

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### Sertraline 50 mg and 100 mg film-coated Tablets

#### Sertraline hydrochloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you:

- Keep this leaflet as you may wish to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes possible side effects not listed in this leaflet.



What is in this leaflet:

1. What Sertraline film-coated Tablets are and what they are used for
2. What you need to know before you take Sertraline film-coated Tablets
3. How to take Sertraline film-coated Tablets
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#### 1. What Sertraline film-coated Tablets are and what they are used for

Sertraline is one of a group of medicines called selective serotonin re-uptake inhibitors (SSRI) antidepressants.

Sertraline is used to treat:

- depression and prevention of recurrence of depression (in adults)
- social anxiety disorder (in adults)
- Post traumatic stress disorder (in adults)
- Panic disorder (in adults)
- Obsessive compulsive disorder (OCD) (in adults and children and adolescents aged 6-17 years old).

#### 2. What you need to know before you take Sertraline film-coated Tablets

Do not take Sertraline:

- If you are allergic (hypersensitive) to Sertraline or any of the other ingredients in Sertraline film-coated Tablets (listed in Section 6). An allergy may include rash, itching, swollen face or lips or shortness of breath.
- If you are taking medicines known as non-selective monoamine oxidase inhibitors (also called MAOIs) or reversible MAOIs type A which are also used to treat depression), since serious or even fatal reactions can occur. Treatment with Sertraline should only be started 2 weeks after discontinuation of an irreversible MAOI (for instance tranylcypromine). However treatment with Sertraline can be started the following day after discontinuation of certain MAOIs called reversible MAOI-A (for instance moclobemide). Do not take any MAOIs for at least five weeks after you stop taking Sertraline. If Sertraline has been prescribed for a long period and/or at a high dose, a longer interval needs to be considered by your doctor. Examples of MAOIs include nialamide, iproniazide, selegiline, phenelzine, moclobemide, tranylcypromine, isocarboxazid and tolaxatone.
- If you are taking pimozide
- If you have significant liver problems (you will appear jaundiced)
- If you are less than 6 years old with symptoms of OCD
- If you are under the age of 18 and feeling depressed (see next section)

#### Warnings and precautions

Talk to your doctor or pharmacist before taking Sertraline

- If you develop a rash or other allergic reactions (like itching, swollen lips or face or shortness of breath), stop taking the tablets straight away and contact your doctor immediately
- If you start to experience fever, muscle stiffness or tremor, changes in your mental state like confusion, irritability and extreme agitation; you may suffer from the so called serotonin syndrome or neuroleptic malignant syndrome. Although this syndrome occurs rarely it may result in potentially life threatening conditions, contact your doctor immediately, the use of Sertraline might need to be discontinued.
- If you have epilepsy or have had a fit in the past; if you have a fit (seizure) or experience an increase in seizure frequency, contact your doctor immediately, the use of Sertraline might need to be discontinued.
- If you have diabetes. You may need to adjust your dose of insulin or other antidiabetic treatment.
- If you have any kidney or liver problems, you should discuss this with your doctor, as he may wish to reduce the dose.
- If you have any heart problems
- If you are taking diuretics (water tablets), especially when you are elderly
- If you have suffered from mania in the past; if you have a manic episode, contact your doctor immediately, the use of sertraline might need to be discontinued.
- If you have a history of bleeding disorders or you develop bruises or unusual bleeding or if you are using medicinal products that effect the coagulation of blood (see 'Other medicines and Sertraline').
- If you are having Electroconvulsive therapy (ECT)

#### Thoughts of suicide and worsening of your depression or anxiety disorder

- 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 all take time to work, usually about two weeks but sometimes longer. You may be more likely to think like this:
- If you have previously had thoughts about killing or harming yourself.
- If you are a young adult. Information from clinical trials has shown an increased risk of suicidal behaviour in adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant.
- If you have thoughts of harming or killing yourself at any time, **contact your doctor or go to a hospital straight away.** 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 Sertraline

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, (up to five weeks ago) including medicines obtained without prescription. This medicine may affect the way some other medicines work (interaction). An interaction could occur with:

