PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S5

AROPAX CR 12,5 Controlled release tablet

AROPAX CR 25 Controlled release tablet

Each AROPAX CR 12,5 tablet contains paroxetine 12,5 mg

Contains sugar (lactose monohydrate 109,67 mg per tablet)

Each AROPAX CR 25 tablet contains paroxetine 25 mg

Contains sugar (lactose monohydrate 109,64 mg per tablet)

Read all of this leaflet carefully before you start taking AROPAX CR.

- 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 healthcare provider.
- AROPAX CR 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 AROPAX CR is and what it is used for
2. What you need to know before you take AROPAX CR
3. How to take AROPAX CR
4. Possible side effects
5. How to store AROPAX CR

6. Contents of the pack and other information.

1. What AROPAX CR is and what it is used for:

AROPAX CR belongs to a class of medicines known as SSRIs (selective serotonin reuptake inhibitors).

AROPAX CR may be prescribed for you if you suffer from any of the following:

- depression
- panic attacks - whether or not you also suffer from a fear of going into public places or open spaces (agoraphobia)
- avoid and/or are fearful of social situations.

2. What you need to know before you take AROPAX CR:

- **Do not take AROPAX CR:**
  - if you are hypersensitive (allergic) to paroxetine or any of the other ingredients of AROPAX CR
  - if you are taking or recently taken (within the last two weeks) medicines for depression called monoamine oxidase inhibitors e.g., tranylcypromine, meclobemide
  - you are taking or have recently taken (within the last two weeks) an antibiotic medicine called linezolid
  - you are taking or have recently taken (within the last two weeks) a medicine called methylthioninium chloride (methylene blue)
  - you are taking a medicine called thioridazine or pimozide (usually used to treat schizophrenia)
  - AROPAX CR should not be used in children under the age of 18 years
  - if you are pregnant.

➔ If you think any of these apply to you, **don't take** AROPAX CR until you have checked with your doctor.

Warnings and precautions:

Take special care with AROPAX CR:

Tell the doctor before you take AROPAX CR if you:

- have taken medicines for depression called monamine oxidase inhibitors and the date you stopped taking them
- have taken an antibiotic called linezolid and the date you stopped taking it
- are taking tamoxifen (used to treat breast cancer)
- you have kidney, liver or heart problems
- if your heart tracing (electrocardiogram/ECG) has an abnormality known as prolonged QT interval or you are taking medicines that may affect the QT interval in the ECG
- have ever had episodes of hyperactivity, elation and irritability (mania)
- you have ever had periods of mania alternating with periods of depression (bipolar mood disorder)
- suffer from epilepsy or have a history of fits (seizures)
- suffer from a disease where there is high pressure inside your eye (glaucoma)
- bruise or bleed easily, or are already taking a medicine that may increase bleeding
- are pregnant, may be pregnant or breastfeeding (see 'Pregnancy' below)
- are having/taking any form of antidepressant treatment
- if you are diagnosed with schizophrenia and are taking medicines to treat this condition
- medicines like AROPAX (so called SSRIs) may cause symptoms of sexual dysfunction (see section 4. Possible side effects). In some cases, these symptoms have continued after stopping treatment.

- there is an increased risk of fractures (breaking a bone) in people whilst on treatment with AROPAX CR.

  ➔Check with your doctor if you think any of these applies to you. Your doctor will decide if AROPAX CR is suitable for you, or if you need extra check-ups.

