

NORZAC™ 20 mg HARD CAPSULES fluoxetine (as hydrochloride)

PACKAGE LEAFLET: INFORMATION FOR THE USER

Read all of this leaflet carefully before you start using 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 Norzac Hard Capsules are and what they are used for
2. What you need to know before you take Norzac Hard Capsules
3. How to take Norzac Hard Capsules
4. Possible side effects
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1 WHAT NORZAC HARD CAPSULES ARE AND WHAT THEY ARE USED FOR

Norzac Hard Capsules contain fluoxetine which belongs to a group of medicines called selective serotonin re-uptake inhibitor (SSRI) antidepressants.

This medicine is used to treat the following conditions:

Adults:

- Major depressive episodes
- Obsessive-compulsive disorder
- Bulimia nervosa: Norzac Hard Capsules are 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 improve within 4 – 6 sessions of psychological therapy. Norzac Hard Capsules should only 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 NORZAC HARD CAPSULES

DO NOT take Norzac Hard Capsules and tell your doctor or pharmacist if any of the following apply:

- if you are **allergic** to fluoxetine or any of the other ingredients of this medicine (listed in section 6). An allergy may include rash, itching, swollen face or lips, or shortness of breath.
- if you are **taking medicines known as monoamine oxidase inhibitors** (also called MAOIs) which are also used to treat depression, since serious or even fatal reactions can occur with these medicines. Examples of MAOIs include nialamide, iproniazid, selegiline, moclobemide, phenelzine, tranlycypromine, isocarboxazid, toloxatone and also linezolid (an antibiotic) and methylthionium chloride also called methylene blue (used to treat high levels of methaemoglobin in the blood). (see section 2, 'Other medicines and Norzac Hard Capsules').

Treatment with Norzac should only be started at least 2 weeks after discontinuation of an irreversible MAOI (for instance tranlycypromine). However, treatment with fluoxetine can be started the following day after discontinuation of certain reversible MAOIs (for instance moclobemide, linezolid, methylthionium chloride (methylene blue)).

Warnings and precautions

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 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 of killing or harming yourself
- you are a young adult. Information from clinical trials has shown an increased risk of suicidal behaviour in young adults (less than 25 years old) 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.

Talk to your doctor or pharmacist before taking this medicine if you:

- have **epilepsy** or have had a fit in the past; if you have a fit (seizure) or experience an increase in seizure frequency, contact your doctor **immediately**, as you may need to stop taking fluoxetine.
- have suffered from **mania** in the past; if you have a manic episode, contact your doctor **immediately**, as you may need to stop taking fluoxetine
- have **diabetes**; your doctor may need to adjust your dose of insulin or other antidiabetic treatment.
- have **liver problems**; your doctor may need to adjust your dosage.
- have **heart problems**
- are taking **diuretics** (water tablets), especially if you are elderly
- are having **ECT** (electro-convulsive therapy) treatment
- if you are taking **tamoxifen**, a medicine used to treat breast cancer
- have a **history of bleeding disorders** or you develop bruises or unusual bleeding
- suffer from **high eye pressure** or are at risk of developing **glaucoma**. Taking Norzac Hard Capsules can lead to development of mydriasis (dilation of the pupil).
- are taking **anticoagulant medicines used to thin the blood** (see section 2, 'Other medicines and Norzac Hard Capsules').

The 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 Norzac might need to be discontinued (see section 4).

Children and adolescents

Norzac Hard Capsules 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 in other indications.

Norzac Hard Capsules should not be used in the treatment of children under the age of 8 years.

When taking this type of medicines, patients under 18 years of age have an increased risk of the following side effects:

- suicide attempt
- suicidal thoughts
- hostility (predominantly aggression, oppositional behaviour and anger).

You MUST inform your doctor if any of the signs of illness listed above develop or worsen when patients under 18 are taking this medicine. Additionally, only limited information concerning the long-term safety of Norzac Hard Capsules on

growth, puberty, mental, emotional, and behavioural development in this age group is available. Despite this, your doctor may prescribe this medicine for patients under 18 years of age 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 this medicine for a patient under 18 years of age and you want to discuss this, please go back to your doctor.

