluoxetine may slow growth or possibly delay sexual maturity.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Storing FLUOVEX

Keep out of the reach and sight of children.

- Do not take FLUOVEX after the expiry date which is stated on the pack.
- Do not store your capsules above 25°C.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Further information

What Fluovex looks like and contents of the pack

FLUOVEX 20 capsules are light green-beige containing white powder.
They are available in blister packs of 30 capsules.

What Fluovex contains

The active ingredient is fluoxetine hydrochloride.

The other ingredients are microcrystalline cellulose, silicon dioxide, lactose monohydrate, magnesium stearate.

Hard gelatin capsule shell contains: Titanium dioxide, yellow iron oxide, indigo carmine-FD&C Blue 2, quinoline yellow, gelatine.

Registration No:

MAL08010743AC



Manufacturer:

Aegis Ltd,
17 Athinon Street,
Ergates Industrial Area,
2643 Ergates
p.o. box 28629
2081 Lefkosia
cyprus

Marketing authorisation holder

Apex Pharmacy Marketing Sdn Bhd
No. 2, Jalan SS13/5,
47500 Subang Jaya,
Selangor Darul Ehsan,
Malaysia.

Date of Revision

May 2012