**Fluoxetine leaflet: Information for the patient**

**Fluoxetine 20mg capsules**

*fluoxetine hydrochloride*

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**What is in this leaflet**

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

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**What Fluoxetine capsules are and what they are used for**

Fluoxetine capsules belong to a group of medicines called antidepressants that will relieve the symptoms of depression. It may also be used to treat the eating disorder bulimia nervosa and the condition obsessive-compulsive disorder.

**What you need to know before you take Fluoxetine Capsules**

Do not take Fluoxetine capsules if you:

- are allergic to this medicine or any of the other ingredients (listed in section 6).
- are taking, or have taken within the last two weeks, any irreversible, non-selective monoamine oxidase inhibitors (MAOIs, e.g. iproniazid).
- are taking metaproterol for heart failure.

**Warnings and precautions**

Talk to your doctor, pharmacist or nurse before taking Fluoxetine Capsules if:

- are taking or have had in the past two weeks, any medicine that affects the serotonin levels in your body.
- suffer from heart, kidney or liver problems.
- have glaucoma (increased pressure in the eye).
- suffer from diabetes. Fluoxetine capsules may alter your blood sugar levels. Your doctor may need to adjust the dose of your insulin or other diabetes control medicine.
- have a history of bleeding disorders or develop unexpected bruising, reddening under the skin or bleeding from any other part of the body, or if you are pregnant (see Pregnancy, breast-feeding and fertility).
- are having Electroconvulsive Therapy (ECT).
- are taking buprenorphine/naloxone. The use of these medicines together with Fluoxetine capsules can lead to serotonin syndrome, a potentially life-threatening condition (see “Other medicines and Fluoxetine capsules”).

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**Fluoxetine All Strengths Hard Capsules PIL - UK**

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<td><strong>Revision Date:</strong> 09/12/2020</td>
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<td><strong>Supplier:</strong> Accord Barnstaple</td>
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**Dimensions:** 296x210

**Min Body Text Size:** 9pt

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**Technical Approval**

| Date sent: | n/a |
| Date received: | n/a |

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**Cartons and label leaflets only (labels only when specified)**

**German GTIN 14 (incorporating F2N)**

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**Further information**

See section 3 for withdrawal effects. See section 3 for further information. See section 4, Possible side effects. See section 4, Other medicines and Fluoxetine capsules. See section 2, Other medicines and Fluoxetine capsules. See section 2, Other medicines and Fluoxetine capsules.

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**How to store Fluoxetine Capsules**

Keep out of the sight and reach of children.

Do not store above 25°C.

Do not use this medicine after the expiry date which is stated on the label/carton/bottle. The expiry date refers to the last day of that month.

Do not throw away any medicine via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

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**Contents of the pack and other information**

**What Fluoxetine capsules contain**

- The active substance is 20mg Fluoxetine as fluoxetine hydrochloride.
- The other ingredients are: anhydrous colloidal silica, magnesium stearate and talc. The capsule shell contains: E104, E127, E132, E171 and gelatin. The printing ink contains: shellac glaze and iron oxide black (E172) and propylene glycol.

**What Fluoxetine capsules look like and contents of the pack**

Fluoxetine capsules are Size 3 hard gelatine capsules, light green cap and yellow body. Markings are C on one half and FX on the other. Pack sizes are 30 capsules.

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**Fluoxetine**

- 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 shuffling movements
- blurred vision
- rapid and irregular heartbeat sensations
- flushing
- yawning
- indigestion, being sick
- dry mouth
- rash, urtica, itching
- excessive sweating
- joint pain
- passing urine more frequently
- unexplained vaginal bleeding
- feeling shaly or chilly

**Uncommon**

- (may affect up to 1 in 100 people)
- feeling detached from yourself, strange thinking
- abnormally high mood
- orgasm problems
- teeth grinding
- muscle twitching, involuntary movements or problems with balance or co-ordination
- enlarged (dilated) pupils
- ringing in the ears (tinnitus)
- low blood pressure
- shortness of breath
- difficulty swallowing
- hair loss
- increased tendency to bruising
- cold sweat
- painful urination
- feeling hot or cold
- feeling general discomfort or illness
- feeling abnormal
- memory problems
- nose bleeds
- sexual problems
- abnormal liver test results