Other medicines and Norzac Hard Capsules

Norzac Hard Capsules may affect the way some other medicines work. Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines (within the last five weeks) including medicines obtained without prescription, in particular:

DO NOT take Norzac Hard Capsules in combination with:

- **non-selective MAOIs** (e.g. isocarboxazid) and **reversible Type A MAOIs** (e.g. moclobemide, linezolid, methylthionium chloride (also called methylene blue)) for the treatment of depression. Such medicines **MUST NOT be taken** in combination with Norzac Hard Capsules because serious or even fatal reactions (e.g. serotonin syndrome) can occur (see section 4, 'Possible side effects').
- **type B MAOIs** used to treat Parkinson's disease (e.g. selegiline) **can be taken** with this medicine **provided that your doctor monitors you closely.**
- Treatment with fluoxetine should only be started 2 weeks after you have stopped taking an irreversible MAOI (e.g. tranlycypromine). However treatment with Norzac Hard Capsules can be started the following day after discontinuation of certain reversible MAOIs (e.g. moclobemide). If you have any doubt, talk to your doctor or pharmacist before you start to take fluoxetine.
- **DO NOT take any MAOIs for at least 5 weeks after you stop taking Norzac Hard Capsules.** If Norzac Hard Capsules have been prescribed for a long period and/or at a high dose, your doctor may advise a longer interval

It is important to tell your doctor if you are taking any of the following medicines:

- **lithium, tryptophan, or clozapine** (used to treat certain mental disorders)
- **tricyclic antidepressants** (e.g. imipramine, desipramine and amitriptyline)
- **phenytoin** (for epilepsy)
- **carbamazepine** (for epilepsy)
- **tramadol** (a painkiller)
- **triptans** (for migraine)
- 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), **antimalarial** treatment particularly halofantrine, certain **antihistamines** (astemizole, mizolastine).
- **non-steroidal anti-inflammatory drugs** (NSAIDs, e.g. aspirin, ibuprofen, used to treat inflammation and pain)
- **phenothiazines** (e.g. chlorpromazine hydrochloride, prochlorperazine)
- **flecainide** or **encainide** (for heart problems)
- **warfarin** or other medicines used to thin the blood
- **tamoxifen** (used to treat breast cancer)
- the herbal remedy **St John's wort**. You should not start to take St John's wort while you are being treated with Norzac Hard Capsules since this may result in an increase in side effects. If you are already taking St John's wort, you will need to stop taking the St John's wort before you start to take Norzac Hard Capsules. Make sure you discuss this with your doctor before you start to take Norzac Hard Capsules.

Norzac Hard Capsules with food, drink and alcohol

You can take this medicine with or without food, whichever you prefer. 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 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 Norzac while you are pregnant. However, depending on your circumstances, your doctor may suggest that it is better for you to keep taking Norzac.

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.

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 passes into breast milk and can cause side effects in babies. You should only breast-feed if your doctor recommends it. 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

Norzac Hard Capsules may affect your judgment, vision or co-ordination. DO NOT drive or use machinery unless you are sure you are not affected.

Norzac Hard Capsules contain lactose

Patients who are intolerant to lactose should note that Norzac Hard Capsules contain a small amount of lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3 HOW TO TAKE NORZAC HARD CAPSULES

Always take Norzac Hard Capsules exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Swallow the capsules with a drink of water.

DO NOT chew the capsules. You can take this medicine with or without food, whichever you prefer.

The usual dose is:

Adults

• Depression

The recommended dose is 1 capsule (20 mg) daily.

If necessary, your doctor will review and adjust your dosage within 3 to 4 weeks of the start of treatment. When appropriate, the dosage can be gradually increased up to a maximum of 3 capsules (60 mg) a day. 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.



Design Department Harlow

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Job No: 29931 Art No: - Designer: LT Date: 12-8-13 Component: Leaflet Dimensions: 160x560mm	Tints used: <input type="text"/> Spellcheck: <input type="checkbox"/>	Software used: Indesign CS6
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This is usual because an improvement in depressive symptoms may not occur until after the first few weeks. Your treatment should last for a period of at least 6 months.

Bulimia nervosa

The recommended dose is 3 capsules (60 mg) daily.

Obsessive-compulsive disorder

The recommended dose is 1 capsule (20 mg) daily.

If necessary, your doctor will review and adjust your dosage after 2 weeks of the start of treatment. When appropriate, the dosage can be gradually increased up to a maximum of 3 capsules (60 mg) a day. If you do not begin to feel better within 10 weeks, your doctor will decide whether you should continue treatment.

