

UXETINE CAPSULES

Fluoxetine Hydrochloride (20mg)

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What Uxetine Capsules is used for

Uxetine Capsules is used to treat the following conditions:

Adults:

- Major depressive episodes.
- Obsessive-compulsive disorder (OCD): persistent, obsessive thoughts that make you carry out repetitive behaviour.

How Uxetine Capsules Works

Uxetine Capsules contains the active ingredient fluoxetine, which belongs to a group called selective serotonin reuptake inhibitors (SSRIs). The antidepressant, antiobsessive-compulsive actions of fluoxetine presumed to be linked to its inhibition of reuptake of serotonin by the nerve cells in the brain. Fluoxetine blocks the uptake of serotonin into human platelets.

Before you use Uxetine Capsules

- When you must not use it

Do not take Uxetine Capsules if you:

- are allergic (hypersensitive) to fluoxetine or any of the other ingredients listed at the end of this leaflet.
- are taking another medicine for depression called a monoamine oxidase inhibitor (MAOI) or have been taking a MAOI within the last 14 days. Do not take any MAOIs for at least 5 weeks after you stop taking Uxetine Capsules. Check with your doctor or pharmacist if you are unsure as to whether or not you are taking a MAOI.

Taking Uxetine Capsules with a MAOI may cause a serious, sometimes fatal, reaction with features resembling neuroleptic malignant syndrome. These symptoms may include sweating, extremely high fever, muscle rigidity, rapid heartbeat, confusion and coma.

- Before you start to use it

You should check with your doctor:-

- If you are currently pregnant or breastfeeding, or if you might be pregnant.
- If you are planning to become pregnant.

Do not take this medicine until you and your doctor have discussed the risks and benefits involved.

Tell your doctor if you have or have had any medical conditions, especially the following:

- Kidney problems
- Liver problems
- Heart problems
- Diabetes
- Fits

- Taking Other Medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop. Uxetine Capsules may interact with some other medicines, especially the following:

- MAOIs (see subsection When you must not use it)
- Other medicines for depression, such as tricyclic antidepressants (TCAs)
- Medicines used to treat mental illness, such as lithium
- tryptophan, an amino acid
- Medicines used to treat seizures (fits), such as phenytoin and carbamazepine
- Medicines used to treat heart conditions such as digoxin, propafenone, flecainide

Other medicines not listed above may also interact with Uxetine Capsules.

How to use Uxetine Capsules

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Adults

The usual dose is:

Depression

1 capsule (20mg) daily. If required, the dosage can be gradually increased up to a maximum of 3 capsules (60mg) daily.

Obsessive-compulsive disorder

1 capsule (20mg) daily. If required, the dosage can be gradually increased up to a maximum of 3 capsules (60mg) daily.

Children and adolescents aged 8 to 10 years

Uxetine is not recommended in children and adolescents (under the age of 18), as safety and efficacy have not been established.

Elderly

Your doctor will increase the dose with more caution and the daily dose should generally not exceed 2 capsules (40mg). The maximum dose is 3 capsules (60mg) daily. If you have liver problems or if you are currently taking certain drugs that may interact with Uxetine Capsules, your doctor may prescribe you a lower or less frequent dose (e.g. 1 capsule [20mg] every second day).

- When to use it

Uxetine Capsule is to be taken as a single or divided dose, during or between meals, as directed by your doctor or pharmacist. Swallow the capsule whole.

- How long to use it

It is important to take Uxetine Capsules as long as your doctor prescribes.

- If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose. If you are not sure what to do, ask your doctor or pharmacist.

- If you use too much (overdose)

If you take too many capsules by mistake, contact your doctor immediately or seek medical attention. Symptoms of an overdose may include fits, sleepiness, nausea, rapid heartbeat, and vomiting.

While you are using it

- Things you must do

Take Uxetine Capsules exactly as your doctor has told you. Tell all the doctors, dentists and pharmacist treating you that you are taking Uxetine Capsules. Tell your doctor or pharmacist immediately if:

- You feel Uxetine Capsules is not helping your condition.
- You become pregnant while taking this medication.

- You have significant weight loss.
- You have new episodes of fits.

- Things you must not do

- Do not share your medicines with others even if they have the same diagnosis as you.
- Do not stop taking Uxetine Capsules, or lower the dose, without first checking with your doctor. Your doctor may want you to gradually reduce the amount of Uxetine Capsules you are taking before stopping completely.

- Things to be careful of

Driving and using machines

Uxetine Capsules may affect your ability to drive or use machines. If the capsules make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately. Avoid drinking alcohol during your treatment with Uxetine Capsules.

Suicidality in Children and Adolescent

Uxetine Capsules should normally not be used for children and adolescents under 18 years. Uxetine Capsules increases the risk of suicidal ideation and behaviour in children. Despite this, your doctor may prescribe Uxetine Capsules for patients under 18 when he/she decides that this is in their best interests.

If your doctor has prescribed Uxetine Capsules for a patient under 18 and you want to discuss this, please go back to your doctor. Families or caregivers should pay close attention to your child whenever Uxetine Capsules is started or its dose is changed. Contact your doctor if you notice any sudden or unusual changes in your child's behaviour.

Side Effects

Like all medicines, Uxetine Capsules can cause side effects, although not everybody gets them. Tell your doctor or pharmacist if you experience any side. Effects after taking Uxetine Capsules and they worry you, including:

- Insomnia (difficulty falling or staying asleep)
- Headache
- Diarrhea, nausea
- Fatigue
- Anxiety
- Nervousness
- Lethargy
- Myasthenia (a disease which causes severe muscle weakness)

- Sweating
- Anorexia (an eating disorder characterised by self-starvation and excessive weight loss)

Other side effects not listed above may also occur in some people. Please refer to your doctor or pharmacist if you experience any other symptoms while taking this medication.

You may report any side effect or adverse drug reaction directly to the National Centre for Adverse Drug Reaction Monitoring by calling 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers→Reporting).

Storage and Disposal of Uxetine Capsule

- Storage

Store at temperature 30°C. Protect from the direct light and heat.

- Disposal

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.

Product Description

- What it looks like

No. 4 Hard Gelatin Capsule:

- Cap/body:
Green (with CCP B54 black) / Light milk yellow (with CCP B54 black).
- Content:
A white to off-white powder.

- Ingredients

- Active Ingredients
 - Fluoxetine (Hydrochloride)
- Inactive Ingredients
 - Starch
 - Talc
 - Lactose

- MAL number

MAL06100558A

Manufacturer

China Chemical & Pharmaceutical Co., Ltd.
Hsinfong Plant 182-1, Keng Tze Kou,
Hsinfong, Hsinchu, Taiwan (R.O.C).

Product Registration Holder

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