

**PATIENT INFORMATION LEAFLET
SERRAPRESS 20**

SCHEDULING STATUS:

S5

PROPRIETARY NAME AND DOSAGE FORM:

SERRAPRESS 20 tablets

Read this entire leaflet carefully before you start taking SERRAPRESS 20.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **SERRAPRESS 20** 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.

1. WHAT SERRAPRESS 20 CONTAINS:

The active substance is paroxetine.

Each **SERRAPRESS 20** tablet contains 20 mg paroxetine

The other ingredients are Eudragit, magnesium stearate, mannitol, microcrystalline cellulose, Opadry AMB White, sodium starch glycollate.

SERRAPRESS 20 tablets are sugar free.

2. WHAT SERRAPRESS 20 IS USED FOR:

SERRAPRESS 20 is used to treat a variety of emotional problems.

- **Depression**

Continuing depression that interferes with your ability to function.

- **Obsessive compulsive disorder (OCD)**

A condition identified by unwanted, but stubbornly persistent thoughts, and/or unreasonable rituals you feel compelled to repeat

- **Social Phobia**

A condition characterised by a strong fear of being judged by others, of being embarrassed and marked by shyness or stage fright so intense that it interferes with your work and social life.

- **Panic Disorder**

A crippling emotional problem characterised by sudden attacks of at least four of the following symptoms: rapid heartbeat, sweating, shaking, numbness, chills or hot flashes, shortness of breath, a feeling of choking, chest pain, nausea or abdominal distress, dizziness or faintness, feelings of unreality or detachment, fear of losing control, or fear of dying.

- **Generalised Anxiety Disorder:**

A disease marked by excessive anxiety and worry that persists for at least 6 months and cannot be easily controlled. True cases of generalised anxiety disorder are accompanied by at least three of the following symptoms: restlessness or an on-edge feeling, a tendency to wear out easily, difficulty concentrating or spells when the mind goes blank, irritability, muscle tension, or sleep disturbance.

3. BEFORE YOU TAKE SERRAPRESS 20:

Do not take SERRAPRESS 20:

- If you are hypersensitive (allergic) to paroxetine, or to any of the other ingredients of **SERRAPRESS 20**. If you are unsure about this ask your doctor (see **WHAT SERRAPRESS 20 CONTAINS**).

If you are taking other medicines for depression called monoamine oxidase inhibitors (MAOIs, including moclobemide and linezolid), or have taken them at any time within the last two weeks. Your doctor will advise you how you should begin taking **SERRAPRESS 20** once you have stopped taking the MAOI. You should also not start taking MAO inhibitors for two weeks after **SERRAPRESS 20** treatment is terminated.

- **SERRAPRESS 20** should not be used for children and adolescents under the age of 18 years. (see **Take special care with SERRAPRESS 20**).
- If you have epilepsy or a history of seizures / fits.
- If you are taking a medicine containing pimozide (to treat a mental disorder), as **SERRAPRESS 20** may cause a serious irregular heart beat which can be fatal when taken in combination with these medicines.
- If you have porphyria (an enzyme disorder with symptoms such as severe abdominal pain, pain in your chest, back or legs, vomiting or a rapid heartbeat).

Take special care with SERRAPRESS 20:

- If you are an adolescent or young adult aged less than 18 years.
- 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).
- If you have previously had thoughts about killing or harming yourself.

- Your doctor will monitor your treatment and your progress carefully for the first few weeks. If you have any thoughts of harming or killing yourself at any time, contact your doctor immediately or go to a hospital straight away.
- Do not stop taking **SERRAPRESS 20** without telling your doctor. If you stop taking your **SERRAPRESS 20** tablets suddenly, you may experience withdrawal effects (see **POSSIBLE SIDE EFFECTS**).
- If you suffer from epilepsy or seizures (fits).
- If you experience a feeling of restlessness, usually within the first few weeks of treatment (see **POSSIBLE SIDE EFFECTS**).
- If you are taking other similar medicines for a mental condition as this may lead to Neuroleptic Malignant Syndrome, a life-threatening condition with symptoms such as rigid muscles and fever.
- If you take medicines containing oxitriptan or L-tryptophan (to treat mood disorders) as you may be at risk of serotonergic syndrome (a condition with symptoms such as agitation or restlessness, dilated pupils and heavy sweating)
- If you have episodes of mania (overactive behaviour or thoughts).
- If you are taking medicine to prevent the clotting of blood or are prone to bleed easily as **SERRAPRESS 20** may increase the risk of bleeding.
- If you take a medicine containing risperidone (to treat a mental disorder), as this may lead to toxicity (see **Taking other medicines with SERRAPRESS 20**).
- If you take alcohol, as **SERRAPRESS 20** should not be taken with alcohol.

