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APROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

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RANFLOCS 20 CAPSULES, 20 mg, capsules

Fluoxetine hydrochloride

Read all of this leaflet carefully before you start taking RANFLOCS 20 CAPSULES

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist, nurse or other health care provider.
- RANFLOCS 20 CAPSULES 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 RANFLOCS 20 CAPSULES is and what it is used for
2. What you need to know before you take RANFLOCS 20 CAPSULES
3. How to take RANFLOCS 20 CAPSULES
4. Possible side effects
5. How to store RANFLOCS 20 CAPSULES
6. Contents of the pack and other information

1. What RANFLOCS 20 CAPSULES is and what it is used for

The active substance is fluoxetine hydrochloride equivalent to fluoxetine 20 mg.

Fluoxetine is an antidepressant and anti-obsessive compulsive agent, is a selective serotonin (5-HT) uptake inhibitor in the central nervous system.

RANFLOCS 20 CAPSULES are indicated for the treatment of:

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

2. What you need to know before you take RANFLOCS 20 CAPSULES

Do not take RANFLOCS 20 CAPSULES:

- if you are hypersensitive (allergic) to fluoxetine or any of the other ingredients of RANFLOCS 20 CAPSULES (listed in section 6). If you develop a rash or other allergic reactions such as 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 known as monoamine oxidase inhibitor which is also used to treat depression, since serious or even fatal reactions can occur. Treatment with RANFLOCS 20 CAPSULES should only be started at least 2 weeks after stopping the MAOI.

Do not take any MAOIs (used to treat depression) for at least 5 weeks after you stop taking RANFLOCS 20 CAPSULES. If RANFLOCS 20 CAPSULES has been prescribed for a long period and/or at a high dose, a longer interval needs to be considered by your doctor.

- if you have severe renal function impairment or kidney failure, symptoms can be change in frequency of urination.
- if you are taking an antibiotic called linezolid.
- if you are taking a medicine called metoprolol, used in heart failure.
- If you are taking pimozide (a medicine used in Tourette's syndrome).
- safety and efficacy in children has not been established.

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

Warnings and precautions

Take special care with RANFLOCS 20 CAPSULES:

- 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 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 thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital straight away
- 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 suffer from a condition called “serotonin syndrome”, symptoms included development of fever, muscle stiffness or tremor, changes in your mental state like confusion, irritability and extreme agitation. Although this syndrome occurs rarely, it may result in potentially life-threatening conditions. Contact your doctor immediately if this occurs, as your treatment with RANFLOCS 20 CAPSULES will need to be stopped
- If you have feelings of weakness, drowsiness, extreme agitation or confusion mostly in elderly people(delirium)
- if you have acute heart disease
- if you have a mental health condition that causes extreme mood swings that include emotional highs (mania or hypomania) and lows (depression), inform you doctor if you are feeling this way.

- if you develop a rash or other allergic reactions (such as itching, swollen lips or face or shortness of breath), stop taking the RANFLOCS 20 CAPSULES and immediately contact your doctor
- if you have a history of seizures
- inform your doctor if you are having electro-convulsive therapy (ECT)
- inform your doctor if you are on treatment with tamoxifen, used to treat breast cancer
- if you have kidney or liver impairment or heart disease as your dose of RANFLOCS 20 CAPSULES may need to be adjusted
- if you are underweight as you may lose more weight
- if you have diabetes mellitus as your blood sugar control may change, tell your doctor as there may be need to adjust your dose of insulin or other anti-diabetic treatment
- if you have a bleeding disorder (have tendency to bleed or bruise easily)
- if you have an extrapyramidal disorder (akathisia), where you may start feeling restless and cannot sit or stand still, contact your doctor
- inform you doctor if you notice increased pressure in the eye
- persistent, recurrent problems with sexual response, desire, orgasm or pain.

Children and adolescents

Safety and efficacy of RANFLOCS 20 CAPSULES in children below 18 years of age have not been established.

Other medicines and RANFLOCS 20 CAPSULES:

Always tell your healthcare professional if you are taking any other medication. (This includes complementary or traditional medicines).

