Package leaflet: Information for the user

Fluoxetina Tuneluz 20 mg capsules
Fluoxetine

Read all this leaflet carefully before you start taking this medicine as it contains important information for you.
Keep this leaflet. You may need to read it again.
- If you still have questions, talk to your doctor or pharmacist.
- This medicine has been prescribed for you only. You should not give it to others; the medicine may be harmful to them even if they show the same signs of disease.
- If you experience any undesirable effects, including possible undesirable effects not indicated in this leaflet, talk to your doctor or pharmacist. See section 4.

What is in this leaflet:

1. What is Fluoxetina Tuneluz capsules and what it is used for

Fluoxetina Tuneluz 20 mg capsules contains the active substance fluoxetine that belongs to a group of antidepressant medications called selective serotonin reuptake inhibitors (SSIs).

This medicine is used to treat the following situations:

Adults:
Major Depressive Episodes.
Obsessive-Compulsive Disorder.
Nervous bulimia: Fluoxetina Tuneluz is indicated as a complement to psychotherapy aimed at reducing compulsive food intake and purgative activity.

Children and adolescents with 8 years of age and older:
Moderate to severe major depressive episodes, when depression does not respond to 4-6 sessions of psychological therapy. Fluoxetina Tuneluz should only be used in children and young people with moderate to severe depression only in combination with psychological therapy.

How Fluoxetina Tuneluz works
All people have a substance in their brain called serotonin. People who are depressed or suffering from obsessive-compulsive disorder or bulimia nervosa have lower serotonin levels than others. It is not fully known how Fluoxetina Tuneluz and the other SRIs work, but these can help by increasing the level of serotonin in the brain.
It is important to treat these diseases to help you improve. If left untreated, your disease may not disappear and become more severe and more difficult to treat.
You may need to be treated for a few weeks or months to make sure you are free of any symptoms.

2. What you need to know before taking Fluoxetina Tuneluz

Do not take Fluoxetina Tuneluz if:
• you are allergic to fluoxetine or any other component of this medicine (listed in section 6). If you develop a rash or other allergic reactions (such as itching, swollen lips or swollen face or shortness of breath), stop taking this medicine and contact your doctor immediately.
• you are taking other medicines known as non-selective irreversible monoamine oxidase inhibitors (MAOIs), as serious or even fatal reactions (e.g., iproniazide, used to treat depression) may occur.
. haemorrhagic diseases history ... or if you are pregnant (see "Pregnancy")

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

Do not take any irreversible, non-selective MAOIs for at least 5 weeks after discontinuation of Fluoxetina Tuneluz therapy. If Fluoxetina Tuneluz has been prescribed for a long period and/or in high doses, a longer interval should be considered by your doctor.

• you are taking metoprolol (to treat heart failure) as there is an increased risk that your heart rate will become too slow.

Warnings and precautions

Talk to your doctor or pharmacist before taking Fluoxetina Tuneluz if any of the following apply to you:
• heart problems;
• start having fever, muscle stiffness or tremor, changes in mental status including confusion, irritability, and extreme agitation; you may suffer from the so-called "serotonin syndrome" or "malignant neuroleptic syndrome". Although this syndrome rarely occurs can result in life-threatening conditions; contact your doctor immediately as Fluoxetina Tuneluz may need to be discontinued;
• if you suffer from mania now or in the past; if you have had a manic episode, contact your doctor immediately, you may need to stop taking Fluoxetina Tuneluz;
• have a history of bleeding disorders or develop bruising or unexpected bleeding;
• you are using medicines that make your blood thinner (see "Other medicines and Fluoxetina Tuneluz");
• epilepsy or seizures; if you have a seizure (convulsion) or if you have an increase in the frequency of seizures, contact your doctor immediately as you may need to stop taking Fluoxetina Tuneluz;
• you are taking TEC (Electroconvulsive Therapy);
• continued treatment with tamoxifen (used to treat breast cancer) (see "Other medicines and Fluoxetina Tuneluz");
• start feeling agitated and feel that you cannot be sitting or standing still (achaisia). Increasing your dose of Fluoxetina Tuneluz may worsen this condition;
• diabetes (your doctor may need to adjust your insulin dose or antidiabetic treatment);
• liver problems (your doctor may need to adjust your dose);
• low heart rate at rest and/or if you know you have salt deficiency as a result of prolonged severe diarrhoea and vomiting (feeling sick) or if you use diuretics (tablets for urination);

• you are taking diuretics (tablets for urination), especially if you are elderly;
• glaucoma (increased pressure inside the eyes).