- **Take special care with AROPAX CR if you are aged over 65 years of age as** AROPAX CR 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.**

Other medicines and AROPAX CR:

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

AROPAX CR may particularly affect the action of certain other medicines such as the following:

- other antidepressants
- other medicines that affect serotonin such as, lithium, linezolid, tramadol, tryptophan, St. John's Wort, certain migraine preparations
- fentanyl, mivacurium and suxamethonium used in anaesthesia
- certain medicines used to treat patients with irregular heartbeats (dysrhythmias)
- fosamprenavir and ritonavir used to treat HIV
- tamoxifen used to treat or prevent breast cancer
- risperidone used to treat mental health problems
- atomoxetine used to treat attention deficit disorder (ADHD)
- certain medicines used to treat schizophrenia
- procyclidine, which is used to treat Parkinson's disease or other movement disorders
- metoprolol, which is used to treat high blood pressure, irregular heartbeats

(dysrhythmias) and angina

- certain medicines which may affect blood clotting and increase bleeding, such as warfarin, aspirin and other non-steroidal anti-inflammatory medicines (e.g., ibuprofen)
- certain medicines used to treat epilepsy.

➔ Tell your doctor if you are taking any of these medicines. Your doctor may decide to adjust

AROPAX CR with food and drink:

It is advisable to avoid alcohol while you are taking AROPAX CR.

AROPAX CR tablets should be administered as a single daily dose, usually in the morning, with or without food.

AROPAX CR tablets should not be chewed or crushed and should be swallowed whole.

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 professional for advice, before taking this medicine.

AROPAX CR may affect your sperm. Fertility may be reduced in some men during treatment with AROPAX CR.

Pregnancy: You should not use AROPAX CR when you are pregnant. Ask your doctor or pharmacist for advice before taking AROPAX CR. If you are already taking/using AROPAX CR and have just found out that you are pregnant, or if you are planning to become pregnant, you should talk to your doctor immediately.

A birth complication called persistent pulmonary hypertension of the newborn (PPHN) has been seen in babies whose mothers were taking antidepressants, like AROPAX CR

during pregnancy. In PPHN, the blood pressure in the blood vessels between the baby's heart and the lungs is too high.

If you take AROPAX CR near the end of your pregnancy, there may be an increased risk of excessive 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 AROPAX CR so they can advise you.

There is an increase in the risk of birth defects, particularly heart defects, in babies whose mothers take AROPAX CR during pregnancy.

Breastfeeding: Tell the doctor if you are breastfeeding your baby. You should not be treated with AROPAX CR when breastfeeding your baby.

Driving and using machines:

AROPAX CR may make you feel sleepy. You should take extra care when you are driving or operating machinery if you feel tired while taking AROPAX CR, as it may make you sleepy.

AROPAX CR contains lactose:

Patients who are intolerant to lactose should note that AROPAX CR contains a small amount of lactose. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before you start taking AROPAX CR.

AROPAX CR 12,5 mg tablets contain Sunset Yellow:

AROPAX CR 12,5 mg tablets contain the colouring agent Sunset Yellow which may cause allergic-type reactions. Check with your doctor that AROPAX CR 12,5 mg is suitable for you.

3. How to take AROPAX CR:

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

Always follow your doctor's instructions about how and when to take AROPAX CR.

Your doctor will decide how many tablets you need to take each day.

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

You should continue to take your medicine even if you do not feel better straight away, as it may take a number of weeks for AROPAX CR to work.

Keep taking AROPAX CR until the doctor tells you to stop. The doctor may tell you to continue to take AROPAX CR for several months, even if you feel better, as this will prevent your symptoms from returning. It may be necessary for the doctor to increase or decrease the dose over time. Continue to follow the doctor's instructions.

If you take more AROPAX CR than you should:

If you take more AROPAX CR than you should, you may notice the following side effects:

vomiting, your pupils are enlarged (dilated), fever, changes in your blood pressure, headache, muscle contractions, feeling agitated and anxious and a rapid heartbeat. If overdosage is severe, you could go into a 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 AROPAX CR:

If you forget to take AROPAX CR, take it as soon as you remember, then take your next dose at the normal time the next morning.

If you forget to take your medicine for a whole day, do NOT take double the dose the next day, to make up for the missed dose.

Once you have started using AROPAX CR:

You may be at an increased risk of suicidal behaviour (including suicide attempts) when treated with AROPAX CR.

