

Package leaflet: Information for the patient

Bellsert 50 mg film – coated Tablets Sertraline (as hydrochloride)

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

- Keep this leaflet. You may need 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 any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Bellsert is and what it is used for

BELLSERT contains the active ingredient sertraline.

BELLSERT is one of a group of medicines called Selective Serotonin Re-uptake Inhibitors (SSRIs); these medicines are used to treat depression and/or anxiety disorders.

BELLSERT can be used to treat:

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

Depression is a clinical illness with symptoms like feeling sad, unable to sleep properly or to enjoy life as you used to.

OCD and Panic disorders are illnesses linked to anxiety with symptoms like being constantly troubled by persistent ideas (obsessions) that make you carry out repetitive rituals (compulsions).

PTSD is a condition that can occur after a very emotionally traumatic experience, and has some symptoms that are similar to depression and anxiety. Social anxiety disorder (social phobia) is an illness linked to anxiety. It is characterised by feelings of intense anxiety or distress in social situations (for example: talking to strangers, speaking in front of groups of people, eating or drinking in front of others or worrying that you might behave in an embarrassing manner).

Your doctor has decided that this medicine is suitable for treating your illness.

You should ask your doctor if you are unsure why you have been given BELLSERT.

2. What you need to know before you take BELLSERT

Do not take BELLSERT:

- If you are **allergic** (hypersensitive) to **sertraline** or any of the other ingredients of this medicine (listed in section 6).
- If you are taking or have taken medicines called **monoamine oxidase inhibitors** (MAOIs such as selegiline, moclobemide) or MAOI like drugs (such as linezolid). If you stop treatment with sertraline, you must wait until at least one week before you start treatment with a MAOI. After stopping treatment with a MAOI, you must wait at least 2 weeks before you can start treatment with sertraline.
- If you are taking another medicine called **Pimozide** (a medicine for mental disorders such as psychosis).

Warnings and precautions

Medicines are not always suitable for everyone. Talk to your doctor or pharmacist before you take BELLSERT, if you suffer from or have suffered in the past from any of the following conditions:

- Epilepsy or a history of seizures. If you have a fit (seizure), contact your doctor immediately.
- If you have suffered from manic depressive illness (bipolar disorder) or schizophrenia. If you have a manic episode, contact your doctor immediately.
- If you have or have previously had thoughts of harming or killing yourself (see below – Thoughts of suicide and worsening of your depression or anxiety disorder)
- Serotonin Syndrome or Neuroleptic Malignant Syndrome. In rare cases this syndrome may occur when you are taking certain medicines at the same time as sertraline. (For symptoms, see section 4. Possible Side Effects).
Your doctor will have told you whether you have suffered from this in the past.
- If you have low sodium level in your blood, since this can occur as a result of treatment with Sertraline. You should also tell your doctor if you are taking certain medicines for hypertension, since these medicines may also alter the sodium level in your blood.
- Take special care if you are elderly as you may be more at risk of having low sodium level in your blood (see above).
- Liver disease; your doctor may decide that you should have a lower dose of Sertraline.
- Diabetes; your blood glucose levels may be altered due to BELLSERT and your diabetes medicines may need to be adjusted.
- If you have suffered from bleeding disorders or have been taking medicines which thin the blood (eg acetylsalicylic acid (aspirin), or warfarin) or may increase the risk of bleeding.
- If you are a child or adolescent under 18 years old. Sertraline should only be used to treat children and adolescents aged 6-17 years old, suffering from obsessive compulsive disorder (OCD). If you are being treated for this disorder, your doctor will want to monitor you closely (see Use in children and adolescents).
- If you are having electro-convulsive therapy (ECT).
- If you have eye problems such as certain kinds of glaucoma (increased pressure in the eye)

If your doctor is planning to carry-out a urine test to detect the presence of a drug called benzodiazepines, tell your doctor that you are taking sertraline or have taken it before several days. This is because this medicine may affect the results of the tests.

