

## FLUOXETINE 20mg Capsules

### PACKAGING LEAFLET: INFORMATION FOR THE USER

#### EIGHT IMPORTANT THINGS YOU NEED TO KNOW ABOUT FLUOXETINE

Fluoxetine treats depression and anxiety disorders.

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 is not for use in children and adolescents under 18.** See section 2. Use in children and adolescents aged 8 to 18 years.

**Fluoxetine 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 straight to hospital straight away.** See section 2

**Don't stop taking Fluoxetine** without talking to your doctor. If you stop taking Fluoxetine 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 may make these feelings worse. See section 4, Possible side effects.

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

**If you are pregnant or planning to get pregnant,** talk to your doctor. See Section 2, Pregnancy and breastfeeding.

**Read all this leaflet carefully before you start taking this medicine.**

- 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. Do not pass it on to others. It may harm them even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### In this leaflet:

1. What is Fluoxetine 20mg Capsules and what they are used for
2. Before you take Fluoxetine 20mg Capsules
3. How to take Fluoxetine 20mg Capsules
4. Possible side effects
5. How to store Fluoxetine 20mg Capsules
6. Further information

#### 1. WHAT FLUOXETINE 20MG CAPSULES ARE AND WHAT THEY ARE USED FOR

Fluoxetine is one of a group of medicines called selective serotonin re-uptake inhibitors (SSRI) antidepressants. It is used to treat:

- Depression
- Obsessive-compulsive disorder (also known as OCD)
- The eating disorder bulimia nervosa

#### 2. BEFORE YOU TAKE FLUOXETINE 20MG CAPSULES

##### Do not take Fluoxetine Capsules if you:

- are allergic to Fluoxetine or any of the other ingredients listed in section 6. Symptoms of an allergic reaction include rash, swollen face or lips, itching or breathing difficulties.
- have taken any of the following medicines:
  - Irreversible MAOIs (also known as monoamine oxidase inhibitors) in the last two weeks as serious and sometimes

fatal reactions can occur. Examples of MAOIs include tranylcypromine, phenelzine and isocarboxazid (used to treat depression) or selegiline (used to treat Parkinson's disease)

- Reversible MAOIs (also known as monoamine oxidase inhibitors) within the last 24 hours e.g. moclobemide.

Do not take MAOIs at the same time as taking Fluoxetine. You must wait for at least 5 weeks after stop taking Fluoxetine before starting to take MAOI

If you think any of the above points apply to you, do not take the capsules. Talk to your doctor first and follow the advice given.

#### Take special care and tell your doctor if you:

- are less than 18 years of age
  - suffer from or have a history of seizures, fits or epilepsy
  - suffer from or have a history of mania or hypomania (very high or low moods)
  - suffer from liver problems or heart disease
  - suffer from diabetes
  - suffer from any other psychiatric disorders
  - have a bleeding disorder (e.g. haemophilia) or take medicines that thin your blood or can affect how your blood clots
  - are receiving Electroconvulsive therapy (ECT)
  - are taking St. John's Wort, a herbal medicine for depression
  - have a history of self-harm, suicidal thoughts or attempted suicide.
- It can take 3 to 4 weeks before your illness improves so you may still be at risk. If you get these feelings when you are taking this medicine you must contact your doctor immediately

#### Taking other medicines

Tell your doctor or pharmacist if you are taking or have including medicines—obtained without a prescription.

Tell your doctor if you are taking:

- Any type of Monoamine Oxidase Inhibitors (MAOIs) used to treat depression \* Phenytoin used to treat epilepsy
- Medicines known as 'Serotenergic drugs' such as tramadol or triptans
- Medicines used to treat depressive disorders such as lithium and tryptophan \* Any Other antidepressants e.g. carbamazepine and tricyclic antidepressants
- Blood thinning medicines e.g. warfarin
- St John's Wort, a herbal remedy used for depression

**Taking Fluoxetine 20 mg Capsules with food and drink** You should take this medicine with a drink of water during or after meals. Although fluoxetine does not increase the effect of alcohol, the combination of this type of medicine and alcohol is not advisable as it could make your depression worse.

#### Pregnancy and breast-feeding

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 showing an increased risk of birth defects. In particular, those 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 Prozac 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 Fluoxetine 20 mg capsules. When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like Fluoxetine 20 mg capsules may increase the risk of a serious condition in babies, called persistent pulmonary hypertension of 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.

### Driving and using machines

Caution should be taken because Fluoxetine may affect your ability to drive or operate machines

### 3. HOW TO TAKE FLUOXETINE 20MG CAPSULES

Always take Fluoxetine 20mg capsules exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

This capsules are for adults only and should be swallowed whole with a glass of water.