- Tell your doctor if you experience unexplained bone pain, tenderness, swelling or bruising. **SERRAPRESS 20** may be associated with bone fractures.
- If you have a heart disorder.
- If you suffer from glaucoma (an eye condition that can result in the damage of the optic nerve).
- If you have diabetes, as the dosage of your medicine may have to be adjusted.
- If you have kidney or liver problems.
- If you are or planning to become pregnant, as the use of **SERRAPRESS 20** during the first three months of pregnancy, may cause heart defects in the infant (see **Pregnancy and breastfeeding**).

Children and adolescents under 18

SERRAPRESS 20 must not be used for children and adolescents under 18 years. Patients under 18 have an increased risk of side effects such as suicide attempts, suicidal thoughts and hostility (predominantly aggression, oppositional behaviour and anger) when they take **SERRAPRESS 20**.

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.

Taking SERRAPRESS 20 with food and drink

SERRAPRESS 20 tablets should be taken once a day in the morning with food and should be swallowed not chewed.

Do not drink alcohol while you are taking **SERRAPRESS 20**. Alcohol may worsen your side effects.

Pregnancy and breastfeeding:

The safe use of **SERRAPRESS 20** during pregnancy and breastfeeding has not been established. If you are pregnant, suspect that you are pregnant or breastfeeding your baby, consult your healthcare provider for advice before taking **SERRAPRESS 20**. If you are planning to become pregnant or are breastfeeding, ask your doctor or pharmacist for advice before taking **SERRAPRESS 20**.

If you are already taking **SERRAPRESS 20** and have just found out that you are pregnant you should talk to your doctor immediately. This is because some studies have suggested an increase in the risk of heart defects in babies whose mothers received **SERRAPRESS 20** in the first few months of pregnancy.

Your doctor may decide that it is better for you to gradually stop taking **SERRAPRESS 20** while you are pregnant.

If you use **SERRAPRESS 20** in pregnancy, particularly in late pregnancy, it may cause an increased risk of persistent pulmonary hypertension of your baby (PPHN), with symptoms such as rapid breathing, lack of oxygen, heart problems.

Driving and using machines:

SERRAPRESS 20 may cause drowsiness and dizziness. Make sure you know how you react to **SERRAPRESS 20** before driving a vehicle, operating machinery, or do anything else that could be dangerous.

Important information about some of the ingredients of SERRAPRESS 20:

SERRAPRESS 20 is sugar free.

Taking other medicines with SERRAPRESS 20:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **SERRAPRESS 20** with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or healthcare professional for advice.

Some of the medicines that should not be used in combination with **SERRAPRESS 20** are:

- Medicines called monoamine oxidase inhibitors (MAOIs) including moclobemide and linezolid (see **Do not take SERRAPRESS 20**)
- Debrisoquine (a medicine used to treat high blood pressure) as **SERRAPRESS 20** may increase debrisoquine's effect.
- Risperidone (used to treat psychiatric conditions) as **SERRAPRESS 20** may increase the effect of risperidone.
- Phenytoin or phenobarbitone (used in the treatment and prevention of seizures in epilepsy) may decrease the effect of **SERRAPRESS 20** and lead to symptoms such as diarrhoea and nervousness.

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- Pimozide (used to treat schizophrenia) as **SERRAPRESS 20** may cause a serious irregular heart beat when taken in combination with pimozide.
- Procyclidine (used to treat Parkinsonism) as **SERRAPRESS 20** may increase the effect of procyclidine.
- Aspirin, ibuprofen or other medicines called NSAIDs (non-steroidal anti-inflammatory medicines) used for pain and inflammation as these NSAIDs may cause increased bleeding.
- Sumatriptan (used to treat migraine).
- Theophylline (used in the treatment of asthma).
- Tamoxifen (used to treat breast cancer) as **SERRAPRESS 20** may reduce the effect of tamoxifen.
- The effect of **SERRAPRESS 20** is not affected, or only marginally affected by food, antacids and propranolol
- Digoxin (used in the treatment of heart failure) as **SERRAPRESS 20** may decrease the effect of digoxin.
- Cimetidine (a medicine used to treat heart burn and stomach ulcers) may increase the effect of **SERRAPRESS 20**.
- Spartein (used to treat heart conditions) as **SERRAPRESS 20** may increase the effect of spartein.
- Propafenone (used to treat an irregular heartbeat) or metoprolol used to treat high blood pressure as **SERRAPRESS 20** may increase the effect of these medicines.

- Tryptophan (an amino acid supplement), linezolid (an antibiotic), other SSRIs, or St John's Wort (sometimes used for depression), as taking these medicines with **SERRAPRESS 20** may lead to a condition called "serotonin syndrome" with symptoms such as fits, shaking, restlessness and irritability.
- Warfarin or other medicines preventing blood clots as the use of **SERRAPRESS 20** may result in bleeding.
- Tricyclic antidepressants such as clomipramine, nortriptyline, amitriptyline, imipramine and desipramine as **SERRAPRESS 20** may increase effect of the tricyclic antidepressants.
- The use of alcohol with **SERRAPRESS 20** is not recommended. (see **Take special care with SERRAPRESS 20**).