Restlessness/ Akathisia

The use of sertraline has been linked to a distressing restlessness and need to move, often being unable to sit or stand still (akathisia). This is most likely to occur during the first few weeks of treatment. Increasing the dose may be harmful so if you develop such symptoms you should talk to your doctor.

Withdrawal reactions

Side effects relating to stopping treatment (withdrawal reactions) are common, particularly if the treatment is stopped suddenly (see section 3 If you stop taking Bellsert and section 4 Possible side effects). The risk of withdrawal symptoms depends on the length of treatment, dosage, and the rate at which the dose is reduced. Generally, such symptoms are mild to moderate. However, they can be serious in some patients. They normally occur within the first few days after stopping treatment. In general, such symptoms disappear on their own and wear off within 2 weeks.

In some patients they may last longer (2-3 months or more). When stopping treatment with sertraline it is recommended to reduce the dose gradually over a period of several weeks or months and you should always discuss the best way of stopping treatment with your doctor.

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.

Use in children and adolescents

BELLSERT should not usually be used in children and adolescents less than 18 years old, except for patients with Obsessive Compulsive Disorder (OCD). Patients under 18 have an increased risk of undesirable effects, such as suicide attempt, thoughts of harming or killing themselves (suicidal thoughts) and hostility (mainly aggressiveness, oppositional behaviour and anger) when they are treated with this class of medicines. Nevertheless, it is possible that your doctor decides to prescribe BELLSERT to a patient under 18 if it is in the patient's interest. If your doctor has prescribed BELLSERT to you and you are less than 18 years old and you want to discuss this, please contact him/her. Furthermore, if any of the symptoms listed above appear or worsen while you are taking BELLSERT, you should inform your doctor. Also, the long-term safety of BELLSERT in regard to growth, maturation and learning (cognitive) and behavioural development in this age group has not yet been demonstrated.

Other medicines and BELLSERT:

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Some medicines can affect the way BELLSERT works, or BELLSERT itself can reduce the effectiveness of other medicines taken at the same time.

Taking BELLSERT together with the following medicines may cause serious side effects:

- Medicines called monoamine oxidase inhibitors (MAOIs), like moclobemid (to treat depression) and selegiline (to treat Parkinson's disease) the antibiotic linezolid and methylene blue (to treat high levels of methaemoglobin in the blood). Do not use BELLSERT together with these medicines.

- Medicines to treat mental disorders such as psychosis (pimozide). Do not use BELLSERT together with pimozide.

Talk to your doctor if you are taking the following medicines:

- Herbal medicine containing St. John's Wort (*Hypericum perforatum*). The effects of St. John's Wort may last for 1-2 weeks.
- Products containing the amino acid tryptophan.
- Medicines to treat severe pain (e.g. tramadol).
- Medicines used in anaesthesia or to treat chronic pain (fentanyl)
- Medicines to treat migraines (e.g. sumatriptan).
- Blood thinning medicine (warfarin).
- Medicines to treat pain/arthritis (Non steroidal anti-inflammatory drug (NSAID) such as ibuprofen, acetylsalicylic acid (aspirin).
- Sedatives (diazepam).
- Diuretics (also called 'water tablets').
- Medicines to treat epilepsy (phenytoin, phenobarbital, carbamazepine).
- Medicines to treat diabetes (tolbutamide).
- Medicines to treat excessive stomach acid, ulcers and heartburn (cimetidine, omeprazole, lansoprazole pantoprazole, rabeprazole).
- Medicines to treat mania and depression (lithium).
- Other medicines to treat depression (such as amitriptyline, nortriptyline, nefazodone, fluoxetine, fluvoxamine).
- Medicines to treat schizophrenia and other mental disorders (such as perphenazine, levomepromazine and olanzapine).
- Medicines used to treat high blood pressure, chest pain or regulate the rate and rhythm of the heart (such as verapamil, diltiazem, flecainide, propafenone).
 - Medicine used to treat bacterial infections (rifampicin, clarithromycin, telithromycin, erythromycin).
 - Medicines used to treat fungal infections (such as ketoconazole, itraconazole, posaconazole, voriconazole, fluconazole)
 - Medicines used to treat HIV/AIDS and Hepatitis C (protease inhibitors such as ritonavir, telaprevir).
 - Medicines used to prevent nausea and vomiting after an operation or chemotherapy (aprepitant).