The so-called IRSN/SRIs can cause symptoms of sexual dysfunction (see section 4). In some cases, these symptoms persisted after discontinuation of treatment.

Thoughts related to suicide and worsening of your depression or anxiety disorder
If you are depressed and/or have anxiety disorders, you may sometimes think about self-harming or even suicidal. These thoughts may increase at the beginning of antidepressant treatment, as these medications require time to act, usually about two weeks, but sometimes may take longer.
You may be more predisposed to have this kind of thoughts in the following situations:
- If you have a history of having thoughts about committing suicide or self-harming
- If you're a young adult. Information from clinical studies revealed a higher risk of suicidal behavior in adult individuals under the age of 25 with psychiatric problems treated with antidepressants.
If at any time you may have thoughts of self-harm or suicide, contact your doctor or go to the hospital immediately.
It may be helpful for you to communicate to a person close to you or to a family member that you are depressed or have anxiety disorders and give them this booklet to read. You may also ask them to inform you if they see a worsening of your depression or anxiety, or if they are concerned about changes in your behaviour.

Children and adolescents aged 8 to 18 years:

Patients under 18 years of age when taking this type of medication have an increased risk of undesirable effects such as suicide attempt, suicidal ideation, and hostility (predominantly aggression, oppositional behavior, and anger). Fluoxetina Tuneluz should only be used in children and adolescents aged 8 to 18 years in the treatment of moderate to severe major depressive episodes (in combination with concomitant psychological therapy) and should not be used in other indications.

In addition, there are only few data available on the effects of Fluoxetina Tuneluz on long-term safety in growth, in puberty, mental, emotional, and behavioral development, in this age group. However, if you are a patient under the age of 18, your doctor may prescribe Fluoxetina Tuneluz in moderate to severe depression in combination with concomitant psychological therapy because he thinks it is best for you. If the doctor has prescribed Fluoxetina Tuneluz to a patient under the age of 18 and you want to discuss this, please consult your doctor again. If any of the above symptoms develop or worsen when patients under the age of 18 are taking Fluoxetina Tuneluz, you should tell your doctor.

Fluoxetina Tuneluz should not be used for the treatment of children under 8 years of age.

Other medicines and Fluoxetina Tuneluz

Tell your doctor or pharmacist if you are taking or have recently taken or if you are taking other medicines.

Do not take Fluoxetina Tuneluz with:
• Certain irreversible, non-selective monoamine oxidase (MAOI) inhibitors, some used to treat depression. Irreversible, non-selective MAOIs should not be used with Fluoxetina Tuneluz as serious,

or even fatal reactions (serotonin syndrome) may occur (see section "Do not take Fluoxetina Tuneluz"). Treatment with Fluoxetina Tuneluz should only be started at least 2 weeks after discontinuation of an irreversible, non-selective MAOI (e.g., trancytipromine). Do not take any irreversible, non-selective MAOIs for at least 5 weeks after you have discontinued treatment with Fluoxetina Tuneluz. If Fluoxetina Tuneluz has been prescribed for a long period and/or in high doses, it should be considered an interval longer than 5 weeks by your doctor.

• metoprolol when used for heart failure; there is an increased risk that your heart rate will become too slow.

Fluoxetina Tuneluz may alter the effect of the following medicines (interaction):
• tamoxifen (used to treat breast cancer); since Fluoxetina Tuneluz may alter the blood levels of this drug, thus resulting in a possible reduction in the effect of tamoxifen, your doctor may have to consider treatments with different antidepressants.
• monoamine oxidase A inhibitors (MAOIs-A) including moclobemide, linezolid (an antibiotic) and methylothionine chloride (also called methylene blue, used to treat methemoglobinema): due to the risk of serious or even fatal reactions (known as serotonin syndrome). Treatment with fluoxetine may be started one day after reversible MAOI treatment has been discontinued, but your doctor may want to follow up carefully and use a lower dosage of MAOI-A.
• mequitazine (for the treatment of allergies); Taking this drug with Fluoxetina Tuneluz may increase the risk of changes in the electrical activity of the heart.
• phenytoin (for epilepsy); as Fluoxetina Tuneluz may influence blood levels of this medicine, your doctor may need to introduce phenytoin more carefully and perform medical examinations when taking it with Fluoxetina Tuneluz.
• lithium, selegiline, St. John's wort, tramadol (an analgesic), triptanes (for migraines) and tryptophan; there is an increased risk of mild serotonin syndrome when these medicines are given in combination with Fluoxetina Tuneluz. Your doctor will make you tests more often.
• medicines that may affect heart rate, 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), antimalarial treatment, particularly halofantrin or certain antihistamines (astemizole, mizolastin), because taking these medicines in combination with Fluoxetina Tuneluz may increase the risk of changes of the electrical activity of the heart.
• anticoagulants (such as warfarin), NSAIDs (such as ibuprofen, diclofenac), aspirin and other medicines used to make blood thin (including clozapine, used to treat some mental illnesses). Fluoxetina Tuneluz may alter the effect of these medicines on the blood. If treatment with Fluoxetina Tuneluz is started or terminated when you are taking warfarin, your doctor will need to perform certain tests, adjust the dose, and examine you more often.
• ciproheptadine (for allergies); because it can reduce the effect of Fluoxetina Tuneluz
• medicines that lower blood sodium levels (including medicines that increase urinary frequency, desmopressin, carbamazepine, and oxcarbazepine); because these medicines may increase the risk of sodium levels in your blood becoming too low when these medicines are given with Fluoxetina Tuneluz.
• antidepressants such as tricyclic antidepressants, other selective serotonin reuptake inhibitors (SRIs) or bupropion, mefloquine or chloroquine (used to treat malaria), tramadol (used to treat severe pain) or antipsychotics such as phenothiazines or butyrophenones; Fluoxetina Tuneluz may increase the risk of seizures when taken in combination with these medicines.