- MAOIs (used to treat depression). Non-selective MAOIs and MAOIs type A (moclobemide) should not be used with Sertraline as serious or even fatal reactions (serotonin syndrome) can occur (see section "Do not take"). MAO inhibitors type B (selegiline) can be used with Sertraline film-coated Tablets provided that your doctor monitors you closely.
- Lithium, tryptophan; there is an increased risk of serotonin syndrome when these drugs are co-administered with Sertraline film-coated Tablets. When Sertraline is used in combination with lithium your doctor will carry out more frequent check-ups.
- Tramadol (a painkiller) or triptans (for migraine) or fenfluramine (for eating suppression); there is an increased risk of hypertension
- Tricyclic antidepressants (for example imipramine, desipramine and amitriptyline); because Sertraline film-coated Tablets may possibly change the blood levels of these medicines, your doctor may need to lower their dose when administered with Sertraline film-coated Tablets.
- Warfarin or anti-inflammatory drugs, such as ibuprofen, naproxen, diclofenac, indometacin which thin the blood; Sertraline may alter the effect of these medicines on the blood. If treatment with Sertraline is started or stopped when you are taking warfarin, your doctor will need to perform certain tests.
- You should not start to take the herbal remedy St John's Wort while you are being treated with Sertraline since this may result in an increase of undesirable effects. If you are already taking St John's Wort when you start on Sertraline, stop taking the St John's Wort and tell your doctor at your next visit.

#### Sertraline with food, drink and alcohol

You should avoid alcohol while you are taking this medicine. You can take your tablets with or separately from food.

#### Children and adolescents

Sertraline should not be used by depressed children and adolescents under the age of 18. Children aged 6 years and older who have been diagnosed with OCD by a specialist may be prescribed Sertraline tablets.

#### Pregnancy, breastfeeding and fertility

##### Pregnancy

If you are a woman of childbearing age, you are advised to use contraception whilst taking Sertraline tablets. If you are pregnant, intend to get pregnant or become pregnant whilst taking Sertraline ask your doctor or pharmacist for advice before taking any medicine.

Make sure your midwife and/or doctor know you are on Sertraline. When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like Sertraline may increase the risk of a serious condition in babies, called persistent pulmonary hypertension of the new born (PPHN), making the baby breathe faster and appear bluish. These symptoms usually begin during the first 24 hours after the baby is born. If this happens to your baby you should contact your midwife and/or doctor immediately.

### Breast-feeding

Sertraline is excreted in breast milk and can cause side effects in babies. You should only breast-feed if it is clearly necessary. If breastfeeding is continued, your doctor may prescribe a lower dose of Sertraline.

### Fertility

Some medicines like sertraline may reduce the quality of sperm in animal studies. Theoretically, this could affect fertility, but impact on human fertility has not been observed as yet.

### Driving and using machines

Some medicines may affect your judgement or co-ordination. Do not drive or use machinery unless you are sure that you are not affected.

## 3. How to take Sertraline film-coated Tablets

Sertraline may be prescribed for depressive illness (adults only), obsessive compulsive disorder (OCD) and post traumatic stress disorder (women only). Your doctor will tell you how many tablets to take, and when to take them. The tablets should not be chewed or crushed; they should always be swallowed whole, with a drink of water.

### Dosage information

Your doctor may start you on lower strength of Sertraline (e.g.25mg), but check with your doctor or pharmacist if you are not sure of the correct dose.

- **Depression:** The recommended dose is 50 mg daily. Your doctor will review and adjust your dosage if necessary. The dose should be increased carefully to ensure that you receive the lowest effective dose. You may not feel better immediately when you first start taking your medicine for depression. This is usual because an improvement in depressive symptoms may not occur until after the first few weeks. Patients with depression should be treated for a period of at least 6 months.
- **OCD:** The recommended adult and adolescent (13-17yr old) dose is 50 mg daily; children aged 6-12yr old should only initially be given 25mg daily. Your doctor/specialist will review and adjust your dosage if necessary. When appropriate the dosage can be gradually increased up to a maximum of 200 mg.
- **PTSD, Panic Disorder and Social Anxiety Disorder:** The recommended dose is 25mg daily increasing to 50mg a day after a week. Your treatment will be reviewed if there is no improvement after a few weeks.

Sertraline should NOT be used in children under the age of 6

### If you take more Sertraline film-coated Tablets than you should

If you take too many tablets, go to your nearest hospital emergency department (or casualty) or tell your doctor straight away. Take the pack of Sertraline tablets with you if you can. Symptoms of overdose include: nausea, vomiting, seizures, heart problems (like irregular heart beat and cardiac arrest), lung problems and change in mental condition ranging from agitation to coma.

### If you forget to take Sertraline film-coated Tablets

If you forget to take your dose, do not worry. Take your next dose the next day at the usual time. Do not take a double dose to make up for a forgotten individual dose. Taking your medicine at the same time each day may help you to remember to take it regularly.

