

PATIENT INFORMATION LEAFLET**SCHEDULING STATUS****S5****FLOCSIVE 20 capsules****Fluoxetine hydrochloride equivalent to 20 mg fluoxetine****Sugar free****Read all of this leaflet carefully before you start taking FLOCSIVE**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- FLOCSIVE has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What FLOCSIVE is and what it is used for
2. What you need to know before you take FLOCSIVE
3. How to take FLOCSIVE
4. Possible side effects
5. How to store FLOCSIVE
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1. What FLOCSIVE is and what it is used for

FLOCSIVE capsules contain the active substance fluoxetine which is one of a group of medicines called selective serotonin re-uptake inhibitors (SSRI) antidepressants.

FLOCSIVE is used for the treatment of:

- Major depressive disorder
- Bulimia nervosa
- Obsessive-compulsive disorder

2. What you need to know before you take FLOCSIVE

Do not take FLOCSIVE:

- If you are hypersensitive (allergic) to fluoxetine or any of the other ingredients of FLOCSIVE (listed in section 6). 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 suffer from severe kidney failure.
- If you are taking metoprolol (a medicine used in heart failure)
- If you are taking pimozide (a medicine used in Tourette's syndrome).
- If you are taking other medicines known as monoamine oxidase inhibitors (MAOI) since serious or even fatal reactions can occur. Treatment with FLOCSIVE should only be started at least 2 weeks after stopping the MAOI.

Do not take any MAOIs for at least 5 weeks after you stop taking FLOCSIVE. If FLOCSIVE has been prescribed for a long period and/or at a high dose, a longer interval needs to be considered by your doctor.

Usage in the elderly: If you are elderly and have other illnesses or you are receiving other medicines for other illnesses then FLOCSIVE must be used with caution. Dosages over 20 mg per day are not recommended.

Warnings and precautions

Take special care with FLOCSIVE:

- If you have thoughts of suicide and worsening of your 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. In that time 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 shown an increased risk of suicidal behaviour in adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant.
- 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.
- If you start feeling restless and cannot sit or stand still (akathisia), contact your doctor or pharmacist.
- If you develop fever, muscle stiffness or tremor, changes in your mental state like confusion, irritability and extreme agitation: you may suffer from the so-called "serotonin syndrome". Although this syndrome occurs rarely, it may result in potentially life-threatening conditions. Contact your doctor immediately if this occurs, as your treatment with FLOCSIVE will need to be stopped.
- 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 suffer from epilepsy or fits. If you have a fit (seizures) or experience an increase in seizure frequency, contact your doctor immediately; FLOCSIVE might need to be stopped.
- Tell your doctor if you suffer from kidney disease, liver disease or heart disease as your dose of FLOCSIVE may need adjustment.
- Tell your doctor if you have diabetes as your doctor may need to adjust your dose of insulin or other anti-diabetic treatment.
- FLOCSIVE may cause weight loss, which could be undesirable in underweight depressed patients.
- Tell your doctor if you have a history of bleeding disorders or appearance of bruises or unusual bleeding.
- Tell your doctor if you are at risk of glaucoma (increased pressure in the eye).
- Tell your doctor if you are taking any medicine that thins the blood.
- Tell your doctor if you are having ECT (electro-convulsive therapy).
- Tell your doctor if you are having treatment with tamoxifen used to treat breast cancer.
- Tell your doctor if you have mania now or in the past; if you have a manic episode, contact your doctor immediately because FLOCSIVE may need to be discontinued.

Sexual dysfunction

Medicines like FLOCSIVE (so called SSRIs) may cause symptoms of sexual dysfunction (see section 4). In some cases, these symptoms have continued after stopping treatment.

Children and adolescents

Safety and efficacy of FLOCSIVE in children below 18 years of age have not been established.

Other medicines and FLOCSIVE

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Do not take FLOCSIVE with:

- Certain monoamine oxidase inhibitors (MAOIs), some used to treat depression. If used with FLOCSIVE may cause serious or even fatal reactions (serotonin syndrome) can occur. Treatment with FLOCSIVE should only be started at least 2 weeks after you stop taking a MAOI.
- Do not take any irreversible, non-selective MAOIs for at least 5 weeks after you stop taking FLOCSIVE. If FLOCSIVE has been prescribed for a long period and/or at a high dose, a longer interval than 5 weeks may need to be considered by your doctor.
- Metoprolol when used for heart failure; there is an increased risk of your heartbeat becoming too slow.