Children and adolescents aged 8 to 18 years with depression

Treatment should be started and be supervised by a specialist.

The starting dose 10 mg/day, which has to be given as an alternative form or strength, such as a liquid.

After one to two weeks, their doctor may increase the dose to 20 mg daily (one capsule).

The dose should be increased carefully to ensure that you receive the lowest effective dose. Lower weight children may need lower doses.

Their doctor should review the need for continuing treatment beyond 6 months, and treatment will be reassessed if there is no improvement in your condition after 9 weeks.

The elderly, patients with liver problems, and patients taking other medicines

- If you are 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) per day.
- If you have a liver problem or are using other medication that might have an influence on Norzac Hard Capsules, your doctor may decide to prescribe a lower dose or instruct you to take Norzac Hard Capsules every other day.

If you take more Norzac Hard Capsules than you should

Go to your nearest hospital emergency or casualty department immediately if you have taken, or think that you have taken, more tablets than you should. Take the pack of this medicine with you.

Signs of overdose include: feeling sick, being sick, 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 Norzac Hard 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 Norzac Hard Capsules

Do not stop taking Norzac Hard Capsules until your doctor tells you to. It is important that you keep taking your medicine. DO NOT stop taking Norzac Hard Capsules without asking your doctor first, even when you start to feel better. Make sure you do not run out of capsules. **You may notice the following effects when you stop taking Norzac Hard 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, feeling sick or being sick, tremor (shakiness), headaches.

These symptoms are called **withdrawal effects**.

When stopping this medicine, your doctor will help you to reduce your dose slowly over one or two weeks - this should help reduce the chance of withdrawal effects.

Most people find that any withdrawal effects are mild and go away on their own within a few weeks. If you experience withdrawal effects when you stop treatment, contact your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4 POSSIBLE SIDE EFFECTS

Like all medicines, Norzac Hard Capsules can cause side effects, although not everybody gets them.

STOP taking the capsules straightaway and tell your doctor immediately if you get:

- a rash or allergic reaction such as itching, swollen lips/tongue or wheezing/shortness of breath.

Tell your doctor immediately if you have any of the following side effects:

- thoughts of harming or killing yourself; **contact your doctor or go to a hospital straightaway.**
- a combination of symptoms including unexplained fever with faster breathing or heart rate, sweating, muscle stiffness or tremor, confusion, extreme agitation or sleepiness (only rarely); these symptoms may be a sign of serotonin syndrome or neuroleptic malignant syndrome. As these syndromes may result in potentially life-threatening conditions, your doctor may need to stop your treatment with fluoxetine.
- red, often itchy spots, similar to the rash of measles, which starts on the limbs and sometimes on the face and the rest of the body. The spots may blister or may progress to form raised, red, pale-centred marks. You may have fever, sore throat, headache and/or diarrhoea.
- fits or seizures
- irritability and extreme agitation
- you feel restless and feel like you cannot sit or stand still; you may be experiencing a medical condition called akathisia.

The following side effects have been reported:

Very common side effects (affecting more than 1 in 10 people):

- difficulty sleeping
- headache
- diarrhoea
- feeling sick
- fatigue.

Common side effects (affecting more than 1 in 100 people, but less than 1 in 10 people):

- decrease or loss of appetite
- anxiety, nervousness, restlessness or tension
- decrease or loss of sexual drive
- sleeping problems and abnormal dreams or nightmares
- disturbance in attention
- dizziness
- taste disturbances
- lethargy
- sleepiness or drowsiness
- shaking or tremors
- blurred vision
- fast or irregular heart beats
- flushing
- yawning
- being sick
- an uncomfortable feeling in the stomach or belching after eating or indigestion
- dry mouth
- rash, itching or hives
- excessive sweating
- joint pain or swollen joints
- frequent urination
- vaginal bleeding
- painful erections or inability to develop and maintain an erection
- problems with ejaculation
- feeling jittery
- chills
- weight loss.

