

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about **Flusac**. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist. Please read this entire leaflet carefully before you start to take your medicine. This medicine is for you. Never give it to other people even if their condition appears to be the same as yours. If you have any questions about this medicine ask your pharmacist. Keep this leaflet, you may need to read it again.

1. WHAT IS FLUSAC USED FOR

Flusac is used to treat:

- Depression
- Obsessive compulsive disorder (OCD)
- Premenstrual dysphoric disorder (PMDD)

Ask your doctor if you have any questions about why this medicine was prescribed for you. Your doctor may have prescribed it for another reason.

2. HOW FLUSAC WORKS

Fluoxetine hydrochloride belongs to a group of medicines called selective serotonin reuptake inhibitors (SSRIs). SSRIs are thought to work by their action on brain chemicals, called amines, which are involved in controlling mood.

3. BEFORE YOU TAKE FLUSAC

Do not take this medicine if

- You are hypersensitive to the active ingredient or any ingredients in the formulation or any other similar medicines.
- You are taking monoamine oxidase inhibitor (MAOI), including the selective MAOI selegiline and the reversible MAOI (RIMA) moclobemide or have just stopped using it for less than 2 weeks and 5 weeks respectively.

If you are not sure whether you should start taking **Flusac**, talk to your doctor.

Before you start taking this medicine

Tell your doctor if you:

- Have allergies to any other medicines, food, preservatives or dyes.
- Have or have had any medical conditions, especially:
 - liver or kidney problems,
 - seizures,
 - any other psychiatry conditions,
 - heart problems,
 - diabetes
 - bleeding disorder.
- Are pregnant or breastfeeding or intend to become pregnant.
- Undergoing Electroconvulsive Therapy (ECT).

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines obtained without prescription.

These medicines may be affected by **Flusac**, or may affect how well it works. You may need different amount of your medicines, or you may need to take different medicines. Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking **Flusac**.

Tell your doctor if you are taking the following:

- monoamine oxidase inhibitors, eg: selegiline
- other antidepressants such as imipramine and desipramine
- anticonvulsant or antiepileptic, eg: carbamazepine and phenytoin
- antipsychotics, eg: clozapine, haloperidol and zotepine
- benzodiazepines, eg: diazepam and alprazolam
- tramadol for pain relief
- sumatriptan for migraine
- lithium, for bipolar disorder

- tryptophan, a type of amino acid
- flecanide, ecainide, for irregular heart beat
- vinblastine, for cancer treatment
- warfarin, to prevent blood clot formation
- alcohol
- St. John's Wort

Pregnancy and lactation

If you are pregnant while taking this medicine, consult your doctor immediately for more information on the safety of **Flusac** use during pregnancy. Fluoxetine is excreted into breast milk and may affect your baby. Nursing is not recommended while you are using **Flusac**

4. HOW TO TAKE FLUSAC

Take your medication exactly as directed by your doctor.

How much to take:

The usual dosage is one capsule daily to be taken in the morning. Depending on your condition, a higher dosage might be given by your doctor.

How to take:

Swallow the capsule with a glass of water.

When to take:

Fluoxetine may be administered with or without food, preferably in the morning.

How long to take it

Continue taking your medicine for as long as your doctor tells you. Most antidepressant takes time to work. The duration of treatment depends on how quickly your symptoms improve. It is very important that you do not stop taking **Flusac** suddenly.

If you forget to take it

Take your dose as soon as you remember, and continue to take it as you would normally. If it is almost time for your next dose, skip the dose you missed

and take your next dose when you are meant to. Do not take a double dose to make up for the dose that you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you take too much

If you or anyone else takes too many tablets, you tell your doctor and go to your nearest hospital emergency department immediately. Do this even if there are no signs of discomfort or poisoning. Take the carton or any remaining tablets you have with you.

Symptoms of an overdose may include nausea, vomiting, seizures, restlessness and excitation.

5. WHILE YOU ARE USING FLUSAC

Things you must do

- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking this medicine.
- Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.
- If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.
- Keep all of your doctor's appointments so that your progress can be checked.
- Tell your doctor if you become pregnant while taking this medicine.

Things you must not do

- Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not stop taking your medicine or change the dosage without checking with your doctor.

Things to be careful of

- Be careful driving or operating machinery until you know how this medicine affects you. *Flusac* may impair judgement or skills. Do not

drive or operate machinery until you are certain that it is safe to do so.

- Consuming alcohol while taking *Flusac* may worsen the symptoms of dizziness and drowsiness.

6. POSSIBLE SIDE EFFECTS

Like all medicines, *Flusac* can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

- chills or fever
- diarrhea
- nausea, vomiting
- indigestion
- loss of appetite, change in taste
- dry mouth
- low sodium salt
- agitation
- short term memory loss
- sleep disorders
- change in personality
- euphoria
- dizziness, drowsiness
- headache
- fatigue, weakness
- abnormal movement
- restlessness
- frequent or difficulty in urination
- sexual problems
- hair loss
- vision disturbances
- joint or muscular pain
- sudden drop in blood pressure when changing position
- a sudden drop in blood pressure when changing position causing dizziness or fainting.

Inform your doctor immediately if you notice the following while taking this medication:

- severe allergic reactions such as rashes and itchiness, swelling of the face, lips, tongue, or limbs, or difficulties in breathing.
- seizure or increase frequency of seizures attack.
- psychological effects such as mania, suicidal thought, hallucination, anxiety, and confusion.
- weight loss
- Bleeding problems (easily bruise, blue-purple patch under skin)

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell. Other side effects not listed above may also occur in some people.

7. HOW TO STORE FLUSAC

Storage

Keep medicines in original packaging. Store in a cool (below 30°C), dry place, away from direct heat and light and excessive moisture. Do not leave your medicine in the car.

Keep all medicines out of the reach of children.

Disposal

Medicines should not be disposed of via household waste. Ask your doctor and pharmacist how to dispose of medicines.

8. PRODUCT DESCRIPTION

What *Flusac* looks like and contents of the pack.

Green-ivory capsule imprint with "SPS" in black

Active ingredient: each capsule contains 22.36mg of Fluoxetine hydrochloride (equivalent to 20.0mg of fluoxetine)

Other ingredients: sodium lauryl sulfate, sodium starch glycolate, methyl paraben, propyl paraben, colloidal silicon dioxide, croscarmellose sodium, lactose, cornstarch.

Packing: Blisters of 10 tablets packed in 3 x 10's 10 x 10's and 50 x 10's tablets per box

Registration No: MAL06061672A

9. MANUFACTURER AND MARKETING AUTHORIZATION HOLDER

Manufactured by
SRIPRASIT PHARMA CO., LTD.
619 Charoenrat Road, Khlong San,
Bangkok 10600, Thailand

Marketing Authorization Holder

IMEKS Pharma Sdn. Bhd.
No. 1 & 2, Jalan 6/33B,
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52000 Kuala Lumpur, Malaysia

Date of revision

January 2012