

Package leaflet: Information for the user
Bellzac 20 mg Capsules
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 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 Bellzac 20 mg Capsule is and what it is used for
2. What you need to know before you take Bellzac 20 mg Capsules
3. How to take Bellzac 20 mg Capsules
4. Possible side effects
5. How to store Bellzac 20 mg Capsules
6. Contents of the pack and other information.

1. What Bellzac 20 mg Capsule is and what it is used for

Bellzac 20 mg Capsules contains the active substance fluoxetine which is one of a group of medicines called selective serotonin reuptake inhibitors (SSRI) antidepressants.

This medicine is used to treat the following conditions:

Adults:

- Major depressive episodes: Obsessive-Compulsive disorder:
- Bulimia nervosa: Bellzac 20mg Capsule is used alongside psychotherapy for reduction of binge eating and purging activity.

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. Bellzac 20mg Capsules should be offered to a child or young person with moderate to severe major depressive disorder **only** in combination with psychological therapy.

How Bellzac 20mg Capsules 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 Bellzac 20mg Capsules 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 Bellzac 20 mg capsules

Do not take Bellzac 20 mg capsules:

- If you are **allergic to fluoxetine** or any of the 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 non selective monoamine oxidase inhibitors or reversible monoamine oxidase inhibitors type A (MAOIs) since serious or even fatal reactions can occur. Examples of such MAOIs include medicines used to treat depression such as nialamide, iproniazide, moclobemide, phenelzine, tranylcypromine, isocarboxazid, toloxatone and also linezolid (an antibiotic) and methylthioninium chloride also called methylene blue (used to treat medicinal or chemical induced methaemoglobinemia).

Treatment with Bellzac 20mg Capsules should only be started at least 2 weeks after discontinuation of an irreversible MAOI (for instance tranylcypromine).

However, treatment with fluoxetine can be started the following day after discontinuation of certain reversible MAOIs (for instance moclobemide, linezolid, methylthioninium chloride (methylene blue)).

Do not take any MAOIs for at least 5 weeks after you stop taking Fluoxetine 20mg Capsules. If Bellzac 20mg Capsules 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 Bellzac 20 mg capsules if any of the following applies to you:

- epilepsy or fits. If you have a fit (seizures) or experience an increase in seizure frequency, contact your doctor immediately; Bellzac 20mg Capsules might need to be discontinued;
- mania now or in the past; if you have a manic episode, contact your doctor immediately because Bellzac 20mg 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 (electro-convulsive therapy);
- history of bleeding disorders or appearance of bruises or unusual bleeding;
- ongoing treatment with medicines that thin the blood (see ‘*Other medicines and Bellzac 20mg Capsules*’);
- ongoing treatment with tamoxifen (used to treat breast cancer) (see ‘*Other medicines and Bellzac 20mg Capsules*’);
- starting to feel restless and cannot sit or stand still (akathisia). Increasing your dose of Bellzac 20mg Capsules may make this worse;
- 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 Bellzac 20mg Capsules might need to be discontinued.

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.

Bellzac 20 mg Capsules should only be used in children and adolescents aged 8 to 18 years for the treatment of moderate to severe major depressive episodes and it should not be used to treat other conditions.

Additionally, only limited information concerning the long-term safety of Bellzac 20 mg Capsules on growth, puberty, mental, emotional and behavioural development in this age group is available. Despite this, if you are a patient under 18 years, your doctor may prescribe Bellzac 20 mg Capsules for moderate to severe major depressive episodes, because he/she decides that this is in their best interests. If your doctor has prescribed Bellzac 20 mg capsules 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 Bellzac 20 mg Capsules.

Bellzac 20mg capsules should not be used in the treatment of children under the age of 8 years.

Other medicines and Bellzac 20 mg capsules:

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Bellzac 20mg capsules may affect the way some other medicines work (interaction), especially the following:

- Certain **monoamine oxidase inhibitors (MAOIs)**, some used to treat depression. Nonselective MAOIs and MAOIs type A must not be used with Bellzac 20 mg Capsules as serious or even fatal reactions (serotonin syndrome) can occur (see section “**Do not take Bellzac 20 mg Capsules**”). Treatment with Bellzac 20 mg capsules should only be started at least 2 weeks after discontinuation of an irreversible MAOI (for instance tranylcypromine). However, treatment with fluoxetine can be started the following day after discontinuation of certain reversible MAOIs (for instance moclobemide, linezolid, methylthionium chloride (methylene blue)). Some MAOIs type B (selegiline) can be used with Bellzac 20mg Capsules provided that your doctor monitors you closely.
- **lithium, tryptophan**; there is an increased risk of serotonin syndrome when these drugs are taken with Bellzac 20mg Capsules. Your doctor will carry out more frequent check-ups.
- **phenytoin** (for epilepsy); because Bellzac 20mg 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 Bellzac 20mg Capsules.
- **tramadol** (a painkiller) or **triptans** (for migraine); there is an increased risk of hypertension (raised blood pressure).
- medicines that may affect the heart’s rhythm, e.g. **Class IA and III antiarrhythmics, antipsychotics** (e.g. fentiazine derivatives, pimozide, haloperidol), **tricyclic antidepressants**, certain **antimicrobial agents** (e.g. sparfloxacin, moxifloxacin, erythromycin IV, pentamidine), anti-malaria treatment particularly halofantrine, certain **antihistamines** (astemizole, mizolastine).
- **flecainide** or **encainide** (for heart problems), **carbamazepine** (for epilepsy), tricyclic antidepressants (for example **imipramine, desipramine** and **amitriptyline**); because Bellzac 20mg Capsules may possibly change the blood levels of these medicines, your doctor may need to lower their dose when administered with Bellzac 20mg Capsules.