• flecainide, propaphenone, nebivolol or encainide (for heart problems), carbamazepine (for epilepsy), atomoxetine or tricyclic antidepressants (e.g., imipramine, desipramine and amitriptyline) or risperidone (for schizophrenia); as Fluoxetina Tuneluz may eventually change the levels of these medicines in your blood, your doctor may need to lower your dose when given in combination with Fluoxetina Tuneluz.

Fluoxetina Tuneluz with food, drink and alcohol
• You can take Fluoxetina Tuneluz with or without food as you prefer.
• You should avoid alcohol while you are taking this medicine

Pregnancy, breastfeeding and fertility

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

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

If you take Fluoxetina Tuneluz near the end of pregnancy there may be an increased risk of abundant vaginal bleeding shortly after delivery, especially if you have a history of bleeding disorders. Your doctor or maternal and obstetric nursing specialist should be aware that you are taking Fluoxetina Tuneluz so that they can advise you.

There have been some studies describing an increased risk of heart-affecting birth defects in babies whose mothers took fluoxetine during the first months of pregnancy. In the general population, about 1 in 100 babies are born with a heart defect. This figure increases to 2 in 100 when mothers have taken fluoxetine. So, you and your doctor may decide that it is best for you to gradually stop taking Fluoxetina Tuneluz while you are pregnant. However, depending on the circumstances, your doctor may suggest that it is best for you to continue the treatment with Fluoxetina Tuneluz.

When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines such as fluoxetine can increase the risk of a serious condition in babies, called persistent lung hypertension of the newborn (HPPN), which makes the baby's breathing faster and gives it a bluish appearance. These symptoms usually appear during the first 24 hours after the baby's birth. 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 benefits outweigh the potential risk. Thus, you and your doctor may decide that it is best for you to gradually stop taking Fluoxetina Tuneluz while you are pregnant or before becoming pregnant. However, depending on the circumstances, your doctor may suggest that it is best for you to continue the treatment with Fluoxetina Tuneluz.

Care should be taken when using during pregnancy, especially during the final part of pregnancy or even before delivery, as the following undesirable effects have been reported in newborns: irritability, tremor, weakness in muscles, persistent crying, difficulty sucking or sleeping.

Lactation
Fluoxetine is excreted in breast milk and may cause undesirable effects in babies. You should only breastfeed if absolutely necessary. If you continue to breastfeed, your doctor may prescribe you a lower dose of fluoxetine.

Fertility
In animal studies, fluoxetine has been shown to reduce sperm quality. Theoretically, this can affect fertility, but no impact on human fertility has yet been observed.

Driving vehicles and using machinery
Psychotropic medications such as Fluoxetina Tuneluz can affect your judgment or coordination. Do not drive or use machines until you notice the effects of Fluoxetina Tuneluz in you.

Fluoxetina Tuneluz contains monohydrated lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact them before taking this medicine.

3. How to take Fluoxetina Tuneluz capsules

Always take this medicine exactly as directed by your doctor or pharmacist. Talk to your doctor or pharmacist if you have questions. Do not take more capsules than the ones the doctor has indicated to you.

Swallow the capsules with a glass of water. Don't chew the capsules.