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

- Lithium, there is an increased risk of serotonin syndrome when lithium is taken with FLOCSIVE.
- Use of other medicines with serotonergic activity (e.g. Serotonin and Norepinephrine Reuptake Inhibitors (SNRIs), other Selective Serotonin Reuptake Inhibitors (SSRIs), such as triptans, tryptophan, selegiline, St. John's Wort or tramadol) may result in serotonin syndrome.
- When taking other medicines such as phenytoin, carbamazepine, haloperidol, clozapine, diazepam, alprazolam, imipramine and desipramine changes in blood levels have been observed.
- If you are taking tryptophan, you may experience agitation, restlessness and stomach distress.
- Anti-coagulants (such as warfarin), Non-Steroidal Anti-inflammatory, NSAID (such as

ibuprofen, diclofenac), aspirin and other medicines which can thin the blood. FLOCSIVE may alter the effect of these medicines on the blood. If FLOCSIVE treatment is started or stopped when you are taking warfarin, your doctor will need to perform certain tests, adjust your dose and check on you more frequently.

- Tamoxifen (used to treat breast cancer); because FLOCSIVE may change the blood levels of this medicine, resulting in the possibility of a reduction in the effect of tamoxifen, your doctor may need to consider prescribing a different antidepressant treatment.
- Medicines that may affect the heart's rhythm, e.g. Class IA and III antidysrhythmics, antipsychotics (e.g. phenothiazine derivatives, pimozide, haloperidol), tricyclic antidepressants, certain antimicrobial medicines (e.g. moxifloxacin, erythromycin IV, pentamidine), anti-malaria treatment particularly halofantrine or certain antihistamines (astemizole, mizolastine), because taking one or more of these medicines with FLOCSIVE may increase the risk of changes in the electrical activity of the heart.
- Cyproheptadine (for allergies); because it may reduce the effect of FLOCSIVE.
- Medicines that lower sodium levels in the blood (including, medicines that causes increase in urination, desmopressin, carbamazepine and oxcarbazepine); because these medicines may increase the risk of sodium levels in the blood becoming too low when taken with FLOCSIVE.
- Anti-depressants such as tricyclic anti-depressants, other selective serotonin reuptake inhibitors (SSRIs) or bupropion, mefloquine or chloroquine (used to treat malaria), tramadol (used to treat severe pain) or anti-psychotics such as phenothiazines or butyrophenones; because FLOCSIVE may increase the risk of seizures when taken with these medicines.

FLOCSIVE with food, drink and alcohol

- You can take FLOCSIVE with or without food.
- You should avoid alcohol while you are taking FLOCSIVE.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking FLOCSIVE.

Pregnancy

Safety in pregnancy has not been established.

If you take FLOCSIVE near the end of your pregnancy there may be an increased risk of heavy vaginal bleeding shortly after birth, especially if you have a history of bleeding disorders. Your doctor or midwife should be aware that you are taking FLOCSIVE so they can advise you.

In babies whose mothers took fluoxetine, as in FLOCSIVE, during the first few months of pregnancy, there have been some studies describing an increased risk of birth defects affecting the heart.

When taken during pregnancy, particularly in the last 3 months of pregnancy, FLOCSIVE may increase the risk of a serious condition in babies, called persistent pulmonary hypertension of the newborn (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.

Caution should be exercised when used during pregnancy, especially during late pregnancy or just before giving birth since the following effects have been reported in newborn children: irritability, tremor, muscle weakness, persistent crying, and difficulty in sucking or in sleeping.

Breastfeeding

The safety of FLOCSIVE has not been established in breastfeeding women.

FLOCSIVE is excreted in human breast milk and can cause side effects in babies. You should only breastfeed if it is clearly necessary. If breastfeeding is continued, you doctor may prescribe a lower dose of FLOCSIVE.

Fertility

Fluoxetine, as in FLOCSIVE, has been shown to reduce the quality of sperm in animal studies. Theoretically, this could affect fertility, but impact on human fertility has not been observed as yet.

Driving and using machines

FLOCSIVE may affect your judgment and/or co-ordination.

Do not drive or use machinery if you experience any side effects that may affect your ability to do so.

It is not always possible to predict to what extent FLOCSIVE may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which FLOCSIVE affects them.

3. How to take FLOCSIVE

Do not share medicines prescribed for you with any other person.

Always take FLOCSIVE exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

FLOCSIVE is for oral use in adults only.

- **Major depressive disorder:** Adults and elderly: A dose of 20 mg/day is recommended, preferably in the morning.
- **Bulimia nervosa:** A dose of 60 mg/day is recommended.
- **Obsessive-compulsive disorder:** A dose of 20 to 60 mg/day is recommended.

Your doctor will tell you how much FLOCSIVE you need and how long your treatment will last. Your doctor may increase or decrease your dose.

If you have the impression that the effect of FLOCSIVE is too strong or too weak, tell your doctor or pharmacist.

FLOCSIVE capsules are not suitable for increasing or decreasing your dose by titration in small dose quantities.