Uncommon side effects (affecting more than 1 in 1,000 people, but less than 1 in 100 people):

- feelings of unreality and strangeness, feeling detached, dream-like feelings
- elevated mood
- feeling of extreme happiness
- abnormal thoughts
- abnormal orgasm, or inability to orgasm

- excessive grinding of the teeth or clenching of the jaw
- feelings of extreme restlessness accompanied by muscle spasms, tremors and twitching (psychomotor hyperactivity)
- uncontrollable twitching or jerking movements of the arms and legs, or brief muscle twitches
- clumsiness and lack of coordination, affecting balance and manner of walking, limb or eye movements and/or speech
- problems with balance
- dilated pupils
- low blood pressure, dizziness or light-headedness
- shortness of breath or difficulty breathing
- difficulty swallowing
- unusual hair loss or thinning
- increased tendency to bruise
- cold sweats
- muscle twitches
- pain when passing urine
- sexual problems
- feeling generally unwell, abnormal, hot, or cold.

Rare side effects (affecting more than 1 in 10,000 people, but less than 1 in 1,000 people):

- a serious life threatening allergic reaction (an itching rash, hives or nettle rash, inflamed blood vessels, swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing)
- a delayed allergic reaction (occurring 4 – 10 days after the start of the treatment)
- a low concentration of sodium in your blood. You may experience symptoms such as feeling sick, muscle cramps, slurred speech, confusion, or change in behaviour.
- elation, hyperactivity, and irritable mood
- extreme excitement, euphoria, and delusions
- hallucinations
- agitation
- panic attacks
- convulsions
- restlessness or difficulty sitting still
- involuntary movements of the tongue or mouth (buccoglossal syndrome)
- widening or narrowing of blood vessels
- sore throat, discomfort or difficulty swallowing
- gullet pain
- bruising of the skin
- sensitivity to light
- unusual bleeding or bruising under the skin or purple or red-brown spots visible through the skin
- inability to urinate
- production or unusual secretion of breast milk.
- heart problems, such as fast or irregular heart rate, fainting, collapsing or dizziness which may indicate abnormal functioning of the heart rate.

Very rare side effects (affecting less than 1 in 10,000 people):

- low blood platelet count and bleeding or bruising more easily than normal.

Side effects of unknown frequency:

- excessive release of an antidiuretic hormone. This causes the blood to contain too much fluid, and leads to lowering of levels of sodium in your blood. You may experience symptoms such as feeling sick, muscle cramps, slurred speech, confusion, or change in behaviour.
- suicidal thoughts and behaviour
- confusion
- unexplained fever with faster breathing or heart rate, sweating, muscle stiffness or tremor, confusion, extreme agitation or sleepiness (serotonin syndrome)
- problems with memory
- buzzing, hissing, whistling, ringing or other persistent noise in the ears
- lung problems such as inflammation or scarring of the lungs
- bleeding from the nose
- bleeding of the digestive organs
- hepatitis. You may experience tiredness, aching bones or joints, loss of appetite, fever, yellowing of the skin and whites of your eyes (jaundice), dark urine and pale stools.
- redness of the skin caused by increased blood flow
- aching muscles, muscle tenderness or weakness (not caused by exercise)
- problems with urination
- persistent painful erection which can occur without sexual arousal
- bleeding in your mouth, nose, gullet, stomach, intestines, bronchi, or genitals
- problems with your liver.
- stuttering.

Additional side effects in children and adolescents (8-18 years):

- Norzac Hard Capsules may slow growth or possibly delay sexual maturity.

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

IRELAND: FREEPOST, Pharmacovigilance Section, Irish Medicines Board, Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2, Ireland. Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.imb.ie,

e-mail: imbpharmacovigilance@imb.ie.

5 HOW TO STORE NORZAC HARD 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 blister and carton after 'EXP'. The expiry date refers to the last day of that month.

Do not store above 30°C. Store in the original package in order to protect from moisture.

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 Norzac Hard Capsules contain

- The active substance is fluoxetine hydrochloride equivalent to fluoxetine base 20 milligrams (mg).
- The other ingredients are lactose monohydrate, microcrystalline cellulose, magnesium stearate, colloidal anhydrous silica, gelatin, titanium dioxide (E171), yellow iron oxide (E172), quinoline yellow (E104) and indigo carmine (E132).

What Norzac Hard Capsules look like and contents of the pack

Norzac Hard Capsules are hard, light green, opaque capsules.

They are packaged in blisters sealed with aluminium foil and are available in the following pack sizes: 7, 14, 21, 28, 30, 50, 56, 60, 84, 90, 100, 112 and 120 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer Marketing Authorisation Holder

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This leaflet was last revised in December 2013.



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