PATIENT INFORMATION LEAFLET FOR SERDEP 50

TABLETS

SCHEDULING STATUS

S5

SERDEP 50 (50 mg tablets)

Sertraline hydrochloride

Read all of this leaflet carefully before you start taking SERDEP 50

- 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.
- **SERDEP 50** 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 **SERDEP 50** is and what it is used for
2. What you need to know before you take **SERDEP 50**
3. How to take **SERDEP 50**
4. Possible side effects
5. How to store **SERDEP 50**
6. Contents of the pack and other information

1. What SERDEP 50 is and what it is used for:

SERDEP 50 belongs to a group of medicines called selective serotonin reuptake inhibitor (SSRI) antidepressants.

SERDEP 50 is used to treat the following conditions:

- Major depressive disorders, such as single episodes and recurrent depression.
- Obsessive- compulsive disorder (OCD).
- Panic disorder, with or without agoraphobia (fear of open places).

2. What you need to know before you take SERDEP 50

Do not take **SERDEP 50**:

- if you are allergic (hypersensitive) to sertraline or any of the other ingredients of SERDEP 50 (see **section 6**)
- if you are taking any medicines called monoamine oxidase inhibitors (MAOIs)
- If you are under the age of 18 years
- if you have liver or kidney problems.

Warnings and precautions

Take special care with **SERDEP 50:**

- If you have suffered from a manic-depressive illness
- If you have epileptic fits or a history of seizures
- If you have or have had thoughts of harming or killing yourself
- If you are being treated with electroconvulsive therapy (ECT)

- if you have diseases or conditions that affect your metabolism or your blood responses
- if you have a history of heart disease
- If you have liver problems
- If you have kidney problems.

Talk to your doctor before taking **SERDEP 50,** especially if you have:

- history of bleeding disorders, or if you are pregnant.

Other medicines and SERDEP 50

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

Do not take **SERDEP 50** with:

- Medicines called monoamine oxidase inhibitors) (MAOIs), like selegiline (to treat Parkinson's disease), moclobemide (to treat depression)
- alcohol
- Tryptophan (used to treat mental illness) or fenfluramine (used to treat weight loss).

Tell your doctor if you are taking the following medicines:

- Diazepam (sedative), tolbutamide (used to treat diabetes)
- Cimetidine (used to treat excessive stomach acid and ulcers
- Warfarin (blood thinning medicine)
- Lithium or other antidepressant medicines or anti-obsessional medicines to treat mania and depression.

SERDEP 50 with food and drink

SERDEP 50 may be taken with or without food.

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 **SERDEP 50**.

SERDEP 50 should not be taken while you are pregnant or breastfeeding your baby. Women of child-bearing age should use adequate methods of contraception when using **SERDEP 50**.

If you take **SERDEP 50** 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. You doctor or nurse should be aware that you are taking **SERDEP 50** so they can advise you.

Driving and using machines

Caution should however be taken when driving a car or operating a machine.

It is not always possible to predict to what extent **SERDEP 50** 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 **SERDEP 50** affects them.

3. How to take SERDEP 50

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

Always take **SERDEP 50** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will tell you how long your treatment with **SERDEP 50** will last. If you have the impression that the effect of **SERDEP 50** is too strong or too weak, tell your doctor or pharmacist.

The usual dose is:

Depression:

Take 1 tablet (50 mg) daily.

The starting dose is 50 mg daily. Your doctor may choose to increase your dosage at 2 weekly intervals to a maximum of 150-200 mg.

Obsessive-Compulsory Disorders:

The minimum effective dose is 50 mg tablet daily.

Your doctor may choose to increase your dosage at 2 weekly intervals.

Panic Disorder:

Starting dose is a half 50 mg tablet daily (25 mg).

After one week, the dose will be increased to 50 mg tablet daily**.**

Elderly:

Adult dose is recommended.

Children:

Children should not take **SERDEP 50.**

When discontinuing treatment, a gradual reduction in the dose rather than an abrupt stop is recommended.

If you take more SERDEP 50 than you should

If you take more **SERDEP 50** than you should, you may experience an increase in side effects listed below (see **section 4**).

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

If you forget to take SERDEP 50

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

SERDEP 50 can have side effects.

Not all side effects reported for **SERDEP 50** are included in this leaflet. Should your general

health worsen or if you experience any untoward effects while taking **SERDEP 50**, please consult your healthcare provider for advice.

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

- rash
- palpitations
- agitation
- diarrhoea/loose stools
- if you develop yellow skin and eyes which may mean liver damage
- excessive sweating
- depressive symptoms.

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:

- decreased appetite, increased appetite, nausea, stomach disorders, shaking, dizziness, insomnia (difficulty sleeping), sleepiness, dry mouth, sexual disorders (loss of sex drive and delay in ejaculation in men).

Side effects with unknown frequency:

- Headache, skin tingling, twitching, uncontrolled muscle movements
- Constipation, vomiting, flatulence, abdominal pain
- Fatigue, hot flushes, fever and back pain

- Thirst
- Muscle pain
- nervousness, anxiety, yawning, impaired concentration, feeling strange
- heavy vaginal bleeding shortly after birth
- Menstrual irregularities
- Running nose
- Abnormal vision, tinnitus and taste perversion
- Urinary disorders.

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

Side effects may also be reported directly to Cipla Medpro (Pty) Ltd: drugsafetysa@cipla.com.

By reporting side effects, you can help provide more information on the safety of **SERDEP 50.**

5. How to store SERDEP 50

Store all medicines out of reach of children.

Store in the original packaging, protected from light at a temperature below 25°C.

Do not use after the expiry date stated on the packaging material.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems, for example toilets.

6. Contents of the pack and other information

What SERDEP 50 contains

The active substance is sertraline hydrochloride equivalent to 50 mg sertraline.

The other ingredients are magnesium stearate, maize starch, microcrystalline cellulose, purified talc, sodium starch glycollate.

Flexicoat Protect Blue V6 (coating material) contains blue no 2 lake, carmoisine lake (E122), kollicoat protect, talc and titanium dioxide (E171).

What SERDEP 50 looks like and contents of the pack

Blue, oblong, film-coated, biconvex tablets with a central breakline on one side and plain on the other.

Blister strips of 10 tablets packed in 30’s.

Holder of certificate of registration

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This leaflet was last revised

August 2021

Registration number

38/1.2/0020