PATIENT INFORMATION LEAFLET FOR SERDEP 100 TABLETS

SCHEDULING STATUS

S5

PROPRIETARY NAME (STRENGTH AND DOSAGE FORM)

SERDEP 100 (Tablets)

COMPOSITION

Each SERDEP 100 tablet contains sertraline hydrochloride 112 mg equivalent to 100 mg sertraline.

Other inactive ingredients include:

Core Tablet:

Calcium hydrogen phosphate dihydrate, magnesium stearate, maize starch, microcrystalline cellulose and sodium starch glycolate.

Film Coating:

Ferric oxide (yellow), hypromellose (methocel E50LV premium), propylene glycol, purified talc and Titanium dioxide.

Sugar Free

INDICATIONS

Sertraline is a selective serotonin reuptake inhibitor (SSRI). It is used for the treatment of depression, panic disorder, and obsessive-compulsive disorder (OCD). It helps to elevate mood by treating depression and reduces panic attacks and the unpleasant thoughts associated with OCD.

BEFORE TAKING THIS MEDICINE

Contra-indications

This medication should not be used by anyone who:

- is allergic to sertraline or any of the ingredients of this product.
- is taking a MAO inhibitor (e.g. phenelzine, tranylcypromine, meclobemide) or has taken a MAO inhibitor within the last 14 days.
- is taking pimozide.

Precautions and Warnings

Caution is recommended when sertraline is taken by people with a history of seizures. The medicine should be stopped in anyone who develops seizures.

Occupational Hazards: This medicine may impair judgment, thinking, or motor skills, and people taking it are advised to avoid driving a car or operating hazardous machinery until they are reasonably certain that the medicine treatment does not.

Children: The safety and effectiveness of sertraline in children below the age of 18 have not been established.

Talk to your doctor before taking SERDEP 100 tablets if you have suffered from bleeding disorders or have been taking medicines which thin the blood (e.g. acetylsalicylic acid (aspirin or warfarin) or may increase the risk of bleeding, or if you are pregnant (see **"Pregnancy and Breastfeeding"**).

INTERACTIONS

Medicine Interactions: Sertraline can interact with a number of medicines. Be sure to tell any health professional of all the medicines you are taking, including those that can be bought without a prescription.

Special precautionary monitoring is advised with the following

Protein bound medicines

Serotonergic agents

Non-steroidal anti-inflammatory drugs (NSAIDS)

Acetylsalicylic acid (aspirin)

If you are taking other medicines on a regular basis, concomitant use of this medicine may cause undesirable interactions. Please consult your doctor or pharmacist.

Pregnancy and Breastfeeding: The safety of sertraline during pregnancy and breastfeeding has not been established and therefore, it should not be used in women of childbearing potential or nursing mothers, unless, in the opinion of the physician, the potential benefits to the patient outweigh the possible risks to the unborn child.

If you take SERDEP 100 tablets 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 SERDEP 100 tablets so they can advise you.

If you are breastfeeding your baby while taking this medicine please consult your doctor, pharmacist or health care professional for advice.

HOW TO TAKE THIS MEDICINE

Recommended dose ranges from 50 mg to 200 mg once daily taken with food at the evening meal.

SIDE-EFFECTS

Not all side-effects reported for this medicine are included in this leaflet. If your general state of health worsens while taking this medicine, please consult your doctor.

The most common side-effects associated with the use of sertraline are: nausea, diarrhoea/loose stools (especially at beginning of therapy) and heartburn; male sexual problems; insomnia and drowsiness; tremor: increased sweating and dry mouth; and dizziness.

Frequency unknown: Heavy vaginal bleeding shortly after birth (postpartum haemorrhage) has been reported. See **"Pregnancy and Breastfeeding"** for more information.

STORAGE AND DISPOSAL INFORMATION

DO NOT SHARE MEDICINES PRESCRIBED FOR YOU WITH OTHERS.

Store in a dry place at or below 25 °C. Protect from light. Keep the blisters in the outer carton until required for use.

KEEP OUT OF REACH OF CHILDREN.

PRESENTATION

Blister strips of 10 tablets packed in 30’s in a carton.

IDENTIFICATION

Yellow coloured, round, biconvex, film coated tablets with a score line on one side and plain on the other side.

REGISTRATION NUMBER

A38/12.2/0617

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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