Fluocim, Tablets and Capsules

ACINO PHARMA

What is Fluocim and when is it used?
Fluocim acts on the central nervous system. It is used to treat depressive moods of various causes.
Fluocim is also effective for eating disorders (bulimia).
Fluocim may only be used with a doctor's prescription.

When must Fluocim not be used/taken?
Fluocim must not be taken if you are allergic to any of the ingredients contained in Fluocim. Treatment with Fluocim or with any other antidepressant should not be commenced in states with abnormally elevated mood, known as acute manic states.

Fluocim must not be taken together with certain medicines used to treat depression or Parkinson's disease (so-called MAO inhibitors), since otherwise severe or even fatal reactions may develop (serotonin syndrome, see "What are the possible side effects of Fluocim?").

Fluocim must not be taken before 14 days after the end of a treatment with an irreversible MAO inhibitor or 1 days after the end of treatment with a reversible MAO inhibitor. Your must wait at least 5 weeks after discontinuing Fluocim before you take an MAO inhibitor. Switching from Fluocim to an MAO inhibitor, and the other way around, may only be done under careful medical supervision.

When is caution needed while taking Fluocim?
Inform your doctor and stop taking the medicine if you suffer from liver or kidney function disorders, problems with your blood pressure, heart, dilation of the pupils (mydriasis).

If a skin rash or other signs of an allergy occur during treatment with Fluocim, contact your doctor without delay and stop taking the medicine. In diabetics, treatment with Fluocim may make a dose adjustment of the insulin and/or oral antidiabetic necessary. Diabetics should therefore consult their doctor regarding treatment with Fluocim.

Consult your doctor if you take certain antidepressants – so-called selective serotonin reuptake inhibitors (SSRI) or St. John's wort, certain medicines used to treat migraine, lithium or L-tryptophan, since under treatment with these medicines there is an increased risk of serotonin syndrome (see "What are the possible side effects of Fluocim?"). If you take fluoxetine in combination with lithium, your doctor will check you more frequently.
Tell your doctor or consult with him/her any used of other medicines at the same time with this treatment such as sleeping pills, tranquillizers, antiepileptics, blood thinners and medicines used to treat irregular heartbeat (antiarrhythmics).
Depression symptoms may get worse under treatment with Fluocim. Contact your doctor in such cases.
Taking medicines from the class to which Fluocim belongs may rarely result in bleeding, for example in the skin, mucous membranes of the mouth, genital mucous membranes in women, in the gastrointestinal tract or in other organ systems. Contact your doctor right away if this occurs.
Be very careful when using Fluocim and oral anticoagulants at the same time, since the latter medicines are known to prolong bleeding time or influence blood platelet function (e.g. atypical neuroleptics such as clozapine, phenothiazine, most tricyclic antidepressants, acetylsalicylic acid, non-steroidal antirheumatics) or other substances that increase the risk of bleeding, or if you have previously suffered from bleeding.
Treatment of children and adolescents under 18 years of age with Fluocim is not recommended.
The medicine must not be discontinued suddenly and this may only be done in consultation with your doctor, since otherwise withdrawal symptoms may develop.
Talk to your doctor if you are taking other natural or herbal preparations which contain St. John's wort and you should avoid taking such preparations at the same time as Fluocim.
You should avoid drinking alcohol during treatment with Fluocim.
This medicine may affect your reactions and your ability to drive or to use tools or machines.
Tell your doctor or pharmacist if you suffer from other illnesses, have any allergies or are taking or externally using any other medicines (including those purchased without a prescription!).

May Fluocim be taken during pregnancy or breast-feeding?
Inform your physician if you are pregnant or plan a pregnancy. Fluocim should not be used during pregnancy unless expressly prescribed by your doctor.
The following symptoms may occur in newborn children whose mothers had taken fluoxetine during the later stages of the pregnancy, either immediately or shortly after birth: Eating and sleeping disorders, difficulty breathing, attacks of cramps, body temperature irregularities, low blood sugar levels, tremor, excessively relaxed musculature, vomiting, temporary nervousness, irritability and constant crying. These symptoms normally disappear over time.
Newborn children whose mothers were treated with selective serotonin reuptake inhibitors (the class of antidepressants that also includes Fluocim) after the first 20 weeks of pregnancy may be at increased risk for so-called persistent pulmonary hypertension. In this disease, the blood pressure in the blood vessels between the heart and lungs of the newborn child is too high.
Little data is available on breastfeeding mothers, so that Fluocim should not be used while breastfeeding. If taking this medicine is absolutely necessary, the child must be weaned from breastfeeding.

How is Fluocim taken?
Unless otherwise prescribed, keep strictly to the dose.

Depressive moods
The recommended dose is one capsule or tablet per day, preferably in the morning. The medication may be taken with a meal. If necessary, the dose may be gradually increased by a doctor after a few weeks.
The highest dose is four capsules or tablets per day. With a dose of more than one capsule or tablet per day, the dose should be distributed over the day (morning and evening). Your doctor may also prescribe a different schedule (e.g. only every second day).

Eating disorders
The recommended dose for eating disorders is three capsules or tablets per day.
Older patients and patients with a low body weight should not take more than three capsules or tablets per day.
The doctor will also adjust the dose for patients with restricted renal function or liver function disorders.
Fluocim tablets can either be swallowed whole, entire tablet or ½ tablet, or dispersed in approx. 100 ml (1 glass) of water (mix well).

