

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### **Biozac 20mg Hard Capsules** Fluoxetine (as hydrochloride)

**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.
- If you are a carer or are helping someone else to take their capsules, please read this leaflet before you give the first dose.

#### **What is in this leaflet**

1. What Biozac Hard Capsules are and what they are used for
2. What you need to know before you take Biozac Hard Capsules
3. How to take Biozac Hard Capsules
4. Possible side effects
5. How to store Biozac Hard Capsules
6. Contents of the pack and other information

#### **1. What Biozac Hard Capsules are and what they are used for**

Biozac Hard Capsules contain fluoxetine which is one of a group of medicines called selective serotonin reuptake inhibitor (SSRI) antidepressants.

Biozac Hard Capsules are used in the treatment of:

##### **Adults:**

- Severe depression
- Anxiety disorders with compulsive thoughts or actions, which means that you may have uncontrollable thoughts or carry out repetitive actions. This condition is known as obsessive compulsive disorder.
- Binge-eating (bulimia nervosa), alongside psychotherapy, in order to avoid binge-eating and vomiting

##### **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. Fluoxetine 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 Biozac Hard Capsules**

Do not take Biozac Hard Capsules:

- 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 other medicines used to treat depression, known as irreversible non-selective monoamine oxidase inhibitors (non-selective MAOI, for example: iproniazid) since serious or even fatal reactions can occur.

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

Do not take these 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 needs to be considered by your doctor.

- If you are taking metoprolol, a medicine used for the treatment of heart failure.

### Warnings and precautions

Talk to your doctor or pharmacist before taking Biozac Hard Capsules if any of the following applies to you:

- have epilepsy or fits (seizures) or experience an increase in seizure frequency, contact your doctor immediately; fluoxetine might need to be discontinued.
- mania now or in the past; if you have a manic episode, contact your doctor immediately because fluoxetine 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.
- weight loss
- are taking diuretics (water tablets), especially if you are elderly.
- are having ECT (electro-convulsive therapy) treatment.;
- have a history of bleeding disorders or you develop bruises or unusual bleeding.
- are taking medicines that thin the blood (see taking other medicines)
- have glaucoma (increased pressure in the eye).
- are taking treatment with tamoxifen (used to treat breast cancer).
- start to feel restless and cannot sit or stand still (akathisia).
- 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, fluoxetine might need to be discontinued.
- have 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 this:

- if you have previously had thoughts of 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 about harming or killing yourself at any time, **contact your doctor or go to a hospital straight away.**

**You may find it useful 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 that your depression or anxiety disorder is getting worse, or if they are worried about changes in your behaviour.

### Children and adolescents aged 8 to 18 years

Patients younger than 18 have an increased risk of suicide attempts, suicidal thoughts and hostility (mainly aggression, oppositional behaviour and rage) if they are treated with medicines from this therapeutic class

(known as selective serotonin reuptake inhibitor). 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 Biozac Hard Capsules to patients younger than 18 years for moderate to severe major depressive episodes in combination with psychological therapy because it is in the patients interest. If your doctor has prescribed Biozac Hard Capsules to a patient who is younger than 18 years, and you want to discuss this, you are requested to contact your doctor. If one of the symptoms listed above develops or worsens in patients younger than 18 years while they are taking Biozac Hard Capsules, you are requested to inform your doctor of this.

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

### **Other medicines and Biozac Hard Capsules**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines (up to 5 weeks ago). This includes medicines obtained without a prescription.

The effects of this medicine may change especially if you are taking:

- Certain MAO-inhibitors (some used to treat depression). Non-selective MAO-inhibitors and MAO-inhibitors type A must not be used with fluoxetine as serious or even fatal reactions (serotonin syndrome) can occur (see section 'Do not take Biozac Hard Capsules). Treatment with Biozac Hard 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 MAO-inhibitors type B (selegiline) can be used with fluoxetine provided that your doctor monitors you closely.
- Metoprolol (for the treatment of heart failure). Biozac Hard Capsules increases the chances of side effects when taken with metoprolol.
- Tamoxifen (used to treat breast cancer), because Biozac Hard 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
- Mequitazine (used to treat allergies), increases the chances of side effects (such as changes in heart beat) when taken Biozac Hard Capsules.
- Phenytoin (for epilepsy). When taken with fluoxetine, the amount of phenytoin in the blood can change, which may cause side effects. If necessary, the doctor will adjust the dosage and check you regularly.
- Medicines that can increase the possibility of serotonin syndrome, such as tramadol (a pain-killer), lithium (for manic depressive disorders), tryptophan (for depression), tryptans (medicines for migraine) and St. John's wort (*Hypericum perforatum*). Tryptans also increase the chance of side effects. If you are taking any of these medicines your doctor will keep a close eye on you.
- Certain drugs that are broken down by the same enzyme as fluoxetine such as flecainide or encainide (for disturbance of heart rhythm), carbamazepine (for epilepsy) and some drugs for depression (the tricyclic antidepressants). The doctor will begin with a low dosage of these drugs, or lower the dosage of fluoxetine. This also applies if you have taken fluoxetine in the last 5 weeks.
- 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).