BELLSERT with food, drink and alcohol:

BELLSERT can be taken with or without food.

Alcohol should be avoided whilst taking BELLSERT.

Sertraline should not be taken in combination with grapefruit juice, as this may increase the level of sertraline in your body.

Pregnancy, breast-feeding and fertility:

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

The safety of sertraline has not fully been established in pregnant women. BELLSERT will only be given to you when pregnant if your doctor considers that the benefit for you is greater than any possible risk to the developing baby. If you are a woman capable of having children you should use a reliable method of contraception (such as the contraceptive pill) when taking sertraline.

Make sure your midwife and/or doctor know you are on BELLSERT. When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like BELLSERT may increase the risk of a serious condition in babies, called persistent pulmonary hypertension of the newborn (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.

Your new born baby might also have other conditions, which usually begin during the first 24 hours after birth. Symptoms include:

- **Trouble with breathing**
- **A blueish skin or being too hot or cold**
- **Blue lips**
- **Vomiting or not feeding properly**
- **Being very tired, not able to sleep or crying a lot**
- **Stiff or floppy muscles**
- **Tremors, jitters or fits**
- **Increased reflux reactions**
- **Irritability**
- **Low blood sugar**

If your baby has any of these symptoms when it is born, or you are concerned about your baby's health, contact your doctor or midwife who will be able to advise you.

There is evidence that sertraline passes into human breast milk. Sertraline should only be used in women during breast-feeding, if your doctor considers that the benefit exceeds any possible risk to the baby.

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 yet.

Driving and using machines

Psychotropic drugs such as BELLSERT may influence your ability to drive or use machines. You should therefore not drive or operate machinery, until you know how this medication affects your ability to perform these activities.

3. How to take BELLSERT

Always take this medicine exactly as your doctor has told you.
BELLSERT tablets may be taken with or without food.
Take your medication once daily either in the morning or evening.
You should check with your doctor or pharmacist if you are not sure.

The recommended dose is:

Adults:

Depression and Obsessive Compulsive Disorder

For depression and OCD, the usual effective dose is 50 mg/day. The daily dose may be increased in 50 mg increments and at intervals of at least one week over a period of weeks. The maximum recommended dose is 200 mg/day.

Panic disorder, Social anxiety disorder and Post Traumatic Stress Disorder

For panic disorder, social anxiety disorder and post traumatic stress disorder, treatment should be started at 25 mg/day, and increased to 50 mg/day after one week.

The daily dose then may be increased in 50 mg increments over a period of weeks. The maximum recommended dose is 200 mg/day.

Children and adolescents:

BELLSERT must only be used to treat children and adolescents suffering from OCD aged 6-17 years old.

Obsessive Compulsive Disorder

Children aged 6 to 12: the recommended starting dose is 25 mg daily.

After one week, your doctor may increase this to 50 mg daily. The maximum dose is 200 mg daily.

Adolescents aged 13 to 17: the recommended starting dose is 50 mg daily.

The maximum dose is 200 mg daily.

If you have liver or kidney problems, please tell your doctor and follow the doctor's instructions.

Your doctor will advise you on how long to take this medication for. This will depend on the nature of your illness and how well you are responding to the treatment. It may take several weeks before your symptoms begin to improve. Treatment of depression should usually continue for 6 months after improvement.

If you take more BELLSERT than you should

If you accidentally take too much BELLSERT contact your doctor at once or go to the nearest hospital casualty department. Always take the labelled medicine package with you, whether there is any medication left or not.

Symptoms of overdose may include drowsiness, nausea and vomiting, rapid heart rate, shaking, agitation, dizziness and in rare cases unconsciousness.

