

PACKAGE LEAFLET

Package leaflet: Information for the patient

Gerozac 20 mg Capsules, Hard fluoxetine

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 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 Gerozac is and what it is used for
2. What you need to know before you take Gerozac
3. How to take Gerozac
4. Possible side effects
5. How to store Gerozac
6. Contents of the pack and other information.

1. What Gerozac is and what it is used for

The name of your medicine is Gerozac 20 mg Capsules, hard. It contains the active substance fluoxetine.

Gerozac belongs to a group of medicines called selective serotonin reuptake inhibitor (SSRI) antidepressants.

Gerozac can be given to treat the following conditions:

Adults:

- Major depressive episodes
- The symptoms of a condition called obsessive-compulsive disorder (OCD)
- The eating disorder bulimia nervosa. This medicine 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. Gerozac should be offered to a child or young person with moderate to severe major depressive disorder only in combination with psychological therapy.

2. What you need to know before you take Gerozac

Do not take Gerozac:

- if you are allergic to fluoxetine 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 the medicine metoprolol, used to treat heart failure
- if you are taking medicines known specifically as irreversible, non-selective monoamine oxidase inhibitors (MAOIs) since serious or even fatal reactions can occur. An example of such a medicine is ipronazid, which is used to treat depression.

Treatment with fluoxetine should only be started two weeks after discontinuation of an irreversible MAOI (for instance tranylcypromine).

Do not take any MAOIs for at least 5 weeks after stopping 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.

Warnings and precautions

Talk to your doctor or pharmacist before taking Gerozac

- if you have epilepsy or fits. If you have a fit (seizures) or experience an increase in seizure frequency, contact your doctor immediately; Gerozac might need to be discontinued
- if you are experiencing mania now or have experienced it in the past; if you have a manic episode, contact your doctor immediately because Gerozac might need to be discontinued
- if you have liver problems (your doctor may need to adjust your dosage)
- if you have heart problems
- if you have low resting heart rate and/or you know that you may have salt depletion as a result of severe diarrhoea and vomiting (being sick) or usage of diuretics (water tablets)
- if you are recovering from a heart attack
- if you are having electro-convulsive treatment (ECT)
- if you have diabetes, as your doctor may need to adjust the dose of your diabetic medicine
- if you have a history of mental illness
- if you have a history of bleeding disorders or appearance of bruises or unusual bleeding
- if you have glaucoma (increased pressure in the eye)
- if you are already taking certain other medicines. See below, 'Other medicines and Gerozac'
- if you are starting to feel restless and cannot sit or stand still (akathisia). Increasing your dose of fluoxetine may make this worse;
- if you have appearance of 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, since fluoxetine might need to be discontinued.

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

If you are unsure what medicines you are already taking, check with your doctor.

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 aged 8 to 18 years:

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, your doctor may prescribe fluoxetine 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 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 Gerozac

Tell your doctor or pharmacist if you are taking, have recently taken (up to 5 weeks ago) or might take any other medicines.

Do not take Gerozac 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 2 'Do not take Gerozac'). 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 to treat heart failure; there is a risk of your heart beat becoming too slow.

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

- certain medicines known as monoamine oxidase inhibitors A (MAOI-A), used to treat conditions such as depression and Parkinson's disease) including moclobemide, linezolid (an antibiotic) and methylthioninium chloride (also called methylene blue, used for the treatment of a blood disorder known as methemoglobinemia): due to the risk of serious or even fatal reactions (called serotonin syndrome).
- lithium, tryptophan, buprenorphine, tramadol, selegiline, the herbal remedy St. John's wort or medicines known as 'triptans' (e.g. sumatriptan, zolmitriptan); there is an increased risk of serotonin syndrome when these drugs are taken with fluoxetine. Your doctor will carry out more frequent check-ups.
- phenytoin (for epilepsy); because fluoxetine 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.
- flecainide, propafenone or nebivolol (for heart problems), atomoxetine (for attention-deficit hyperactivity disorder, ADHD), carbamazepine (for epilepsy), risperidone (for mental illness), tricyclic antidepressants (for example imipramine, desipramine and amitriptyline); because fluoxetine 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 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.
- medicines that affect the heart's rhythm (antiarrhythmics) e.g. procainamide, disopyramide, sotalol, antipsychotics (e.g. phenothiazines, pimozide, haloperidol), tricyclic antidepressants, certain antimicrobials (e.g. sparfloxacin, moxifloxacin, erythromycin given through a vein, pentamidine), antimalarial treatment particularly halofantrine, certain antihistamines used to treat allergies (astemizole, mizolastine) because taking one or more of these medicines with fluoxetine may increase the risk of changes in the electrical activity of the heart.