Tell your doctor immediately or go to the nearest hospital if you have any distressing thoughts or experiences.

AROPAX CR will not relieve your symptoms straight away. People generally start feeling better in a few weeks or so.

Also contact your doctor if you experience any worsening of your depression/other symptoms at any time during your treatment.

You may have feelings of restlessness or agitation combined with an inability to sit or stand still, particularly during the first few weeks of treatment. If you experience these symptoms, tell your doctor as soon as possible.

If you stop taking AROPAX CR:

DO NOT stop treatment with AROPAX CR 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 AROPAX CR, especially if this is done suddenly, you may experience unwanted symptoms.

Symptoms on stopping AROPAX CR treatment may include:

- dizziness
- sensory disturbances such as, pins and needles, burning sensations and electric shock-like sensations
- sleep disturbances, including intense dreams
- agitation or anxiety
- feeling sick
- shaking or tremors
- confusion
- sweating

- headache
- diarrhoea.

These are likely to occur in the first few days of stopping treatment or if you miss a dose. However, they are more likely to occur if you stop taking AROPAX CR too quickly. Therefore always consult your doctor before stopping your medicine. If you feel that the unwanted symptoms are too severe, see your doctor who will suggest how to manage stopping treatment more slowly.

4. Possible side effects:

AROPAX CR can have side effects.

Not all side effects reported for AROPAX CR are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while taking AROPAX CR, please consult your doctor, pharmacist, or other healthcare professional.

Some people may be hypersensitive (allergic) to medicines. If any of the following happens, stop taking AROPAX CR and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the eyelids, face, lips, mouth or tongue, or throat with difficulty breathing or swallowing
- lumpy skin rash or 'hives' anywhere on the body
- itching.

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

Thoughts of suicide or worsening of your condition:

If you are depressed, you may sometimes have suicidal thoughts or thoughts of harming yourself. Since AROPAX CR takes time to work (usually about 2 weeks, but sometimes

longer), suicidal thoughts or thoughts of harming yourself may continue or increase, particularly when you start taking AROPAX CR.

You may be more likely to think like this if you:

- are a young adult
- have previously had thoughts of this nature
- have recently had a change in dose.

You may find it helpful to tell a relative or close friend that you are depressed and ask them to read this leaflet. You might ask them to tell you if they think your depression is getting worse, or if they are worried about changes in your behaviour.

If you have distressing thoughts or experiences, or if you notice that you feel worse or develop new symptoms while you're taking AROPAX CR:

➔ Contact your doctor or go to a hospital straight away.

Serotonin Syndrome and Neuroleptic Malignant syndrome:

Medicines that may increase serotonin activity in the brain can cause a condition called Serotonin Syndrome. This is a serious side effect of AROPAX CR. Taking AROPAX CR with other medicines which may also raise serotonin activity in the brain, can increase the risk of this serious side effect. Another condition called Neuroleptic Malignant Syndrome is a rare side effect of medicines used to treat mental health problems.

The symptoms of both Serotonin Syndrome and Neuroleptic Malignant Syndrome are similar.

Usually more than one of the following symptoms will occur:

- tremor
- sudden uncontrollable jerky movements
- muscle stiffness
- difficulty sitting still
- feeling very agitated or irritable

- feeling hot or sweaty
- increase in heart rate.

The severity can increase, leading to loss of consciousness.

➔ Contact your doctor urgently if you get any of these symptoms**.**

Other side effects: Tell your doctor if you notice any of the following.

Frequent side effects of AROPAX CR are:

- feeling nauseous (taking your medicine in the morning with food will reduce the chance of this happening)
- having a dry mouth
- drowsiness or weakness
- sweating
- a change in normal sexual functioning e.g., impotence, premature ejaculation
- dizziness
- feeling agitated
- tremor (uncontrolled trembling)
- blurred vision
- sleepiness, inability to sleep
- yawning
- diarrhoea, constipation (bowel movements may be hard and passed infrequently or with difficulty)
- loss of appetite
- feeling weak
- abnormal dreams (including nightmares)
- weight gain
- increase in cholesterol.