Concurrent disease: A lower or less frequent dose will be given to you if you suffer from liver disease or other diseases.

If you take more FLOCSIVE than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take the pack of FLOCSIVE with you.

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

If you forget to take FLOCSIVE

If you miss a dose, 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 stop taking FLOCSIVE

Do not stop taking FLOCSIVE without asking your doctor first, even when you start to feel better. It is important that you keep taking FLOCSIVE.

Stopping your treatment with FLOCSIVE may lead to the following effects (withdrawal symptoms), such as dizziness, paraesthesia (an unusual or unexplained tingling, pricking, or burning sensation on the skin), headache, inability to sleep, tremor, confusion, sensory disturbances, unusual tiredness or weakness, agitation, anxiety and nausea.

When stopping FLOCSIVE, 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 this medicine, ask your doctor or pharmacist.

4. Possible side effects

FLOCSIVE can have side effects.

Not all side effects reported for FLOCSIVE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking FLOCSIVE, please consult your health care provider for advice.

If any of the following happens, stop taking FLOCSIVE and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to FLOCSIVE. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- If you have thoughts of harming or killing yourself at any time.
- If you feel restless and cannot sit or stand still, you may have akathisia; increasing your dose of FLOCSIVE may make you feel worse.
- If your skin starts to turn red or you develop a skin reaction, or your skin starts to blister or peel.
- 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;

- Feelings of weakness, drowsiness or confusion mostly in elderly people;
- Prolonged and painful erection;
- Irritability and extreme agitation;
- Heart problems, such as fast or irregular heart rate, fainting, collapsing or dizziness upon standing which may indicate abnormal functioning of the heart rate;

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent

- Insomnia
- Memory impairment
- Headache
- Diarrhoea, feeling sick (nausea)
- Fatigue
- Not feeling hungry/weight loss
- Nervousness, anxiety
- Restlessness, poor concentration
- Feeling tense
- Decreased sex drive or sexual problems (including difficulty maintaining an erection for sexual activity)
- Sleep problems, unusual dreams, tiredness or sleepiness
- Dizziness
- Change in taste
- Uncontrollable shaking movements
- Blurred vision
- Rapid and irregular heartbeat sensations
- Flushing

- Yawning
- Indigestion, vomiting
- Dry mouth
- Rash, urticaria, itching
- Excessive sweating
- Joint pain
- Passing urine more frequently
- Unexplained vaginal bleeding
- Feeling shaky or chills

Less frequent

- Feeling detached from yourself
- Strange thinking
- Abnormally high mood
- Orgasm problems
- Thoughts of suicide or harming yourself
- Teeth grinding
- Muscle twitching, involuntary movements or problems with balance or co-ordination
- Enlarged (dilated) pupils
- Ringing in the ears
- Low blood pressure
- Shortness of breath
- Nose bleeds
- Difficulty swallowing
- Hair loss
- Increased tendency to bruising
- Unexplained bruising or bleeding

- Cold sweat
- Difficulty passing urine
- Feeling hot or cold
- Liver disease, abnormal liver function test results
- Low levels of salt in the blood
- Reduction in blood platelets, which increases risk of bleeding or bruising
- Reduction in white blood cell count
- Untypical wild behaviour
- Hallucinations
- Agitation
- Panic attacks
- Confusion
- Stuttering
- Fits (seizures)
- Vasculitis (inflammation of a blood vessel)
- Rapid swelling of the tissues around the neck, face, mouth and/or throat
- Pain in the tube that takes food or water to your stomach
- Hepatitis
- Lung problems
- Sensitivity to sunlight
- Muscle pain
- Problems urinating
- Producing breast milk

Frequency unknown side effects:

- Heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see “Pregnancy”, in section 2 for more information.

- Bone fracture

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of FLOCSIVE.

5. How to store FLOCSIVE

Store all medicines out of reach of children.

- Store at or below 25 °C.
- Keep the blisters in the original package until required for use.
- Do not use after the expiry date stated on the label / carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What FLOCSIVE contains

- The active substance is fluoxetine.

Each FLOCSIVE capsule contains fluoxetine hydrochloride equivalent to 20 mg fluoxetine.

- The other ingredient is pregelatinized starch and the capsule components are allura red, brilliant blue FCF, gelatin, quinoline yellow and titanium dioxide.

What FLOCSIVE looks like and contents of the pack

FLOCSIVE capsule is an opaque light green (cap)/ opaque off white (body) size “3” EHG capsule containing a white powder.

FLOCSIVE capsules are supplied in Alu/PVC blister packs. Each blister contains 14 capsules. Pack size: 28 capsules (2 blisters packed in a carton).

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Access to the corresponding Professional Information

<https://www.pharmaq.co.za>