

# MAGRILAN CAPSULE

Fluoxetine (20mg)

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## What MAGRILAN is used for

This medicine is used to treat the following conditions:

### Adults:

- Major depressive episodes
- Obsessive-compulsive disorder (persistent, obsessive thoughts that make you carry out repetitive behaviour)
- Premenstrual dysphoric disorder (PMDD) (a severe form of premenstrual syndrome that affect the woman's daily activities and relationship with others before menstruation)

## How MAGRILAN works

MAGRILAN contains the active ingredient fluoxetine hydrochloride. MAGRILAN belongs to a group of medicines called selective serotonin re-uptake inhibitor (SSRI) antidepressants. When serotonin is released from the nerve cells in the brain, it acts to lighten mood. SSRIs work by preventing serotonin from being reabsorbed back into the nerve cells in the brain. This helps prolong the mood lifting effect of any released serotonin, thus relieving depression.

## Before you use MAGRILAN

### - When you must not use it

Do not take MAGRILAN:

- If you are hypersensitive (allergic) to fluoxetine or any of the other ingredients of MAGRILAN (see section **Product description**). If you develop a rash or other allergic reactions (like itching, swollen lips or face or shortness of breath), stop taking the capsules straight away and contact your doctor immediately.
- If you are taking other medicines used to treat depression, known as

non-selective monoamine oxidase inhibitors (MAOIs) or reversible monoamine oxidase inhibitors type A, since serious or even fatal reactions (serotonin syndrome; see section **Side effects**) can occur. Examples of MAOIs include nialamide, iproniazide, selegiline, moclobemide, phenelzine, tranylcypromine, isocarboxazid and toloxatone.

- Treatment with MAGRILAN should only be started 2 weeks after discontinuation of an irreversible MAOI (for instance tranylcypromine). However, treatment with fluoxetine can be started the following day after discontinuation of certain reversible MAOIs (for instance moclobemide).
- Check with your doctor or pharmacist if you are unsure as to whether or not you are taking a MAOI. Your doctor will know when it is safe to start MAGRILAN after the MAOI has been stopped, or to start another MAOI after discontinuing MAGRILAN treatment.

### - Before you start to use it

Tell your doctor if any of the following applies to you:

- If you have epilepsy or fits (seizures) (see also Things to be careful of)
- If you suffer or have suffered from mania (uncontrollable excitement that causes unusual behaviour)
- If you have diabetes
- If you have kidney or liver problems
- If you have heart problems
- If you are having ECT (electro-convulsive therapy) treatment (usually used for severe depression)
- If you have a history of bleeding disorders or appearance of bruises or unusual bleeding
- If you have a history of suicide-related events (see also Things to be careful of)

### Pregnancy and breast-feeding

- Talk to your doctor as soon as possible if you are pregnant, if you might be pregnant, or if you are planning to become pregnant.

- Fluoxetine can be excreted into human breast milk and cause irritability in the infant.
- Fluoxetine should not be prescribed during pregnancy and lactation unless considered essential by your doctor.

### - Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines (up to 5 weeks ago) including medicines obtained without prescription.

MAGRILAN may affect the way some other medicines work (interaction), especially the following:

- MAOIs (see When you must not use it)
- Lithium (used to treat mental disorder), tryptophan (an amino acid)
- Other medicines used to control depression or mood swings (e.g. tricyclic antidepressants)
- Medicines used to control fits (e.g. phenytoin, carbamazepine)
- Medicines used to treat heart condition (e.g. flecainide, encainide)
- Warfarin or other medicines used to thin the blood
- You should not start to take the herbal remedy St John's wort while you are being treated with MAGRILAN

## How to use MAGRILAN

### - How much to use

*Adults aged 18 years and over:*

The usual dose is:

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

**Obsessive-compulsive disorder:** The recommended dose is 1 capsule (20 mg) daily. If required, the dosage can be gradually increased up to a maximum of 3 capsules (60 mg) daily.

**Pre-menstrual Dysphoric Disorder (PMDD):** A dose of 20 mg per day is recommended. Initial treatment should be limited to 6 months, after which patients should be reassessed regarding the benefit of continued therapy.

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**Children and adolescents aged above 8 years:** The use of MAGRILAN in children is not recommended as safety and efficacy have not been established.

**Liver impairment:** If you have a liver problem or are using other medication that might affect MAGRILAN, your doctor may decide to prescribe a lower dose or tell you to use MAGRILAN every other day.

- When to use it

- Always take MAGRILAN exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.
- Do not take more capsules than your doctor tells you.
- Swallow the capsule whole with a drink of water. Do not chew the capsules. MAGRILAN 20mg capsules may be taken as a single or separate dose, during or between meals.

- How long to use it

**DO NOT** stop taking MAGRILAN without asking your doctor first, even when you start to feel better. It is important that you keep taking your medicine. Make sure you do not run out of capsules.