- Warfarin, NSAID (pain killers) or other medicines which can thin the blood (including clozapine, used to treat certain mental disorders, and aspirin); Biozac Hard Capsules may alter the effect of these medicines on the blood. If Biozac Hard Capsules treatment is started or stopped when you are taking warfarin, your doctor will need to perform certain tests.
- Cyproheptadine (used to treat allergies), reduces the antidepressant effect of Biozac Hard Capsules.
- Diuretics (water tablets), carbamazepine and oxcarbazepine (used to treat epilepsy) may decrease blood sodium levels
- Certain antidepressant medications (TCAs, other SSRIs, phenothiazines, butyrophenones, mefloquine, chloroquine, bupropion, tramadol) may increase risk of seizures.
- Flecainide or encainide (for heart problems), carbamazepine (for epilepsy), tricyclic antidepressants (for example imipramine, desipramine and amitriptyline); because Biozac Hard Capsules may possibly change the blood levels of these medicines, your doctor may need to lower their dose when administered with Biozac Hard Capsules.

If you are having electro-convulsive therapy (electroshock treatment), which can be used for the treatment of seizures (fits), any seizure that you have may go on for longer than normal. The doctor will monitor you more closely.

### **Biozac Hard Capsules with food, drink and alcohol**

- You can take fluoxetine with or without food, whatever you prefer
- Fluoxetine does not increase the effect of alcohol. However, the use of alcohol is not recommended during treatment with fluoxetine.

### **Pregnancy, breast-feeding and fertility**

#### Pregnancy

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

Make sure your midwife and/or doctor know you are on Biozac 20mg Hard Capsules. When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like Biozac 20mg Hard Capsules 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.

#### Breast-feeding

Fluoxetine passes into the breast-milk and can cause adverse effects in babies. If you are breast-feeding your baby, you must consider stopping breast-feeding. If you continue to breast-feed your doctor will prescribe the lowest possible effective dose of fluoxetine. Ask your doctor or pharmacist for advice before taking any medicine.

#### 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**

Biozac 20mg Hard Capsules can cause side effects which may affect concentration and/or co-ordination. Do not drive or operate machines until you are sure that fluoxetine has no effect on your ability to drive or use machines.

**Biozac Hard Capsules contain lactose**

If your doctor has told you that you do not tolerate certain sugars, contact your doctor before you take this medicine.

**3. How to take Biozac Hard Capsules**

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

The information below is only a guideline: Your doctor will tell you what the correct dose for you is. Do not take more capsules than your doctor tells you.

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

**Adults and older people**

*Depression:*

The recommended dose is 1 capsule (20 mg) per day. After 3 to 4 weeks the doctor may increase the dosage if the effect is not adequate. If required the dosage can be gradually increased up to a maximum of 3 capsules (60mg) 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 medicines for depression. This is usual because an improvement in depressive symptoms may not occur after the first few weeks. Patients with depression should be treated for at least 6 months.

*Obsessive compulsive disorders*

The recommended dose is 1 capsule (20 mg) per day. After 2 weeks the doctor may review and adjust your dosage. If required, the dosage can be gradually increased up to a maximum of 3 capsules (60mg) daily.

If the treatment has not had any effect after 10 weeks, the doctor will reconsider your treatment.

*Binge-eating (bulimia nervosa)*

The recommended dosage is 60 mg (3 capsules per day).

**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 10mg/day. After 1 to 2 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 will review the need for continuing treatment beyond 6 months, and treatment will be reassessed if no improvement is seen.

**Older people**

For older people the recommended maximum dosage is 40 mg, and in exceptional cases 60 mg per day.