Do not take the following medicines with RANFLOCS 20 CAPSULES:

- Monoamine oxidase inhibitors (MAOI), used to treat depression. This may cause serious or even fatal reactions (serotonin syndrome) if used with RANFLOCS 20 CAPSULES.

Treatment with RANFLOCS 20 CAPSULES should only be started at least 2 weeks after you stop taking a MAOI.

- Medicines metabolized by cytochrome P450 2D6 (CYP2D6) – RANFLOCS 20 CAPSULES is an inhibitor of cytochrome P450 2D6 (CYP2D6). There is potential for interaction with other medicines that are metabolized by this enzyme, therefore, a reduction in dosage of such medicines, with initiation of therapy at the low dose range for medicines having a relatively narrow therapeutic index, may be needed when used concurrently with RANFLOCS 20 CAPSULES or within 5 weeks of discontinuing RANFLOCS 20 CAPSULES.
- Metoprolol, used to treat heart failure. It may increase the risk of your heartbeat becoming too slow.
- CNS active medicines
- Lithium – both increased and decreased concentrations of lithium have been reported when used concurrently with RANFLOCS 20 CAPSULES.
- Phenytoin, carbamazepine, haloperidol, clozapine, diazepam, alprazolam, imipramine and desipramine – changes in blood levels, sometimes with clinical signs of toxicity.
- Tryptophan - adverse reactions, including agitation, restlessness and gastro-intestinal distress have been reported when RANFLOCS 20 CAPSULES has been used in combination with tryptophan.
- Medicines used to prevent blood clots called Anti-coagulants (such as warfarin), Non-Steroidal Anti-inflammatory, NSAID (such as ibuprofen, diclofenac), aspirin and other medicines which can thin the blood.
- Tamoxifen, medication used to treat breast cancer in men and women, as the effect of tamoxifen may be reduced.
- Medicine that makes your heart beat slower such as pimozide, moxifloxacin and mizolastine
- Cyproheptadine (for allergies); because it may reduce the effect of RANFLOCS 20 CAPSULES.

- Medicine that lower sodium levels in the blood such as diuretics, desmopressin, carbamazepine and oxcarbazepine, when used with RANFLOCS 20 CAPSULES
- Medicines used for epilepsy (for example, TCAs, other SSRIs, phenothiazines, butyrophenones, mefloquine, chloroquine, bupropion, tramadol) used together with RANFLOCS 20 CAPSULES may lead to an increased risk of seizures.
- Protein bound medicines such as RANFLOCS 20 CAPSULES is bound to plasma protein, its plasma concentration or that of other protein bound medicines such as warfarin and digoxin could be altered when used together.

RANFLOCS 20 CAPSULES with food and drink and alcohol:

RANFLOCS 20 CAPSULES can be taken with or without food.

Avoid use of alcohol.

Pregnancy, breastfeeding, and fertility:

If you are pregnant or breast feeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care professional for advice before taking RANFLOCS 20 CAPSULES.

If you take RANFLOCS 20 CAPSULES 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 RANFLOCS 20 CAPSULES so they can advise you.

RANFLOCS 20 CAPSULES when taken in the last three months of pregnancy, 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. Call your doctor or nurse immediately if this happens to your baby.

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 RANFLOCS 20 CAPSULES has not been established in breastfeeding women. RANFLOCS 20 CAPSULES is excreted in human breast milk and can cause side effects in babies. You should only breastfeed if it is clearly necessary. If you continue to breastfeed you, you doctor may prescribe a lower dose of RANFLOCS 20 CAPSULES.

Fertility

Fluoxetine, as in RANFLOCS 20 CAPSULES, 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:

Do not drive or operate any tools or machines until you know how RANFLOCS 20 CAPSULES affects you because your concentration may be affected.

It is not always possible to predict to what extent RANFLOCS 20 CAPSULES 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 RANFLOCS 20 CAPSULES affects them.

3. How to take RANFLOCS 20 CAPSULES

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

Always take RANFLOCS 20 CAPSULES exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The usual doses are:

Major depressive disorders

Adults: 20 mg daily, preferably in the morning.

Obsessive-compulsive disorders

Adults: 20 mg - 60 mg daily.