You may notice the following effects when you stop taking MAGRILAN: 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; nausea/vomiting (feeling sick or being sick); tremor (shakiness); headaches.

Most people find that any symptoms on stopping MAGRILAN are mild and disappear within a few weeks. If you experience symptoms when you stop treatment, contact your doctor.

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

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

- If you forget to use it

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.

- If you use too much (overdose)

If you take too many capsules, go to your nearest hospital emergency department (or casualty) or tell your doctor straight away. Take the pack of MAGRILAN with you if you can.

Symptoms of overdose include: nausea, vomiting, seizures, heart problems (like irregular heart beat and cardiac arrest), lung problems and change in mental condition ranging from agitation to coma.

**While you are using it**

- Things you must do

- Take your medicine exactly as your doctor has told you.
- Tell all doctors, dentists and pharmacists treating you that you are taking MAGRILAN.
- Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

- Do not stop taking the medicine unless advised your doctor.
- Do not take any new medicines without consulting your doctor.
- Do not give MAGRILAN to anyone else, even if they have the same symptoms or condition as you.
- You should avoid alcohol while you are taking this medicine.

- Things to be careful of

If you have seizure or an increase in seizure frequency, contact your doctor immediately. MAGRILAN might need to be discontinued.

*Driving and using machines:*

Antidepressants can affect your judgment or co-ordination. Do not drive or use machinery unless you are sure that you are not affected.

*Thoughts of suicide and worsening of 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 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.

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.

*Suicidality in Children and Adolescents*

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

If your doctor has prescribed MAGRILAN for a person 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 MAGRILAN 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, MAGRILAN can cause side effects, although not everybody gets them.

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

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stop taking the capsules straight away and tell your doctor immediately.

- 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 feel restless and cannot sit or stand still, you may have akathisia; increasing your dose of MAGRILAN may make you feel worse. If you feel like this, contact your doctor.

Some patients have had:

- a combination of symptoms (known as “serotonin syndrome”) including unexplained fever with faster breathing or heart rate, sweating, muscle stiffness or tremor, confusion, extreme agitation or sleepiness (only rarely);
- feelings of weakness, drowsiness or confusion mostly in elderly people and in (elderly) people taking diuretics (water tablets);
- prolonged and painful erection;
- irritability and extreme agitation.

If you have any of the above side effects, you should tell your doctor immediately.

If you have any of the following symptoms and they bother you, or last for some time, tell your doctor or a pharmacist:

- chills
- sensitivity to light
- gastrointestinal disorders such as diarrhoea, nausea, vomiting, dyspepsia (indigestion), dysphagia (difficulty in swallowing), altered taste, dry mouth
- abnormal liver function tests
- hepatitis (inflammation of the liver)
- headache
- abnormal dreams, insomnia
- dizziness
- lack of appetite
- fatigue (with somnolence, drowsiness)
- euphoria (a feeling or state of intense excitement and happiness)
- abnormal movement (twitching, tremor), restlessness
- fits
- hallucinations (hearing voices and seeing things which are not there),

manic reaction, confusion, anxiety, nervousness

- impaired concentration and thought process
- panic attacks
- urinary difficulties, frequent urination
- delayed or absent ejaculation, anorgasm (failure to achieve climax of sexual excitement)
- milky secretion from the breasts
- hair loss
- yawn
- blurred vision
- bruises
- sweating
- joint and muscle pain
- low blood pressure
- low level of sodium in blood

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.

You may report any side effects or adverse reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-7883 5550, or visiting the website [portal.bpfk.gov.my](http://portal.bpfk.gov.my) (*Consumers* → *Reporting*)

## Storage and disposal of MAGRILAN

### - Storage

- Keep out of the reach and sight of children.
- Store “MAGRILAN” capsules below 25°C, in the original packing, in order to protect from light and moisture.

### - Disposal

- Do not take MAGRILAN after the expiry date which is stated on the pack.
- If you have any other questions please talk to your doctor or pharmacist. If your doctor decides to stop treatment, return any left-over capsules to a pharmacist.
- Medicines should not be disposed of via wastewater or household waste. These measures will help to protect the environment.

## Product Description

### - What it looks like

MAGRILAN capsules are yellow-violet hard gelatin capsule of size ‘4’.

### - Ingredients

- Active ingredient

- The active substance is fluoxetine hydrochloride.

- Inactive ingredients

• Other ingredients are: lactose monohydrate, cellulose microcrystalline, magnesium stearate, titanium oxide (E171), gelatin, erythrosine (E127), Iron oxide yellow (E172), Iron oxide black (E172), Indigotine (E132).

### - MAL No.

MAL10100126A

## Manufacturer

MEDOCHEMIE LTD, 1-10  
Constantinopoleos Street, 3011  
Limassol, Cyprus

## Product Registration Holder

KOMEDIC SDN BHD, 4 Jalan PJS  
11/14, Bandar Sunway, 46150 Petaling  
Jaya

## Date of Revision

01/09/2015

## Serial Number

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