If you notice that Biozac Hard Capsules are too strong or not strong enough, ask your doctor or pharmacist for advice

**Liver impairment**

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

**How long should/must you take Biozac Hard Capsules**

Fluoxetine, and most other medicines for depression, do not work immediately. You will only notice an effect after about 3 to 4 weeks. Your doctor will tell you how long you must take Biozac Hard Capsules for.

**If you take more Biozac Hard Capsules than you should**

If you have taken too many capsules, you should tell your doctor or go to your local hospital immediately. Take the pack of Biozac with you if you can.

The following symptoms may occur: nausea, vomiting, fits, disturbances of the heart and blood vessels (ranging from an irregular heart beat to cardiac arrest), disturbances in the action of the lungs and changes in the central nervous system, varying from agitation to coma.

**If you forget to take Biozac Hard Capsules**

If you have forgotten a dose, the effectiveness will usually be maintained. Take the next capsule at the usual time. Do not take a double dose to make up for a forgotten capsule. If you are not sure, ask your doctor or pharmacist.

**If you stop using Biozac Hard Capsules**

Do not stop taking fluoxetine 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.

Withdrawal symptoms often occur, especially if you stop suddenly. These symptoms also depend on how much and how long you have used fluoxetine. The following symptoms can occur: dizziness; sensory disturbances such as pins and needles for no reason; insomnia, vivid dreams or other sleep disturbances; weakness, irritability or anxiety; nausea and/or vomiting; tremors and headache. These symptoms mostly occur in the first few days after discontinuation of the treatment, and are mild to moderate.

When stopping fluoxetine, 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
- If you develop a rash/itching or allergic reaction such as swollen lips/tongue/eyelids or difficulty breathing, stop taking the capsules immediately and contact your doctor straight away.
- If you experience restlessness and cannot sit or stand still, you may have something called 'akathisia'; increasing your dose of fluoxetine may make these feelings worse. If you feel like this, contact your doctor.
- If your skin starts to peel or blister or you develop a varied skin reaction or redness, you should contact your doctor immediately, although 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 elderly people and in (elderly) 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 Biozac Hard Capsules

**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)
- 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 co-ordination

- 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 weak, 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
- reduction in white blood cells or neutrophils in the blood
- imbalance of the fluid and chemicals in the body
- untypical wild behaviour
- hallucinations
- agitation
- panic attacks
- confusion
- stuttering
- aggression
- fits
- interruptions to the heart rhythm
- 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.

In children and adolescents (8-18 years) – In addition to the possible side effects listed above, Biozac Hard Capsules may slow growth or possibly delay sexual maturity. Suicide-related behaviours (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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earsfort

Terrace , IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); e-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie).

By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Biozac Hard Capsules**

Keep out of the sight and reach of children.

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

Do not store above 30°C.

If you have any other questions please talk to your doctor or pharmacist.

If your doctor decides to stop treatment, return any left-over capsules to a pharmacist. Only keep them if your doctor tells you to.

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 protect the environment.

## **6. Contents of the pack and other information**

### **What Biozac Hard Capsules contain**

- The active substance is fluoxetine (as hydrochloride). Each hard capsule contains 20mg fluoxetine (as hydrochloride).

The other ingredients are:

Lactose monohydrate, microcrystalline cellulose (E460(i)), magnesium stearate (E572) and crospovidone.

Each capsule shell contains gelatine, yellow and black iron oxide (E172), indigo carmine (E132) and titanium dioxide (E171).

The printing ink contains shellac black iron oxide (E172) ,propylene glycol (E1520) and ammonium hydroxide (E527)

### **What Biozac Hard Capsules look like and contents of the pack**

Biozac 20mg Hard Capsules are olive-coloured/green capsules marked FLE 20.

The capsules are packed in blister packs.

A carton contains 10, 14, 20, 28, 30, 50, 60, 100, 200, 250, 500 or 1000 hard capsules.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

#### **The Marketing Authorisation Holder is:**

Niche Generics Ltd,  
1 The Cam Centre,  
Wilbury Way,  
Hitchin,  
Hertfordshire, SG4 OTW,  
United Kingdom

#### **The Manufacturer is:**

Niche Generics Limited, 151 Baldoyle Industrial Estate, Baldoyle, Dublin 13, Ireland

**This Medicinal Product Is Authorised In The Member States Of The EEA Under The Following Names:**

Ireland: Biozac 20mg Hard Capsules

United Kingdom: Oxactin 20mg Capsules

**This leaflet was last revised in July 2015**