**Rare**

- (may affect up to 1 in 1,000 people)
- low levels of salt in the blood
- uterine or bladder problems
- hallucinations (seeing things that are not there)
- agitation
- panic attacks
- fits
- vascular thrombosis or stroke
- vasodilation (widening of the blood vessels)
- vasculitis (inflammation of the blood vessels)
- fits
- agitation
- hallucinations (sensing (seeing, hearing or feeling) things that are not there)
- untypical wild behaviour
- increased skin sensitivity (itching, redness)
- fits
- agitation
- hallucinations (see hallucinations)
- speech problems
- aggression
- high level of prolactin in the blood (as seen in blood tests)
- pain in the tube that takes food or water to your stomach
- speech problems
- increased vomiting
- eye problems (e.g. inflammation of the eye)
- muscle twitching, involuntary movements or problems with balance or co-ordination
- fits
- agitation
- hallucinations (see hallucinations)
- speech problems
- aggression
- high level of prolactin in the blood (as seen in blood tests)
- confusion, hallucinations, drowsiness, fits, coma, difficulty breathing (syndrome of inappropriate high secretion of antidiuretic hormone [SIADH])
- lung problems
- bruising
- muscle pain
- problems urinating
- elation or over excited mood
- bleeding from the mucous membranes such as eyes, mouth, anus

**Not known**

- (frequency cannot be estimated from the available data)
- Heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see Pregnancy, breast-feeding and fertility in section 2 for more information.

**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.

**Additional side effects in children and adolescents:**

In children and adolescents (8-18 years) – In addition to the possible side effects listed above, fluoxetine may slow growth or possibly delay sexual maturity. 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 the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

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**Eight important things you need to know about Fluoxetine capsules**

**Fluoxetine capsules treat depression.**

- Like all medicines, it can have unwanted effects. It is therefore important that you and your doctor weigh up the benefits of treatment against the possible unwanted effects, before starting treatment.

**Fluoxetine capsules are not for use in children and adolescents under 18.** See section 2, Use in children and adolescents aged 8 to 18 years.

**Fluoxetine capsules won’t work straight away.** Some people taking antidepressants feel worse before feeling better. Your doctor should ask to see you again a couple of weeks after you first start treatment. Tell your doctor if you haven’t started feeling better. See section 3, How to take Fluoxetine capsules.

**Some people who are depressed or anxious think of harming or killing themselves.** If you start to feel worse, or think of harming or killing yourself, see your doctor or go to a hospital straight away. See section 2.

**Don’t stop taking Fluoxetine capsules without talking to your doctor.** If you stop taking Fluoxetine capsules suddenly or miss a dose, you may get withdrawal effects. See section 3 for further information.

**If you feel restless and feel like you can’t sit or stand still, tell your doctor.** Increasing the dose of Fluoxetine capsules may cause these feelings to worsen. See section 4, Possible side effects.

**Taking some other medicines with Fluoxetine capsules can cause problems.** You may need to talk to your doctor. See section 2, Other medicines and Fluoxetine capsules.

**If you are pregnant or planning to get pregnant, talk to your doctor.** See section 2, Pregnancy, breast-feeding and fertility.

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, pharmacist or nurse.

**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, pharmacist or nurse. This includes any possible side effects not listed in the leaflet. See section 4.
Fluoxetine Capsules

20mg x 30 (UK)

approved for print/date

Item number: BBB0027

Originator: T.Hull

Origation Date: 09.12.2020

Revision Date: 09.12.2020

Revised By: T.Hull

Dimensions: 296x210

Min Body Text Size: 9pt

Supplier: Accord Bnarstaple

Colours

1. Black

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Fluoxetine All Strengths Hard Capsules PIL - UK

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German GTIN 14 (incorporating P2N):

296x210 Leaflet Reel Fed Bi Fold Profile (BST)

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Fluoxetine capsules belong to a group of medicines called antidepressants that will relieve the symptoms of depression. It may also be used to treat the eating disorder bulimia nervosa and the condition obsessive-compulsive disorder.