### If you stop taking Sertraline film-coated Tablets

Always follow your doctor's instructions on how many Sertraline film-coated Tablets to take and for how long to take them. Keep taking your medicine until your doctor asks you to stop. Do not stop taking your medicine without asking your doctor first, even when you start to feel better. Make sure you do not run out of tablets.

When your doctor does instruct you to stop taking Sertraline he/she will help you to reduce your dose slowly over one to two weeks – this should help reduce the chance of withdrawal effects.

You may notice the following effects when you stop taking Sertraline: dizziness; tingling feelings like pins and needles; sleep disturbances (vivid dreams, nightmares, inability to sleep); feeling restless or agitated; unusual tiredness or weakness; feeling anxious; nausea/vomiting (feeling sick/being sick); tremor (shakiness); headaches.

Most people find that any symptoms on stopping Sertraline (under guidance from your doctor) are mild and go away on their own within a few weeks. If you experience symptoms when you stop treatment, contact your doctor.

## 4. Possible side effects

Like all medicines, Sertraline may sometimes cause side effects, as well as the effects that are needed.

### Tell your doctor immediately if:

- You have distressing thoughts, thoughts of harming yourself or committing suicide
- You get a rash or an allergic reaction such as itching, swollen lips, tongue or face, wheezing or shortness of breath. If this happens, stop taking the tablets straight away and tell your doctor immediately.

- A combination of symptoms (known as Serotonin Syndrome), including unexplained fever with faster breathing or heart rate, sweating, muscle stiffness or tremor, confusion, extreme agitation or sleepiness (only rarely).
- Feelings of weakness, drowsiness or confusion mostly in elderly people and in (elderly) people on diuretics (water tablets)
- Irritability and extreme agitation
- Light headedness upon standing and palpitations

If you have any of the following and they bother you, or last for some time, tell your doctor or a pharmacist:

- **Whole body** - chills, sensitivity to sunlight, weight loss
- **Digestive system** - diarrhoea and stomach upsets indigestion, difficulty swallowing or a change in taste, or a dry mouth. Abnormal liver function has been reported rarely, with very rare cases of hepatitis.
- **Nervous system** - headache, sleep problems or unusual dreams, dizziness, poor appetite, tiredness, abnormally high mood, uncontrollable movements, fits, extreme restlessness, hallucinations, untypical wild behaviour, confusion, agitation, anxiety, nervousness, not being able to concentrate or think properly, panic attacks or thoughts of suicide or harming yourself.
- **Urogenital system and reproductive disorders** – difficulty passing urine or passing urine too frequently, poor sexual performance, prolonged erections and producing breast milk
- **Other** - hair loss, yawning, blurred vision, unexplained bruising or bleeding, sweating, hot flushes, feeling dizzy when you stand up, or joint or muscle pain, low levels of sodium in the blood
- **An increased risk of bone fractures has been observed in patients taking this type of medicine.**

Most of these are usually nothing to worry about and go away after the first few weeks while you are taking your medicine.

If any of the side effects get serious or you notice any other side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

**Do not stop taking Sertraline film-coated Tablets until your doctor tells you to.**

## 5. How to store Sertraline film-coated Tablets

This medicinal product does not require any special storage conditions. Do not use Sertraline film-coated Tablets after the expiry date which is stated on the carton and the blister. The expiry date refers to the last day of that month. Keep your Sertraline film-coated Tablets in a safe place out of the reach and sight of children. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## 6. Contents of the pack and other information

### What Sertraline film-coated Tablets contain

- The active substance is sertraline hydrochloride
- The other ingredients are cellulose microcrystalline, calcium hydrogen phosphate dihydrate, colloidal silica, sodium starch glycolate, hydroxypropyl cellulose, magnesium stearate, polysorbate 80, hypromellose, titanium dioxide (E171), propylene glycol.

### What Sertraline film-coated Tablets look like and contents of the pack

Sertraline 50mg and 100mg film-coated Tablets are white tablets, and marked with either '50' or '100' on one side, and 'S' and 'ET' on the other side.

Your Sertraline film-coated Tablets are presented in blister packs. They are supplied in boxes containing 28, 30 or 100 tablets. Not all pack sizes may be marketed.

### Marketing Authorisation Holder and Manufacturer:

Dr. Reddy's Laboratories (UK) Ltd, 6 Riverview Road, Beverley, HU17 0LD

Sertraline 50mg film-coated Tablets: PL08553/0243  
Sertraline 100mg film-coated Tablets: PL08553/0244

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