- **tamoxifen** (used to treat breast cancer), because Bellzac 20mg 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.
- **warfarin, NSAID** or other medicines which can thin the blood (including clozapine, used to treat certain mental disorders, and aspirin); Bellzac 20mg Capsules may alter the effect of these medicines on the blood. If Bellzac 20mg Capsules 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 Bellzac 20mg Capsules since this may result in an increase in side effects. If you are already taking St John's wort when you start on Bellzac 20mg Capsules, stop taking St John's wort and tell your doctor at your next visit.
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Bellzac 20 mg capsules with food, drink and alcohol:

- You can take Bellzac 20mg capsules with or without food, whatever you prefer
- Do not drink 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're pregnant, if you might be pregnant, or if you're planning to become pregnant.

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. 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.

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 new born (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.

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

3. How to take Bellzac 20 mg capsules

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

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

Adults:

The recommended dose is:

- **Depression:** 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 of 3 capsules (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 3 capsules (60mg) daily.
- **Obsessive-compulsive disorder:** The recommended dose is 1 capsule (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 3 capsules (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 10 mg/day (given as 2.5 ml of Fluoxetine 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.

Older people:

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.

Liver impairment:

If you have a liver problem or are using other medication that might affect Fluoxetine 20mg Capsules, your doctor may decide to prescribe a lower dose or tell you to use Fluoxetine 20mg Capsules every other day.

If you take more Bellzac 20 mg 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.

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 Bellzac 20mg 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 Bellzac 20 mg capsules

Do not stop taking Bellzac 20 mg capsules 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 Bellzac 20mg Capsules: 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 Bellzac 20mg Capsules are mild and disappear within a few weeks. If you experience symptoms when you stop treatment, contact your doctor.

When stopping Bellzac 20mg Capsules, 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 20mg Capsules 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.

The most frequent side effects (very common side effects that may affect more than 1 user in 10) are insomnia, headache, diarrhoea, feeling sick (nausea) and fatigue.

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 older people and in older 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 Bellzac 20mg Capsules:

Common: (may affect up to 1 to 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)
- sleep problems, unusual dreams, tiredness or sleepiness
- dizziness
- change in taste
- uncontrollable shaking movements
- blurred vision
- rapid and irregular heartbeat sensations
- flushing
- yawning
- indigestion, vomiting
- dry mouth
- rash, 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
- strange thinking
- abnormally high mood
- orgasm problems
- thoughts of suicide or harming yourself
- teeth grinding
- muscle twitching, involuntary movements or problems with balance or coordination
- memory impairment
- enlarged (dilated) pupils
- ringing in the ears
- low blood pressure
- shortness of breath
- nose bleeds
- difficulty swallowing
- hair loss
- increased tendency to bruising
- unexplained bruising or bleeding
- cold sweat

- difficulty passing urine
- feeling hot or cold
- abnormal liver function test results

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

- low levels of salt in the blood
- reduction in blood platelets, which increases risk of bleeding or bruising
- untypical wild behaviour
- hallucinations
- agitation
- panic attacks
- confusion
- stuttering
- fits
- vasculitis (inflammation of a blood vessel)
- 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
- hepatitis
- lung problems
- sensitivity to sunlight
- muscle pain
- problems urinating
- producing breast milk

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

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

Additional side effects in children and adolescents

In children and adolescents (8-18 years) - In addition to the possible side effects listed above, Bellzac 20mg capsules may slow growth or possibly delay sexual maturity. Suicide-related (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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRa Pharmacovigilance, Earlsfort Terrace, IRL-Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie, e-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Bellzac 20 mg capsules

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

Do not take this medicine after the expiry date which is stated on the carton and blister strip after Exp.. The expiry date refers to the last day of that month.

Store in the original package

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 to protect the environment.

6. Contents of the pack and other information

What Bellzac 20 mg capsules contains

The active substance is fluoxetine hydrochloride

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

The other ingredients are:

Pre-gelatinised maize starch, gelatin, water, sodium laurilsulfate and black ink containing shellac, black iron oxide and potassium hydroxide.

The capsules are coloured with yellow iron oxide (E172), brilliant blue (E133), titanium dioxide (E171).

What Bellzac 20 mg capsule looks like and contents of the pack

Bellzac 20 mg Capsules are green/off-white hard gelatin self locked capsules of size '2' imprinted with 'R / FXT 20' on cap / body in black edible ink containing white powder.

Bellzac 20 mg Capsules are available in blister packs containing 10, 14, 20, 30, 50, 70 or 100 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

Ranbaxy Ireland Ltd
Spafield, Cork Road,
Cashel, Co. Tipperary,
Ireland

This leaflet was last approved in January 2015