If you forget to take BELLSERT

If you forget to take a dose, do not take the missed dose. Just take the next dose at the right time. Do not take a double dose to make up for a forgotten dose.

If you stop taking BELLSERT

Do not stop taking BELLSERT unless your doctor tells you to. Your doctor will want to gradually reduce your dose of BELLSERT over several weeks, before you finally stop taking this medicine. If you suddenly stop taking this medicine you may experience side effects such as dizziness, numbness, sleep disturbances, agitation or anxiety, headaches, feeling sick, being sick and shaking. If you experience any of these side effects, or any other side effects whilst stopping taking BELLSERT, please speak to your doctor.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you get any side effects talk to your doctor, or pharmacist. This includes any side effects not listed in this leaflet.

Nausea is the most common side effect. The side effects depend on the dose and often disappear or lessen with continued treatment.

Tell your doctor immediately:

If you experience any of the following symptoms after taking this medicine, these symptoms can be serious.

- If you develop a severe skin rash that causes blistering (erythema multiforme), (this can affect the mouth and tongue). These may be signs of a condition known as Stevens Johnson Syndrome, or Toxic Epidermal Necrolysis (TEN). Your doctor will stop your treatment in these cases.
- Allergic reaction or allergy, which may include symptoms such as an itchy skin rash, breathing problems, wheezing, swollen eyelids, face or lips.
If you experience agitation, confusion, diarrhoea, high temperature and blood pressure, excessive sweating and rapid heartbeat. These are symptoms of Serotonin Syndrome. In rare cases this syndrome may occur when you are taking certain medicines at the same time as sertraline. Your doctor may wish to stop your treatment.
- If you develop yellow skin and eyes which may mean liver damage.
- If you experience depressive symptoms with ideas of harming or killing yourself (suicidal thoughts).
- If you start to get feelings of restlessness and are not able to sit or stand still after you start to take BELLSERT. You should tell your doctor if you start to feel restless.
- If you have a fit (seizure)
- If you have a manic episode (see section2 “**Warnings and precautions**”)

The following side effects were seen in clinical trials in adults.

Very common side effects (occurs in more than 1 out of 10 patients)

- insomnia, dizziness, sleepiness, headache, diarrhoea, feeling sick, dry mouth, ejaculation failure, fatigue.

Common side effects (occurs in between 1 and 10 out of 100 patients)

- sore throat, anorexia, increased appetite
- depression, feeling strange, nightmare, anxiety, agitation, nervousness, decreased sexual interest, teeth grinding
- numbness and tingling, shaking, muscle tense, abnormal taste, lack of attention
- visual disturbance, ringing in ears
- palpitations, hot flush, yawning
- abdominal pain, vomiting, constipation, upset stomach, gas
- rash, increased sweating, muscle pain, erectile dysfunction, chest pain
- joint pain
- malaise

Uncommon side effects (occurs in between 1 and 10 out of 1.000 patients):

- chest cold, runny nose
- hypersensitivity
- low thyroid hormones
- hallucination, feeling too happy, lack of caring, thinking abnormal, aggression
- convulsion, involuntary muscle contractions, abnormal coordination, moving a lot, amnesia, decreased feeling, speech disorder, dizziness while standing up, passing out, migraine
- enlarged pupils
- ear pain, fast heartbeat, high blood pressure, flushing
- breathing difficulty, possible wheezing, shortness of breath, nose bleed
- inflammation of the oesophagus, difficulty swallowing, haemorrhoids, increased saliva, tongue disorder, burping
- eye swelling, purple spots on skin, face oedema, hair loss, cold sweat, dry skin, hives, itching
- osteoarthritis, muscular weakness, back pain, muscle twitching
- night time urination, unable to urinate, increase in urination, increase in frequency of urination, problem urinating, urinary incontinence

- vaginal haemorrhage, sexual dysfunction, female sexual dysfunction, menstrual irregularities, swelling in legs, chills, fever, weakness, thirst, increase in liver enzyme levels, weight decreased, weight increased.