Less frequent side effects that might occur while taking AROPAX CR include:

- bruising easily or unusual bleeding especially from the skin or mucous membranes
- seeing or hearing things that are not really there (hallucinations)
- uncontrolled movements of the face, twisting movements of the body, arms and legs, tremor
- dilated pupils
- confusion
- rapid heartbeat
- low blood pressure (may cause dizziness, light-headedness or fainting when standing up from sitting or lying position
- skin rashes
- inability to urinate (pass water) or an uncontrollable, involuntary passing of urine (urine incontinence).

Other side effects experienced include:

- skin rash, which may blister, and looks like small targets (central dark spots surround by a paler area, with a dark ring around the edge) called erythema multiforme
- a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome)
- a widespread rash with blisters and skin peeling on much of the body surface (toxic epidermal necrolysis)
- fits (seizures)
- a feeling of restlessness or agitation which may be accompanied by the inability to sit or stand still (akathisia)
- uncontrollable excitement, behaviour and overactivity (mania) irresistible urge to move the legs (Restless Legs Syndrome)
- low sodium levels in the blood (especially in elderly people)
- high pressure inside the eye (acute glaucoma)

- a change in liver enzyme test results or symptoms of liver disorder which may appear as nausea, vomiting, loss of appetite, generally feeling unwell, fever, itching, yellowing of the skin and eyes, and dark coloured urine
- producing breast milk when not breastfeeding
- menstrual period disorders (including heavy periods, bleeding between periods and absence of periods)
- Postpartum haemorrhage. Postpartum haemorrhage has been reported for the therapeutic class of SSRIs
- swelling of the arms/legs
- bleeding in the stomach
- reduced number of platelets in the blood
- sensitivity of the skin to sunlight
- 'serotonin syndrome' (a collection of symptoms which can include restlessness, confusion, sweating, hallucinations, increased reflexes, muscle spasms, shivering, increased heart beat and shaking)
- increased levels of a hormone (ADH) that causes fluid or water retention.

If any symptoms become particularly troublesome, tell the doctor.

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 or pharmacist. 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 AROPAX CR.

5. How to store AROPAX CR:

Store in a dry place at a temperature not exceeding 25 °C.

Store all medicines out of reach of children.

Do not use after the expiry date stated on the pack.

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 AROPAX CR contains:

AROPAX CR tablets 12,5 mg and 25 mg contain paroxetine hydrochloride hemihydrate equivalent to 12,5 mg and 25 mg paroxetine free base, respectively.

AROPAX CR tablets contain lactose.

The other ingredients include:

Hypromellose, povidone, lactose monohydrate, magnesium stearate, colloidal silicon dioxide, glyceryl dibehenate, methacrylic acid and ethyl acrylate copolymer dispersion, talc, triethyl citrate, Opadry yellow, Opadry Pink, colourants: yellow ferric oxide (12,5 mg tablets) and red ferric oxide (25 mg tablets).

What AROPAX CR looks like and contents of the pack:

AROPAX CR 12,5: Carton containing PVC/Aluminium child -resistant blister packs of 28 or 30 tablets.

AROPAX CR 25: Carton containing PVC/Aluminium child -resistant blister packs of 28 or 30 tablets.

AROPAX CR 12,5: Yellow, round, biconvex, debossed, film-coated tablets with bevelled edges. One face is engraved with ‘GSK’ and the other face is engraved with ‘12.5’.

AROPAX CR 25: Pink, round, biconvex, debossed, film-coated tablets with bevelled edges. One face is engraved with ‘GSK’ and the other face is engraved with ‘25’.

Holder of Certificate of Registration:

GlaxoSmithKline South Africa (Pty) Ltd

39 Hawkins Avenue

Epping Industria 1, 7460

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