PATIENT INFORMATION LEAFLET

SERRAPRESS 20

SCHEDULING STATUS

S5

SERRAPRESS 20, Film coated tablets

Paroxetine

SERRAPRESS 20 contains sugar alcohol (Mannitol 133,6 mg)

Read all of this 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, pharmacist, nurse or other healthcare provider.
- 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.

What is in this leaflet

1. What SERRAPRESS 20 is and what it is used for
2. What you need to know before you take SERRAPRESS 20
3. How to take/use SERRAPRESS 20
4. Possible side effects
5. How to store SERRAPRESS 20
6. Contents of the pack and other information

1. What SERRAPRESS 20 is and what it is used for

Paroxetine (the active ingredient in SERRAPRESS 20) belongs to a group of medicines called SSRIs (selective serotonin reuptake inhibitors).

Everyone has a substance called serotonin in their brain. People who are depressed or anxious have lower levels of serotonin than others. It is not fully understood how paroxetine and other SSRIs work, but

they may help by increasing the level of serotonin in the brain. Treating depression or anxiety disorders properly is important to help you get better.

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.

2. What you need to know before you take SERRAPRESS 20

Do not take SERRAPRESS 20:

- if you are hypersensitive (allergic) to paroxetine, or to any of the ingredients of SERRAPRESS 20

(see section 6).

- 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 or thioridazine (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.
- if you are pregnant or breastfeeding your baby (see Pregnancy).

Warnings and precautions

Take special care with SERRAPRESS 20

Talk to your doctor before taking 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 film coated 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 tamoxifen (used to treat breast cancer).
- 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 are pregnant and your doctor has prescribed SERRAPRESS 20 for you in the month before your baby is due, there is a risk of excessive bleeding after childbirth.
- 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).
- medicines like SERRAPRESS 20 (so called SSRIs) may cause symptoms of sexual dysfunction (see Possible side effects). In some cases, these symptoms have continued after stopping treatment.

Take special care with SERRAPRESS 20 if you are aged over 65 years of age, as SERRAPRESS 20 may cause a reduction in the amount of sodium in your blood which may lead to symptoms such as weakness, sleepiness and lethargy. If you experience these problems, please contact your doctor as soon as possible.

Children and adolescents under 18 years

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.

Other medicines and SERRAPRESS 20

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

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
- fentanyl, mivacurium and suxamethonium (used in general anaesthesia) and tramadol or pethidine (for pain)
- lithium (used to treat depression), as SERRAPRESS 20 may increase the effect of lithium
- 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
- 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 (nonsteroidal 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)
- fosamprenavir and ritonavir used to treat HIV.

SERRAPRESS 20 with food and drink

SERRAPRESS 20 film coated 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, 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 healthcare provider for advice before taking this medicine.

Pregnancy

You should not take SERRAPRESS 20 whilst pregnant (see Do not take 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.
In late pregnancy, increased risk of persistent pulmonary hypertension with symptoms such as rapid breathing, lack of oxygen and/or heart problems. At the end of pregnancy, the increased risk of heavy vaginal bleeding shortly after birth especially in patients with a history of bleeding disorders. Therefore, SERRAPRESS 20 should not be used in pregnancy (see Do not take SERRAPRESS 20).
Your doctor may decide that it is better for you to gradually stop taking SERRAPRESS 20 while you are pregnant.

Breastfeeding

Tell the doctor if you are breastfeeding your baby. You should not be treated with SERRAPRESS 20 when breastfeeding your baby.

Fertility

SERRAPRESS 20 may influence the quality of your sperm, but the effects are reversible.

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

3. How to take/use SERRAPRESS 20

Do not share medicines prescribed for you with any other person. Always use SERRAPRESS 20 exactly

as your doctor has told you. You should check with your doctor or pharmacist if you are unsure.

Adults:

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

Children:

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 film coated 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 because you may experience unwanted side effects. If you have the impression that the effect of SERRAPRESS 20 is too strong or too weak, tell your doctor or pharmacist.

If you take/use more SERRAPRESS 20 than you should

In the event of overdosage, 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 film coated tablets.

If you forget/use to take 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 film coated tablet at the usual time. Do not take a double dose to make up for forgotten individual doses.