4. HOW TO TAKE SERRAPRESS 20:

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

Always take **SERRAPRESS 20** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose is one **SERRAPRESS 20** tablet (20 mg paroxetine) once a day in the morning, with food. The tablet should be swallowed and not chewed. Your doctor will advise you on your tablet dose, based on your specific condition.

The safety and efficacy of **SERRAPRESS 20** in children under the age of 18 years have not been established. **SERRAPRESS 20** should therefore not be used in the treatment of children and adolescents under the age of 18 years.

Take your tablets once a day, every day, at about the same time each day. Your doctor will tell you how long your treatment with **SERRAPRESS 20** will last. Do not stop treatment early or abruptly because you may experience withdrawal symptoms (see **Effects when treatment with SERRAPRESS 20 is stopped**).

If you have the impression that the effect of **SERRAPRESS 20** is too strong or too weak for you, tell your doctor or pharmacist.

If you take more SERRAPRESS 20 than you should:

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

Symptoms of overdose may include vomiting, dilated pupils, fever, headache, rapid heartbeat, muscle contractions and feeling anxious.

Do not forget to take the product pack with you, as well as the remaining tablets.

If you forget to take a dose of SERRAPRESS 20:

Take the missed dose as soon as possible. However, if it is almost time for your next dose, continue to take the next tablet at the usual time. **Do not take a double dose.**

5. POSSIBLE SIDE EFFECTS:

SERRAPRESS 20 can have side effects. Not all side effects reported for **SERRAPRESS 20** are included in this leaflet. Should your general health worsen while taking **SERRAPRESS 20** please consult your healthcare provider for advice.

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

- swelling of the hands, feet ankles, lips, mouth or throat which may cause difficulty in breathing
- chest pain
- rash or itching

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **SERRAPRESS 20**. You may need urgent medical attention or hospitalisation.

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

- abnormal bleeding of skin, eye or stomach, purpura (purple spots on the skin caused by internal bleeding from the blood vessels)
- various conditions which can only be detected by means of laboratory tests of the blood, urine and the heart
- thinking of killing yourself (suicidal ideation) and suicidal behaviour
- blurred or abnormal vision, dilation pupils or glaucoma (high eye pressure)
- fast irregular heartbeat

- high blood pressure or low blood pressure (feeling dizzy when standing up)
- chest pain, difficulty in breathing
- inflammation of the liver (hepatitis), with symptoms such as fatigue, loss of appetite and muscle, joint ache or liver failure
- yellowing of the skin and eyes, also called jaundice
- seizures, shivering, rapid or slow heartbeat, excessive sweating
- lack of ability to urinate, loss of bladder control, bladder infection

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

Tell your doctor if you notice any of the following:

- bruising
- increased or decreased appetite, weight gain
- not sleeping well (insomnia) or feeling sleepy, feeling confused, having hallucinations (strange visions or sounds), memory loss, impaired concentration, feeling anxious (especially children), depersonalisation (a feeling where your thoughts and feelings seem unreal or not to belong to yourself), panic attacks, inability to sit still, manic reactions
- drowsiness, feeling dizzy or shaky (tremors), twitching, headache, fatigue, migraine (very severe headache), restlessness, nervousness, abnormal dreams, an abnormal sensation, typically
- tingly or prickly (“pins and needles”), overactive/over-responsive muscle reflexes, jerking of the muscles

- anisocoria (characterised by unequal size of the eye pupil), mydriasis (dilation of the pupil of the eye)
- yawning, sinusitis, bronchitis, coughing, sore throat, blocked, red runny nose
- constipation, diarrhoea, dry mouth, nausea, vomiting, indigestion, abdominal pain, excessive gas (wind), heart burn, stomach pain, feeling bloated
- excessive sweating or swelling in any part of the body, skin rashes or other skin conditions, sensitivity to sunlight
- muscle pain or weakness, joint pain, absence of or decrease in body movements and bone fractures
- sexual dysfunction or spontaneous flow of milk from the breasts, painful erection, painful or abnormal menstruation
- swelling of feet and legs (peripheral oedema), feeling weak, unusual tiredness or weakness

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

Effects when treatment with SERRAPRESS 20 is stopped:

Feeling dizzy or shaky (tremors), sleep disturbances, anxiety, headache, nausea, feeling confused, excessive sweating, diarrhoea.

6. STORING AND DISPOSING OF SERRAPRESS 20:

Store at or below 25 °C. Protect from light.

Store tablets in the original container until required for use.

Do not use after the expiry date printed on the label or carton.

Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

KEEP ALL MEDICINES OUT OF THE REACH AND SIGHT OF CHILDREN