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- mequitazine or cyproheptadine, medicines used to treat allergies.
- warfarin, NSAID or other medicines which can thin the blood (including clozapine, used to treat certain mental disorders, and aspirin); fluoxetine may alter the effect of these medicines on the blood. If fluoxetine treatment is started or stopped when you are taking warfarin, your doctor will need to perform certain tests, adjust your dose or check on you more frequently.
- medicines that lower sodium levels in the blood e.g. oxcarbazepine, used to treat epilepsy.
- desmopressin, used to treat certain hormone problems, diuretics (water tablets).
- medicines that can increase the chance of seizures, such as other SSRI antidepressants (e.g. sertraline, citalopram, paroxetine), medicines for nausea and vertigo (e.g. perphenazine, prochlorperazine, chlorpromazine), certain medicines for mental illness called butyrophenones (e.g. benperidol, haloperidol), mefloquine or chloroquine (for malaria), or bupropion (for depression or nicotine dependence).

Gerozac 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 or pharmacist for advice before taking this medicine.

Pregnancy

In babies whose mothers took fluoxetine during the first few months of pregnancy, there have been some reports suggesting an increased risk of birth defects 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.

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 fluoxetine 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 or before being 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, 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

Gerozac may affect your judgment or co-ordination. Do not drive or use machinery without advice from your doctor or pharmacist.

Gerozac contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, such as lactose, contact your doctor before taking this medicine.

3. How to take Gerozac

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Swallow the capsule with a glass of water. Do not chew the capsule.

Adults:

The recommended dose is:

Major depressive episodes: The recommended dose is 1 capsule (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 dose of 60 mg a day (3 capsules). 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. Treatment should be given for at least 6 months.

Obsessive-compulsive disorder (OCD) - The recommended dose is 1 capsule (20 mg) of Gerozac a day. If, after two weeks your condition is no better, your doctor may gradually increase this to the maximum recommended dose of 60 mg (3 capsules) a day. If no improvement is noted within 10 weeks, your doctor will reconsider your treatment.

Bulimia nervosa symptoms – The recommended dose is 3 capsules (60 mg) a day.

Elderly:

Your doctor will increase the dose with more caution and the daily dose should generally not exceed 2 capsules (40 mg). The maximum dose is 3 capsules (60 mg) daily.

Patients with liver problems:

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

Use in children and adolescents aged 8 to 18 years with moderate to severe depression:

Treatment should be started and supervised by a specialist.

The starting dose is 10mg a day. After one to two 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 a satisfactory response to treatment, your doctor should review the need for continuing treatment beyond 6 months. If you have not improved within 9 weeks, your doctor will reassess your treatment.

If you take more Gerozac 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 Gerozac with you if you can.

Signs 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 Gerozac

- 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 capsule.
- Taking your medicine at the same time each day may help you to remember to take it regularly.

If you stop taking Gerozac

- **Do not** stop taking Gerozac 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 Gerozac: 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 on stopping Gerozac are mild and disappear within a few weeks. If you experience symptoms when you stop treatment, contact your doctor.

When stopping Gerozac, 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 any of the following side effects, you should tell your doctor immediately or go to the nearest hospital straight away.

Uncommon (may affect up to 1 in 100 people)

- thoughts of harming or killing yourself at any time (see section 2, “Thoughts of suicide and worsening of your depression or anxiety disorder”).

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

- serious allergic reaction. Such reactions may appear in the form of anaphylaxis (a severe form of allergic reaction) with symptoms such as:
 - rash
 - swelling of the face, lips, mouth, tongue or throat (angioedema)
 - sudden wheezing, fainting or difficulties in swallowing
 - fever, rapid swelling of the tissues around the neck, face, mouth and/or throat, skin rash, enlargement of the lymph nodes (serum sickness)
- if you feel restless and cannot sit or stand still, you may have akathisia; increasing your dose of fluoxetine may make you feel worse.
- skin rash, which may blister, and looks like small targets (central dark spots surrounded by a paler area, with dark ring around the edge) (erythema multiforme)
- widespread rash with blisters and peeling skin, particularly around the body surface, mouth, nose, eyes and genitals (toxic epidermal necrolysis, Stevens-Johnson syndrome).
- fits (convulsions)
- a lower than normal level of sodium in the blood, which may make you feel weak and confused with aching of muscles. This may be due to inappropriate ADH secretion, a hormone that causes the body to retain water and dilute the blood, reducing the amount of sodium
- frequent infections with fever, chills, sore throat or mouth ulcers (reduced number of white blood cells)
- lung problems, scarring and thickening in the lungs with shortness of breath
- liver disease with the following signs; feeling or being sick, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, light coloured bowel motions, dark coloured urine
- a combination of symptoms (known as “serotonin syndrome”) including unexplained fever with faster breathing or heart rate, sweating, muscle stiffness or tremor, confusion, irritability and extreme agitation or sleepiness
- prolonged and painful erection

- heart problems, such as fast or irregular heart rate, fainting, collapsing or dizziness upon standing which may indicate abnormal functioning of the heart rate.