If you stop taking/using SERRAPRESS 20

DO NOT stop treatment with SERRAPRESS 20 until told to do so by the doctor. Your doctor will usually recommend that you stop treatment by slowly reducing the dosage over a period of several weeks. When you stop treatment with SERRAPRESS 20, especially if this is done suddenly, you may experience unwanted symptoms.

Symptoms on stopping SERRAPRESS 20 treatment may include:
Feeling dizzy or shaky (tremors), sensory disturbances such as, pins and needles, burning sensations and electric shock-like sensations sleep disturbances, anxiety, agitation, irritability, swelling headache, palpitations, nausea, feeling confused, excessive sweating, diarrhoea.

4. 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, or if you experience any untoward effects while using SERRAPRESS 20, please consult your healthcare provider for advice.

If any of the following happens, stop using SERRAPRESS 20 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
- 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 to 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 of 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
- serious skin rashes including Stevens-Johnson syndrome and toxic epidermal necrolysis.

These can appear as reddish target-like macules or circular patches often with central blisters on the trunk, skin peeling, ulcers of the mouth, throat, nose, genitals and eyes and can be preceded by fever and flu-like symptoms (very rare side effects, potentially life threatening).

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- increased or decreased appetite, weight gain, anorexia, increased risk of abdominal bleeding, increased or decreased blood sugar levels, increased cholesterol levels
- not sleeping well (insomnia) or feeling sleepy, agitation
- drowsiness, feeling dizzy or shaky (tremors), twitching, headache, fatigue
- blurred or abnormal vision
- yawning
- constipation, diarrhoea, dry mouth, nausea, vomiting, indigestion, abdominal pain, excessive gas (wind), heart burn, stomach pain, feeling bloated
- excessive sweating
- sexual dysfunction.

Less frequent side effects:

- bruising
- 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
- 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
- anisocria (characterised by unequal size of the eye pupil), mydriasis (dilation of the pupil of the eye)
- sinusitis, bronchitis, coughing, sore throat, blocked, red runny nose
- swelling in any part of the body, skin rashes or other skin conditions, sensitivity to sunlight, hair

loss

- muscle pain or weakness, joint pain, absence of or decrease in body movements and bone fractures
- 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.

The following side effects have been reported but the frequency for them to occur is not known:

- low levels of sodium in the blood
- ringing or buzzing noise in one or both ears (tinnitus)
- persistent watery diarrhoea (colitis)
- sensitivity to sunlight, hives
- heavy vaginal bleeding shortly after birth (postpartum haemorrhage) see section 2 for more information.

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 any side effects to SAHPRA via the online service for adverse drug reaction reporting by following the link: https://www.sahpra.org.za/Publications/Index/8 or http://www.sahpra.org.za/document/adverse-drug-reactions-and-quality-problem-reporting-form/. By reporting side effects, you can help provide more information on the safety of SERRAPRESS 20. You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za to ensure safety of the product.

5. How to store SERRAPRESS 20

Store all medicines out of reach of children.

HDPE bottles: Store at or below 25 °C.

Blisters: Store at or below 30 °C.

Protect from light.

Store film coated tablets in the original container until required for use.

Do not use after the expiry date stated on the 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 SERRAPRESS 20 contains:

The active ingredient is paroxetine.

Each SERRAPRESS 20 film coated tablet contains 20 mg paroxetine.

The other ingredients are:

Eudragit, magnesium stearate, mannitol, microcrystalline cellulose, Opadry AMB White, sodium starch glycolate.

What SERRAPRESS 20 looks like and contents of the pack

SERRAPRESS 20: White, round, coated, biconvex film coated tablets, diameter 10 mm, scored on one face and marked with P20 on the other.

PVC/PVDC & PVC/Aluminium blister packs of 30 film coated tablets, contained in a printed outer carton.

White cylindrical polypropylene homopolymer tube with a white natural LDPE cap, containing 30 film coated tablets.*

* *Not all pack types may be marketed*

Holder of Certificate of Registration

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This leaflet was last revised in

23 October 2023

Registration number

A38/1.2/0069

NAM

NS3 08/1.2/0101