Adults:
The recommended dose is:
Depression: the recommended dose is 1 capsule (20 mg) per day. Your doctor will adjust your dose if necessary within 3 or 4 weeks of starting treatment. When necessary the dose can be gradually increased up to a maximum of 3 capsules (60 mg) per day. The dose should be increased carefully to ensure that you take the lowest effective dose. You may not feel better immediately after you have started taking your medication for depression. This is normal because an improvement in symptoms of depression can occur only after the first weeks of treatment. Patients with depression should be treated for a period of at least 6 months.
Nervous Bulimia: the recommended dose is 3 capsules (60 mg) per day.
Obsessive-Compulsive Disorder: the recommended dose is 1 capsule (20 mg) per day. Your doctor will review and readjust your dose if necessary after two weeks of treatment. When appropriate the dose can be gradually increased up to a maximum of 3 capsules (60 mg) per day. If improvement is not noticed within 10 weeks, your doctor will reconsider your treatment.

Use in children and adolescents aged 8 to 18 years with depression:
Treatment should be initiated and monitored by a specialist. The starting dose is 10 mg/day (given in the form of 2.5 ml of oral solution). After one or two weeks your doctor may increase the dose to 20 mg/day. The dose should be increased carefully, so as to ensure that you take the lowest effective dose. Low birth weight children may need lower doses. If you have had a satisfactory response to treatment, your doctor will review the need to continue treatment beyond 6 months. Your doctor

should consider the need to continue treatment beyond six months. If you have not improved within 9 weeks, your doctor will reassess your treatment.

Elderly:
If you are elderly, your doctor will increase the dose more carefully and the daily dose should generally not exceed 2 capsules (40 mg). The maximum dose is 3 capsules (60 mg) per day.

Liver failure:
If you have a liver problem or are taking another medication that may influence Fluoxetina Tuneluz, your doctor may decide to prescribe a lower dose or advise you to take Fluoxetina Tuneluz on alternate days.

If you take more Fluoxetina Tuneluz than you should
- If you take too many capsules, go to the nearest hospital emergency or tell your doctor immediately.
- Take the packaging of Fluoxetina Tuneluz with you if you can.

Symptoms of overdose include: nausea, vomiting, seizures, heart problems (such as irregular heartbeat and cardiac arrest), lung problems and changes in mental status that can go from agitation to coma.

If you forget to take Fluoxetina Tuneluz
- If you forget to take a dose, don't worry. Take the next dose the next day at the usual time. Do not take a double dose to make up for the missed dose.
- Taking your medicine at the same time every day can help you remember to take it regularly.

If you stop taking Fluoxetina Tuneluz
- Do not stop taking Fluoxetine Tuneluz without asking your doctor first, even if you start to feel better. It is important that you continue to take your medicine.
- Make sure you don't let the capsules run out.

If you stop taking Fluoxetina Tuneluz you may notice the following effects (deprivation effects): dizziness, tingling sensation (needles and pins); sleep disorders (intense dreams, nightmares, difficulty sleeping); feeling agitated and restless; abnormal tiredness or weakness; feel anxious; nausea/vomiting (feel sick or get nauseous); tremors (trembling); headache.

Most patients think that when you stop taking Fluoxetina Tuneluz the symptoms are usually mild to moderate and disappear in a few weeks. If you have any symptoms when stopping treatment with Fluoxetina Tuneluz consult your doctor.

When you stop taking Fluoxetina Tuneluz your doctor will help you reduce the dose gradually for a week or two – this should help you overcome possible withdrawal symptoms.

If you still have questions about using this medicine, talk to your doctor or pharmacist.

4. Possible undesirable effects

Like all medicines, this medicine can cause undesirable effects, although these do not manifest in everyone.

. If you think about self-harming or thinking of suicide at any time during treatment, contact your doctor or go to the Hospital immediately (see Section 2).
. If you have a rash or allergic reaction such as itching, swollen lips/tongue or wheezing/shortness of breath, stop taking the capsules and tell your doctor immediately.
. If you feel agitated and feel that you cannot be quiet sitting or standing, you may suffer from acatisia; Increasing your dose of Fluoxetina Tuneluz can make you feel worse. If you experience these symptoms, contact your doctor.
. Contact your doctor immediately if your skin starts to turn red or if you develop a varied skin reaction or the skin starts to blister or peel. This is very rare.

The most common undesirable effects (very common undesirable effects that may affect more than 1 user in 10) are insomnia, headaches, diarrhoea, feeling unwell (nausea) and fatigue.