Other possible side effects

Very common: may affect more than 1 in 10 people

- difficulty sleeping (insomnia)
- headache
- diarrhoea, feeling sick (nausea)
- tiredness (fatigue), feeling unusually weak

Common: may affect up to 1 in 10 people

- not feeling hungry, weight loss
- nervousness, anxiety
- restlessness
- poor concentration
- feeling tense
- decreased sex drive or sexual problems (including difficulty maintaining an erection for sexual activity and problems with ejaculation)
- sleep problems, unusual dreams (including nightmares)
- tiredness or sleepiness
- dizziness
- change in taste
- uncontrollable shaking movements
- blurred vision
- rapid and irregular heartbeat sensations, other changes to the electrical activity of the heart called QT prolongation, which can be seen on an ECG, an electrical recording of the heart
- flushing
- yawning
- indigestion, vomiting
- dry mouth
- rash, hives (urticaria), itching
- excessive sweating
- joint pain
- passing urine more frequently
- unexplained vaginal bleeding
- feeling shaky or chills

Uncommon: may affect up to 1 in 100 people

- feeling detached from yourself
- memory problems
- strange thinking
- abnormally high mood
- ringing in the ears
- nose bleeds
- sexual problems, including orgasm problems, occasionally persisting after treatment discontinuation
- orgasm problems
- teeth grinding
- muscle twitching, involuntary movements or problems with balance or co-ordination
- enlarged (dilated) pupils
- low blood pressure
- shortness of breath
- difficulty swallowing
- abdominal bleeding
- hair loss

- increased tendency to bruising
- cold sweat
- pain when passing urine
- feeling hot or cold
- generally feeling unwell/abnormal
- increase in liver enzymes seen in a blood test

Rare: may affect up to 1 in 1,000 people

- untypical wild behaviour
- seeing, feeling or hearing things that are not there (hallucinations)
- agitation
- panic attacks
- aggression
- confusion
- stuttering or stammering
- inflammation of a blood vessel (vasculitis)
- widening of blood vessels
- pain in the tube that takes food or water to your stomach
- sensitivity to sunlight
- producing breast milk
- increase in prolactin (a hormone) level in the blood
- problems urinating
- sore throat and discomfort when swallowing
- muscle pain
- bruising
- unexplained bruising or bleeding
- difficulty passing urine
- bleeding from the mucosal lining of areas such as the mouth and nose

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.

Side effects in children and adolescents (8-18 years)

The following side effects were only seen in children and adolescents

- slow growth or possibly delay sexual maturity

The following side effects were commonly seen in children and adolescents

- changes in behaviour such as tending to act without thought, anger and irritation.
- changes in mood including aggression and agitation
- thoughts of harming or killing yourself or attempting to kill yourself
- nose bleeds.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance. Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Gerozac

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, blister or bottle after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

Do not throw away any medicines via waste water 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 Gerozac contains

The active substance is fluoxetine hydrochloride.

Each capsule contains fluoxetine hydrochloride equivalent to 20 mg of fluoxetine.

The other ingredients are lactose (see section 2 “Fluoxetine contains lactose”), maize starch, colloidal anhydrous silica, talc, magnesium stearate, gelatin, shellac, sodium lauryl sulphate, propylene glycol, ammonium hydroxide, brilliant blue (E133), quinoline yellow (E104), erythrosine (E127), indigo carmine (E132), titanium dioxide (E171) and iron oxide black (E172).

What Gerozac looks like and contents of the pack

Gerozac is a hard capsule with a light green opaque body and a purple opaque cap printed in black ink “FL20” on the body and “α” on the cap.

Gerozac is available in HDPE bottles with polypropylene screw caps (with pressure sensitive wad) containing 7, 10, 14, 20, 28, 30, 50, 60, 90 and 100 capsules, hard.

Gerozac is also available in PVC/PVDC/Al blisters packs containing 7, 10, 12, 14, 20, 28, 30, 50, 60, 90 and 100 capsules, hard.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

McDermott Laboratories Ltd. T/A Gerard Laboratories
35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

Manufacturers

McDermott Laboratories Ltd. T/A Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

This medicinal product is authorised in the Member States of the EEA under the following names:

Denmark	Fluoxetine Mylan
Austria	Fluoxetin ‘Arcana’ 20 mg – Kapseln
Belgium	Fluoxetine Mylan 20 mg harde capsules
France	Fluoxétine Mylan 20 mg, gélule
Germany	Fluoxetin dura 20 mg
Greece	Fluoxetine/Mylan CAP 20 mg/CAP
Ireland	Gerozac 20 mg Capsules, Hard
Italy	Fluoxetina Mylan Generics
Luxembourg	Fluoxetine Mylan 20 mg harde capsules
Netherlands	Fluoxetine Mylan 20 mg, capsules
Portugal	Fluoxetina Mylan
Spain	Fluoxetina Mylan 20 mg capsulas
United Kingdom (Northern Ireland)	Fluoxetine Capsules 20 mg

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