Bulimia nervosa

Adults: 60 mg daily.

Do not stop taking your medicine suddenly. The dose must be gradually reduced over time before stopping treatment.

Your doctor will tell you how much RANFLOCS 20 CAPSULES 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 RANFLOCS 20 CAPSULES is too strong or too weak, tell your doctor or pharmacist.

RANFLOCS 20 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 have the impression that the effect of RANFLOCS 20 CAPSULES is too strong or too weak, talk to your doctor or pharmacist.

If you take more RANFLOCS 20 CAPSULES than you should:

Symptoms that have been reported include increased pulse, drowsiness, tremor, nausea and vomiting as well as agitation, restlessness, hypomania (mood or energy changes), seizures, lung problems and change in mental condition ranging from agitation to coma.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take RANFLOCS 20 CAPSULES :

Do not take a double dose to make up forgotten individual doses. Wait until the time of your next dose.

If you stop using RANFLOCS 20 CAPSULES:

Do not stop taking RANFLOCS 20 CAPSULES without asking your doctor first, even when you start to feel better. It is important that you keep taking RANFLOCS 20 CAPSULES.
RANFLOCS 20 CAPSULES should be withdrawn gradually to reduce the risk of withdrawal symptoms. These include agitation, anxiety, dizziness, fatigue, headache, malaise, nausea, sweating and vertigo.
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

RANFLOCS 20 CAPSULES can have side-effects.
Not all side-effects reported for RANFLOCS 20 CAPSULES are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult health care provider for advice.

If any of the following happens, stop taking RANFLOCS 20 CAPSULES and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth, or throat which may cause difficulty in swallowing or breathing
- rash or itching
- fainting
- yellowing of the skin and eyes, also called jaundice

- excessive sweating,
- serum sickness
- if you have thoughts of harming or killing yourself at any time.

These are all very serious side-effects. If you have them, you may have had a serious allergic reaction to RANFLOCS 20 CAPSULES. You may need urgent medical attention or hospitalisation. All of these very serious side-effects are very rare.

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

- Changes in the way your heart beats, for example, if your heart is beating faster (palpitations)
- If you feel restless and cannot sit or stand still, you may have akathisia; increasing your dose of RANFLOCS 20 CAPSULES may make you feel worse
- if you develop a skin reaction or your skin starts to blister or peel
- 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:

- Anxiety, drowsiness, headache, insomnia, tremor, nervousness, asthenia.
- Nausea, anorexia, diarrhoea.
- Decreased libido, sexual dysfunction (delayed or inhibited orgasm).
- 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
- Uncontrollable shaking movements
- Blurred vision
- Rapid and irregular heartbeat sensations
- Yawning
- Urticaria
- Passing urine more frequently
- Unexplained vaginal bleeding
- Feeling shaky or chills
- Ear pain
- Flushing (sudden reddening of the skin)

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

Less frequent:

- Weight loss.
- Abnormal dreams, dizziness, fatigue, agitation.
- Visual disturbances.
- Dry mouth, dyspepsia, vomiting.
- Heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see Pregnancy and breast-feeding in section 3 for more information
- Memory impairment
- 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
- 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
- Vasculitis (inflammation of a blood vessel)
- 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 fractures

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 “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of RANFLOCS 20 CAPSULES.

5. How to store RANFLOCS 20 CAPSULES

Store all medicines out of reach of children.

Store at or below 25 °C, protected from light.

Do not take the medicine after the expiry date on the container.

Return any 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 RANFLOCS 20 CAPSULES contains

The active substance is fluoxetine hydrochloride equivalent to fluoxetine 20 mg.

The other ingredients are pregelatinised starch and opaque, hard gelatin capsule shells with a green cap and off-white body imprinted with black edible ink.

What RANFLOCS 20 CAPSULES looks like and contents of the pack

Opaque, hard gelatin, self-locked capsules of size ‘2' with green cap and off-white body imprinted with ‘R/FXT20' in black edible ink on cap/body, containing white granular powder.

Cartons contain 30 capsules in blister strips of 15 capsules each.

Holder of Certificate of Registration

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