The following symptoms have been observed in cases of overdose: vomiting, dizziness, nausea, cramps, racing heart, anxiety, excitement. If you notice or suspect an overdose, you should report this immediately to your doctor or the toxicology centre. They will decide on the countermeasures to be taken.
The effect of Fluocim may become apparent within seven days. The full effectiveness occurs after two to four weeks of treatment.
Do not stop taking your medicine without first consulting your doctor.
Do not change the prescribed dose yourself. If you think that the effect of the medicine is too weak or too strong, talk to your doctor or pharmacist.

What are the possible side effects of Fluocim?
You may not feel better right away when you start taking your medicine to treat depression. This is normal, since improvement of depressive symptoms may not begin until after the first couple of weeks of treatment.
Symptoms of depression may include thoughts of self-injury or suicide. These symptoms of depression may become worse during the first weeks of treatment until the full antidepressant effect is established.
Please tell your doctor immediately or go to the nearest hospital if you have any very unpleasant thoughts or experiences, in particular suicidal thoughts or thoughts about hurting yourself. The risk of suicide is particularly increased in young adults (<25 years). The risk of suicidal behaviour is also raised in children and adolescents, for which reason treatment with Fluocim is not recommended (see also "When is caution needed while taking Fluocim?").
The risk of such thoughts is greater if your depression way very severe before the treatment, when your depression is getting worse or if you suffer from pronounced restlessness, panic attacks or sleep disturbances.
Please tell your doctor immediately or go to the nearest hospital if you experience such symptoms.
Other psychiatric diseases for which Fluocim is prescribed may also involve an increased risk of the experiences described above (thoughts of self-injury or suicide). The same precautions therefore apply if you have other psychiatric illnesses.
Side effects that occur at the beginning of treatment usually get better in the course of treatment.
The most frequent side effects during treatment with Fluocim are:
headache, nausea, sleeplessness, tiredness and diarrhoea.
The following side effects may also occur:
Common: nervousness, sleep disorders, restlessness, tension, anxiety, attention deficit disorder, taste disorders, lethargy, sleepiness, dizziness, tremor, unusual dreams (including nightmares), reduction of libido, vomiting, belching, dry mouth, reduced appetite, weight loss, impaired vision, racing heart, blushing, yawning, skin rash, hives, itching, increased sweating, frequent urination, gynaecological bleeding, erection problems, ejaculation disorders, excitement, chills, liver function disorders.

Uncommon: elevated or euphoric mood, abnormal thoughts, abnormal orgasm, grinding of teeth, movement disorders (dyskinesia), muscle twitching, dilation of pupils, difficulty breathing, flatulence, hair loss, increased tendency to bruising, cold sweat, urination disorders, sexual function disorders (sometimes persisting after treatment is over), malaise, discomfort, feeling of heat, feeling of cold, tightness around heart (angina pectoris), heart attack, circulatory and blood pressure disorders.

Reported rarely or in isolated cases: States of excitation, hallucinations, confusion, seizures, urine retention, prolonged erection, menstrual disorders, breast enlargement, flow of human milk, heart rhythm disorders, vein inflammation, changes in blood count, difficulty swallowing, bleeding in stomach / intestine, bleeding in skin or mucous membranes, nosebleed, memory disorders.
Rashes occasionally occur which may be very rarely accompanied by joint pain and fever. Serious impairment of blood flow has been observed very rarely in patients with rashes. This is probably linked to vasculitis.
Allergic (hypersensitivity) reactions occur rarely. These manifest themselves as, for example, an itchy rash, hives, asthma or allergic swellings of the skin and mucosa. If you experience any of these symptoms, consult your doctor immediately and discontinue the medication.
Please contact your doctor without delay if you experience reddened skin, skin reactions, blister formation or skin peeling. This reaction is very rare.
Disturbances to the fluid and salt balance, e.g. with confusion, convulsions, oedemas (swellings resulting from fluid collection in the tissue spaces, e.g. of the skin and mucosa) occur *in rare cases*.
A further side effect, so-called serotonin syndrome, which occurs in particular in combination with certain other medicines (see "When is caution needed while taking Fluocim?") takes the form of reduced awareness, muscle stiffness, muscle tremor, twitching and fever. If you experience this you must consult your doctor without delay.
If side effects occur which you suspect are related to treatment with Fluocim, please inform your doctor.
If you notice any side effects not described here, you should tell your doctor or pharmacist.

What else should you be aware of?
Keep out of reach of children.
Store at room temperature (15–25°C) in the original package.
This medicine may only be used until the date marked with "EXP" on the pack.
Further information may be obtained from your doctor or pharmacist. These persons have the detailed prescribing information at their disposal.

What does Fluocim contain?
1 capsule of Fluocim contains: active ingredient: fluoxetine hydrochloride, equivalent to 20 mg fluoxetinum, excipients: the colorants quinoline yellow (E 104) and indigo carmine (E 132), and other excipients.
1 tablet of Fluocim (with break score) contains: active ingredient: fluoxetine hydrochloride, equivalent to 20 mg fluoxetinum, excipients: other excipients.

Where can you obtain Fluocim? What packs are available?
At pharmacies, on medical prescription only.
Fluocim Capsules, 20 mg:
Packs of 14, 30 and 100 capsules.
Fluocim Tablets (with break score), 20 mg:
Packs of 14, 30 and 100 tablets.

Marketing Authorisation Holder
Acino Pharma AG
4253 Liesberg
Switzerland

Manufacturerd by
Arena Pharmaceuticals GmbH
4800 Zofingen
Switzerland

This package leaflet was last reviewed by the medicines authority (Swissmedic) in May 2012.