Some patients had:
. A combination of symptoms (known as "serotonin syndrome") including unexplained fever with rapid breathing or heartbeat, sweating, muscle stiffness or tremors, confusion, extreme agitation, or drowsiness (only rarely);
. Feelings of weakness, sedation or confusion, mostly in the elderly and in patients (elderly) taking diuretics (tablets for urinating));
. Prolonged and painful erection;
. Irritability and extreme agitation;
. Heart problems, such as fast or irregular heartbeats, fainting, falls or dizziness when standing, which may indicate abnormal heart rhythm functioning.

If you notice any of the undesirable effects mentioned above, talk to your doctor immediately.

The following undesirable effects have also been reported in patients taking Fluoxetina Tuneluz:

Common (may affect up to 1 in 10 people)
• lack of appetite, weight loss
• nervousness, anxiety
• agitation, lack of concentration
• feeling tense
• decreased sexual desire or sexual problems (including difficulty maintaining an rection during sexual activity)
• sleep problems, strange dreams, tiredness, or insomnia
• dizziness
• changes in taste
• involuntary tremor movements
• blurred vision
• sensations of fast and irregular heartbeat
• flushing
• yawns
• indigestion, vomiting
• dry mouth
• rash, hives and itching
• excessive sweating
• joint pain

• urinate more often
• unexplained vaginal bleeding
• feeling shaking or chills

Uncommon (may affect up to 1 in 100 people)
• feel out of your mind
• strange thoughts
• abnormal euphoria
• orgasm problems
• suicidal or self-harming thoughts
• grinding of teeth
• muscle contraction, involuntary movements or balance or coordination problems
• decreased memory
• dilated pupils
• ringing in the ears
• low blood pressure
• shortness of breath
• nosebleed
• difficulty swallowing
• hair loss
• increased tendency to bruises
• unexplained bruising or bleeding
• cold sweats
• difficulty urinating
• feel hot or cold
• abnormal liver test results

Frequency not known
• Abundant vaginal bleeding shortly after delivery (postpartum haemorrhage), see Pregnancy in section 2 for more information

Rare (may affect up to 1 in 1,000 people)
• low blood salt levels
• reduced platelets in the blood, which increases the risk of bleeding and bruising
• reduction of white blood cells in the blood
• uncharacteristic rebel behavior
• hallucinations
• agitation
• panic attacks
• confusion
• stutter
• aggressiveness
• seizures
• vasculitis (inflammation of blood vessels)
• rapid swelling of tissues around the neck, face, mouth and/or throat
• pain in the canal that carries food or water to the stomach
• hepatitis
• lung problems

• sensitivity to sunlight
• muscle pain
• problems urinating
• milk production by the mammary gland

Bone fractures: there was an increased risk of bone fractures in patients taking this type of medication.

Most of these undesirable effects tend to disappear with continued treatment.

In children and adolescents (8-18 years) – In addition to the possible undesirable effects listed above, Fluoxetina Tuneluz may delay growth or delay sexual maturation. Behaviors related to suicide (suicide attempt and suicidal thoughts), hostility, mania and nosebleeds were also frequently reported in children.

Communication of undesirable effects
If you experience any undesirable effects, including possible undesirable effects not listed in this leaflet, talk to your doctor or pharmacist. You can also report undesirable effects directly to INFARMED, I.P. through the contacts below. By reporting undesirable effects, you are helping to provide more information about the safety of this medicine.

Website : http://www.infarmed.pt/web/infarmed/submissaoram (preferably) or through the following contacts:
Directorate of Drug Risk Management
Lisbon Health Park, Av. Brazil 53
1749-004 Lisbon
Tel: +351 21 798 73 73
Medicine Line: 800222444 (free)
E-mail: farmacovigilancia@infarmed.pt

5. How to store Fluoxetina Tuneluz capsules

Do not store above 30ºC.
Store in a dry place.
Keep out of the sight and reach of children.
Do not use this medicine after the expiry date printed on the carton after (Val).
The expiry date is the last day of the month indicated.

Do not throw away any medicines in the plumbing 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 package and other information

What Fluoxetine Tuneluz capsules contain
The active substance is fluoxetine hydrochloride. Each capsule contains 20 milligrams (mg) of fluoxetine (in the form of fluoxetine hydrochloride).

The other components are:
Corn starch, monohydrated lactose, microcrystalline cellulose 101, talc, magnesium stearate, anhydrous colloidal silica (Aerosil 200), gelatin, indigotine (E132), titanium dioxide (E171) and purified water.

What Fluoxetina Tuneluz capsules look like and pack contents

The Capsules of Fluoxetina Tuneluz are blue and white.

Fluoxetina Tuneluz capsules are available in packs containing 10, 20, 30 or 60 capsules.

It is possible that not all presentations are marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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This leaflet was last revised in november.2020