Rare side effects (occurs in between 1 and 10 out of 10.000 patients):

- intestine problem, ear infection, cancer, swollen glands, high cholesterol, low blood sugar
- physical symptoms due to stress or emotions, drug dependence, psychotic disorder, paranoia, suicidal thoughts, sleep walking, premature ejaculation
- severe allergic reaction
- coma, abnormal movements, difficulty moving, increased sensation, sensory disturbance
- glaucoma, tear problem, spots in front of eyes, double vision, light hurts eye, blood in the eye, problems controlling blood sugar levels (diabetes)
- heart attack, slow heart beat, heart problem, poor circulation of arms and legs, closing up of throat, breathing fast, breathing slow, difficulty talking, hiccups
- blood in stool, sore mouth, tongue ulceration, tooth disorder, tongue problem, mouth ulceration, problems with liver function
- skin problem with blisters, hair rash, hair texture abnormal, skin odour abnormal, bone disorder
- decreased urination, urinary hesitation, blood in urine
- excessive vaginal bleeding, dry vaginal area, red painful penis and foreskin, genital discharge, prolonged erection, breast discharge
- hernia, drug tolerance decreased, difficulty walking, semen abnormal, increase in blood cholesterol levels, injury, relaxation of blood vessels procedure
- cases of suicidal ideation and suicidal behaviours have been reported during sertraline therapy or early after treatment discontinuation (see section 2 Warnings and precautions)

After marketing sertraline, the following side effects have been reported:

- decrease in white blood cells, decrease in clotting cells, endocrine problem, low blood salt, increase in blood sugar levels
- terrifying abnormal dreams, suicidal behaviour
- muscular movement problems (such as moving a lot, tense muscles, difficulty walking and stiffness, spasms and involuntary movements of the muscles) sudden severe headache (which may be a sign of a serious condition known as Reversible Cerebral Vasoconstriction Syndrome (RCVS))
- vision abnormal, unequal sized pupils, bleeding problems (such as stomach bleeding) progressive scarring of lung tissue (Interstitial Lung Disease), pancreatitis, serious liver function problems, yellow skin and eyes (jaundice)
- skin oedema, skin reaction to sun, muscle cramps, breast enlargement, problems with clotting bedwetting

Side effects in children and adolescents

In clinical trials with children and adolescents, the side effects were generally similar to adults (see above). The most common side effects in children and adolescents were headache, insomnia, diarrhoea and feeling sick.

Symptoms that can occur when treatment is discontinued.

If you suddenly stop taking this medicine you may experience side effects such as dizziness, numbness, sleep disturbances, agitation or anxiety, headaches, feeling sick, being sick and shaking (see section 3 “If you stop taking BELLSERT”)

An increased risk of bone fractures has been observed in patients taking this type of medicines.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL-Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie, e-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store BELLSERT

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after “Exp.”. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What BELLSERT contains:

The active substance is sertraline. Each film-coated tablet contains 50 mg of sertraline (as sertraline hydrochloride).

The other ingredients are:

Tablet core: Microcrystalline cellulose, calcium hydrogen phosphate dihydrate, sodium starch glycolate (type A), hydroxypropylcellulose and magnesium stearate.

Tablet coat: Hypromellose, titanium dioxide (E 171), macrogol 400 and talc.

What BELLSERT looks like and contents of the pack

Film-coated tablets

BELLSERT 50 mg film-coated tablets are white film-coated caplet shaped tablet embossed with “50” on one side and break-line on the other side. The tablets can be divided into equal doses.

BELLSERT is available in packs of 20, 28, 30, 50, 98, 100 or a hospital pack: 10 packs containing 30 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Ranbaxy Ireland Limited
Spafield
Cork Road
Cashel
Co Tipperary

This medicinal product is authorised in the Member States of the EEA under the following names:

Germany: SERTRALIN BASICS 50 mg Filmtabletten

Ireland: Bellsert 50 mg Film – coated Tablets

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