**Depression** - The usual dose for depression is one capsule (20 mg) per day for at least 6 months.

**OCD** - The usual dose for Obsessive Compulsive Disorder is one capsule (20 mg) per day.

**Bulimia nervosa** - The usual dose is 3 capsules (60 mg) per day.

For all conditions, your doctor may adjust your dose depending

On your response to the treatment

#### Dosage in the Elderly

Your doctor may prescribe a lower dose up to a maximum of 60mg (3 capsules) a day.

#### Dosage in patient with liver problems

doctor may prescribe a lower or less frequent dose e.g. one capsule every other day

#### Thoughts of harming or killing yourself

Your doctor may prescribe a lower or less frequent dose e.g. one capsule every other day

#### Thoughts of harming or killing yourself

If you are depressed 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 aged less than 25 years with psychiatric conditions Who were treated with an antidepressant.

If you have suicidal feelings or thoughts of harming 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 behavior.

**Do not stop taking Fluoxetine 20mg Capsules until your doctor tells you to** When stopping treatment your doctor will help you reduce the dosage gradually over a period Of at least one to two weeks in order to reduce the risk of withdrawal reactions.

Common withdrawal symptoms include dizziness, pins and needles, trouble sleeping, intense dreams, weakness, headache, agitation, anxiety, shaking, being sick and nausea.

**If you take more Fluoxetine 20 mg Capsules than you should you must contact your doctor or nearest hospital immediately.**

If you forget to take Fluoxetine 20 mg Capsules

Do not take a double dose to make up for a forgotten dose. Take the next dose at the normal time and continue regular dosing.

### 4. POSSIBLE SIDE EFFECTS

Like all medicines. Fluoxetine 20 mg Capsules can cause side effects, although not everybody gets them.

#### Serious Allergic Reactions

These reactions can include:

- Itching, redness, rash or hives
- Swelling of the face, lips, throat, hands or feet
- Feeling generally unwell with rash, swollen or painful joints, fever or swollen lymph glands (this could be a serum-sickness like reaction and could take up to two weeks to appear)

### Other Serious Side Effects

- A combination of symptoms such as unexplained fever, breathing problems, excessive sweating, muscle and joint pain, confusion, excessive agitation and uncontrollable movement. These symptoms could be a sign of serious conditions such as serotonin syndrome or neuroleptic malignant syndrome
- A red or raised rash followed by blistering or peeling of the skin, mouth, eyes and genitals
- Fever, feeling sick, being sick and abdominal pain. This could be a sign of hepatitis.
- Suicidal feelings or thoughts of harming yourself

**If you get any of the above symptoms stop taking the capsules and contact your doctor, pharmacist or nearest hospital IMMEDIATELY**

### Other side effects include:

- Headache
- Dizziness
- Tiredness, drowsiness or yawning
- Diarrhoea
- Feeling sick or being sick
- Low blood pressure
- Dizziness when you stand up
- Indigestion
- Loss of appetite
- Hair loss
- Difficulty swallowing
- Changes in sense of taste
- Dry mouth or sore throat
- Difficult breathing
- Other lung problems
- Euphoria
- Very high or very low moods
- Changes in your normal thought e.g. feeling detached from reality
- Movement problems e.g. twitching, difficulty, walking or balancing, shaking or muscle spasms
- Fits
- Sexual problems such as delayed or absent ejaculation, inability to orgasm, painful and persistent erection, milk production without being pregnant or breastfeeding
- Inability to sit still
- Agitation or anxiety
- Nervousness
- Confusion
- Hallucinations
- Inability to sit still
- Agitation or anxiety causing
- Nervousness
- Confusion
- Hallucinations
- Vision problems such as blurred vision or abnormally large pupils
- Problems sleeping or abnormal dreams
- Sweating or flushing
- Muscle or joint pain
- Sensitivity to light
- Chills
- Unusual bleeding or bruising
- Low salt levels in blood
- Abnormal liver function test
- Problems urinating or increased frequency of urination

An increased risk of bone fractures has been observed in patients taking this type of medicines.

**If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.**

If you stop taking Fluoxetine suddenly you may get withdrawal symptoms such as dizziness, pins and needles, problems sleeping, agitation or anxiety, feeling sick or being sick, shaking or headache. These symptoms are not serious and will disappear.

### 5. HOW TO STORE FLUOXETINE 20 MG CAPSULES

**Keep them out of the reach and sight of children. Store in a cool dry place protected from light below 30°C**

Do not take your capsules after the expiry date on the carton and blister. Medicines should not be disposed of via wastewater or —house hold Waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

### 6. FURTHER INFORMATION


#### What Fluoxetine 20mg capsules contains

The active substance is fluoxetine hydrochloride. The other ingredients are pre-gelatinized maize starch, magnesium stearate.

**Presentation:** 10 x 3 x 10 or Jar 1000

**Shelf Life:**

**Made in Ghana by**

 Kinaphama Ltd.  
B920/10 Mausoleum Lane  
North Industrial Area – Accra.

**Date of Publication:** August 2017