1. **What Fluoxetine capsules are and what they are used for**

Fluoxetine capsules are for use in children and adolescents aged 8 years and over. If you start to feel worse, or think of harming or killing yourself, see your doctor or go to a hospital straight away. See section 2.

2. **How to take Fluoxetine Capsules**

Do not take Fluoxetine capsules suddenly or miss a dose, you may get withdrawal effects. See section 3 for further information.

3. **Possible side effects**

• you are allergic to this medicine or any of the other ingredients (listed in section 6).
• you have been prescribed this medicine (see Pregnancy, breast-feeding and fertility in section 2 for more information).
• you have taken 2 or 3 doses of Fluoxetine capsules
• you are pregnant or planning to get pregnant.
• you are breast-feeding.
• you have a history of mental illness known as mania or hypomania.
• you suffer from heart, kidney or liver problems.
• you have glaucoma (increased pressure in the eye).
• you suffer from diabetes. Fluoxetine capsules may alter your blood sugar levels. Your doctor may need to alter the dose of your insulin or other diabetes control medicine.
• you have a history of bleeding disorders or develop unexpected bruising, reddening under the skin or bleeding from any other part of the body, or if you are pregnant (see Pregnancy, breast-feeding and fertility).
• you are having Electroconvulsive Therapy (ECT).
• you are taking buprenorphine/naloxone. The use of these medicines together with Fluoxetine capsules can lead to serotonin syndrome, a potentially life-threatening condition (see “Other medicines and Fluoxetine capsules”).

4. **Contents of the pack and other information**

The capsule shell contains: E104, E127, E132, E171 and E172. The other ingredients are stated on the label/carton/bottle. The expiry date refers to the day of the month.

5. **How to store Fluoxetine Capsules**

Keep out of the sight and reach of children.

6. **Side effects**

• feeling abnormal
• feeling general discomfort or illness
• feeling hot or cold
• feeling irritable
• feeling low levels of salt in the blood
• feeling not right
• feeling abnormal
• feeling general discomfort or illness
• feeling hot or cold
• feeling low levels of salt in the blood
• feeling not right

### 20mg fluoxetine as fluoxetine hydrochloride

### Package leaflet: Information for the patient

### Fluoxetine 20mg capsules

#### Common
- 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
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#### Uncommon
- confusion, hallucinations, drowsiness, fits, coma, difficulty breathing (syndrome of inappropriate high secretions of antidiuretic hormone (SIADH))
- lung problems
- bruising
- muscle pain
- problems urinating
- elation or over excited mood
- bleeding from the mucous membranes such as eyes, mouth, anus

Not known (frequency cannot be estimated from the available data):

- Heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see Pregnancy, breast-feeding and fertility in section 2 for more information.

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Do not store above 25°C.

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#### What Fluoxetine capsules look like and contents of the pack

Fluoxetine capsules are Serif 20mg capsules, light green cap and yellow body. Markings are C on one half and FX on the other. Pack sizes are 30 capsules.

Marketing Authorisation Holder and Manufacturer

Accord Barnstaple, Ex2 8NQ, UK

This leaflet was last revised in December 2020

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Fluoxetine All Strengths Hard Capsules PIL - UK

**Item number:** BBBBO027

**Originator:** T. Hull

**Origination Date:** 09.12.2020

**Revision Date:** 09.12.2020

**Supplier:** Accord Barnstaple

**Dimensions:** 296x210

**Min Body Text Size:** 9pt

**Proof Round:** 2

**Technical Approval:**

**Date sent:** n/a

**Date received:**

**EU Artwork Support:** accord-healthcare.com

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**German GTIN 14** (incorporating PZN):

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**Colours**

**Non Printing Colours**

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