Fluoxetine 20mg Capsules

5. How to store Fluoxetine Capsules

You may need to be treated for a few weeks or months to ensure that you are free from symptoms.

Fluoxetine capsule is not for use In children and adolescents under 18.

Pregnancy

Other medicines and Fluoxetine

• Certain medicines may affect the way Fluoxetine works. If you are taking any of the following medicines, your doctor may prescribe a different antidepressant treatment.

- If you are taking other medicines known as irreversible, non-selective monoamine oxidase inhibitors (MAOIs), or if you have been treated with irreversible, non-selective MAOIs for at least 5 weeks after you stop taking Fluoxetine. Fluoxetine may have been prescribed for a long period and/or at a high dose, a longer interval than 5 weeks may need to be used.

- If you stop taking Fluoxetine, you may experience an increased risk of a serious condition in babies, called persistent pulmonary hypertension of the newborn. If this happens to your baby, you may need to continue taking Fluoxetine or your doctor may prescribe a different antidepressant treatment.

- If you are a young adult. Information from clinical trials have shown an increased risk of suicidal behavior In adults aged less than 25 years with psychiatric disorders who were treated with an antidepressant.

- If you have thoughts of harming or killing yourself, or if there is any change in your behavior.

- If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital straight away.

- If you have any further questions, ask your doctor or pharmacist.

Children and adolescents aged 8 to 18 years:

- If you feel restless and feel like you can't sit or stand still, tell your doctor.

- You may need to talk to your doctor or go to a hospital straight away.

- If your depression or anxiety is getting worse, or if they are worried about changes in your behavior.

- If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital straight away.

EIGHT IMPORTANT THINGS YOU NEED TO KNOW ABOUT FLUOXETINE CAPSULES

- If you have depression and/or have anxiety disorder you can sometimes have thoughts of harming or killing yourself. You may feel better only after several weeks or months of treatment.

- Some people who are depressed or have anxiety disorders have thoughts of harming or killing themselves. If you have any suicidal thoughts, you should tell your doctor immediately. Talk to your doctor or go to a hospital straight away.

- You may need to be treated for a few weeks or months to ensure that you are free from symptoms.

- If you feel restless and feel like you can't sit or stand still, tell your doctor.

- If you have any suicidal thoughts, you should tell your doctor immediately. Talk to your doctor or go to a hospital straight away.

- If you have any further questions, ask your doctor or pharmacist.

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**Possum Side Effects**

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 Fluoxetine Capsules:

- dizziness
- headache
- feeling sick (nausea)
- irritable bowel syndrome
- skin rashes
- loss of appetite
- feeling sleepy
- loss of weight
- loss of height
- hot flushes
- skin reactions (seen in 1 to 10 in every 1000 patients)

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

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

5. **How to Store Fluoxetine Capsules**

Keep this medicine out of the sight of children.

Do not store above 25°C. Store in the original package.

Do not use the capsules after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. **Contents of the Pack and Other Information**

Fluoxetine Capsules look like and contents of the pack

Fluoxetine capsules are hard gelatin, alganated with green colour cap and off-white colour body printed with ‘FLX’ on cap and ‘MIL’ on body.

This product is available in the blister packs containing 10, 14, 20, 30, 50, 70 or 100 capsules (not all pack sizes may be marketed).

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Milpharm Limited

Address: Ares, Odyssey Business Park West End Road, Hemel Hempstead, Hertfordshire, HP2 4EP, United Kingdom

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This leaflet was last revised in 03/2017

Fluoxetine (known as ‘Prozac’) is used to treat depression, anxiety disorders and some other conditions. It works by increasing the amount of a chemical (serotonin) in your brain. This chemical affects your mood and may also affect other body functions including the heart, stomach and bowels.

Side Effects

Fluoxetine can cause side effects, although not everyone gets them.

- dizziness
- headache
- feeling sick (nausea)
- skin rashes
- fast heart rate
- feeling nervous
- loss of appetite
- loss of weight
- loss of height
- hot flushes
- skin reactions (seen in 1 to 10 in every 100 patients)

**Common side effects**

- dizziness
- headache
- stomach upset
- loss of appetite
- feeling nervous
- sleep disturbance
- nausea
- memory loss
- decreased sex drive or sexual problems (including difficulty maintaining an erection for sexual activity) sleep problems, unusual dreams, tiredness or sleepiness
- appetite change
- increased sweating
- lumps in the breast
- rapid and irregular heartbeat sensations
- breathing
- pain
- agitation, trembling
- nausea
- vomiting
- feeling frightened
- overactive or manic
- irritability and extreme agitation.
- prolonged and painful erection; agitation or sleepiness (only rarely);
- a combination of symptoms (known as “serotonin syndrome”) including unexplained fever reaction or your skin starts to blister or peel. This is very rare.
- 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.

**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**

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