

Module 1.3	Product Information	Version: 2007
Module 1.3.1	Package Leaflet	Replaces: 2019-08

Package leaflet: Information for the user

Sertraline Apotex 50 mg, filmomhulde tabletten
Sertraline Apotex 100 mg, filmomhulde tabletten

sertraline

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

1. What Sertraline is and what it is used for

Sertraline contains the active ingredient sertraline. Sertraline is one of a group of medicines called Selective Serotonin Reuptake Inhibitors (SSRIs).

These medicines are used to treat depression and/ or anxiety disorders.

Sertraline 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, children and adolescents aged 6-17 years old).

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

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

Post-traumatic stress disorder (PTSD) is a condition that can occur after a very emotionally traumatic experience and has some symptoms that are similar to depression and anxiety disorders.

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 Sertraline.

Is your complaint no less, or does it even get worse? Then contact your doctor.

2. What you need to know before you take Sertraline

Do not take Sertraline:

- 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 medicines 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).

When should you be extra careful with this product? Talk to your doctor or pharmacist before taking Sertraline.

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

- If you have epilepsy or a history of fits (seizures). If you have a fit (seizure), contact your doctor immediately.

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- 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).
- If you have Serotonin 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.
- If you are elderly, take special care as you may be more at risk of having low sodium level in your blood (see above).
- If you suffer from liver disease your doctor may decide that you should have a lower dose of Sertraline.
- If you have diabetes your blood glucose levels may be altered due to Sertraline 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 (e.g. 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 below: 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 you have been told that you have an abnormal heart pattern after an electrocardiogram (ECG), known as extended QT interval. If you have a heart condition, low potassium levels or low magnesium levels, one family history of QT prolongation, has a slow heartbeat and you at the same time medicines that prolong the QT interval.

Medicines like Sertraline (so called SSRIs/SNRIs) may cause symptoms of sexual dysfunction (see section 4). In some cases, these symptoms have continued after stopping treatment.

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

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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 Sertraline, 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.
- 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.

Children and young people up to 18 years Sertraline 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 may decide to prescribe Sertraline to a patient under 18 if it is in the patient's interest. If your doctor has prescribed Sertraline to you and you are less than 18 years old and you want to discuss this, please contact him/her.

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Furthermore, if any of the symptoms listed above appear or worsen while you are taking Sertraline, you should inform your doctor. Also, the long-term safety of Sertraline in regard to growth, maturation and learning (cognitive) and behavioural development in this age group has not yet been demonstrated.

Other medicines and Sertraline

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. Some medicines can affect the way Sertraline works or Sertraline itself can reduce the effectiveness of other medicines taken at the same time.

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

- Medicines called monoamine oxidase inhibitors (MAOIs), like moclobemide (to treat depression) and selegiline (to treat Parkinson's disease) and linezolid (to treat infections) and methylene blue (to treat high levels of methaemoglobin in the blood). Do not use Sertraline together with these medicines. 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.
- Pimozide (to treat mental disorders such as psychosis). Do not use Sertraline together with pimozide.

Talk to your doctor before taking Sertraline if you are taking the following:

- Herbal medicine containing St. John's Wort (*Hypericum perforatum*). The effects of St. John's Wort may last for 1-2 weeks.
- Medicines containing amphetamines (used to treat ADHD (attention deficit hyperactivity disorder), narcolepsy (sleeping sickness, sudden irresistible tendency to sleeping) and treating obesity).
- Products containing tryptophan, an amino acid
- 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 'plastic' tablets)
- Medicines to treat epilepsy (phenytoin, phenobarbital, carbamazepin)
- Medicines to treat diabetes (tolbutamide)

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- Medicines to treat excessive stomach acid ulcers and heartburn (cimetidine, omeprazole, lansoprazol, 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).
- Medicines used to treat bacterial infections (such as 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).
- Medicines known to be at risk for changes in electrical activity of the heart (e.g. some antipsychotics and antibiotics).

Sertraline with food, drink and alcohol

Sertraline tablets can be taken with or without food.

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

Alcohol should be avoided whilst taking Sertraline.

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. Sertraline 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 taking 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 newborn (PPHN), making the baby breathe faster and

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

- trouble with breathing
- blueish skin or being too hot or cold
- your baby has blue lips, your baby passes on; your baby is not drinking well, being very tired, not able to sleep or crying a lot
- your baby's muscles are stiff or very weak, your baby vibrates, shakes as if he / she is nervous, or he / she has fits, the reflexes of your baby have been strengthened, your baby reacts irritably, the amount of sugar in your baby's blood is too low (reduced blood sugar levels)..

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 as yet.

Driving and using machines

Psychotropic (mind and behavior altering) medicines such as Sertraline 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 Sertraline

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Sertraline may be taken with or without food.

Take Sertraline once daily, either in the morning or evening.

Sertraline Apotex 50 and 100 mg tablets are scored film-coated tablets, which can be divided into equal doses.

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Dosage

Adults

Depression and obsessive-compulsive disorder (OCD)

The recommended 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 (PTSD)

Treatment should be started at the recommended dose, 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.

Use in Children and adolescents

Sertraline must only be used to treat children and adolescents suffering from obsessive-compulsive disorder (OCD) aged 6-17 years old.

Obsessive-compulsive disorder (OCD)

This drug should only be used to children and adolescents aged 6-17 years who suffer from it
Treat OCD.

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.

Patients with impaired liver or kidney function

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

Way of use

Sertraline tablets can be taken with or without food.

Use your medication once a day, either in the morning or in the evening.

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 Sertraline than you should

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If you accidentally take too much Sertraline 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, vomiting, rapid heart rate, shaking, agitation, dizziness and in rare cases unconsciousness.

If you forget to take Sertraline

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 Sertraline

Do not stop taking Sertraline unless your doctor tells you to. Your doctor will want to gradually reduce your dose of Sertraline 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 (See section 2: Withdrawal reactions). If you experience any of these side effects, or any other side effects whilst stopping taking Sertraline, please speak to your doctor.

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

4. Possible side effects

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

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, as these symptoms can be serious:

- 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, respiratory problems, wheezing, swollen eyelids, face or lips.

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- nervous excitement or restlessness (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.
- Yellow skin and eyes This may be a sign of liver damage.
- Depressive symptoms, with ideas of harming or killing yourself (suicidal thoughts) If you have feelings of restlessness and are unable to sit still after you have used this drug. You must tell your doctor if you start to feel restless.
- convulsions (seizures)
- A manic episode (See section 2: What you need to know before you take this drug).

The following side effects have been observed in clinical research involving adults and after introduction to the market:

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

- insomnia, dizziness, somnolence, headache,
- diarrhea,
- feeling sick, dry mouth,
- not being able to ejaculate,
- fatigue.

Common side effects (occur in fewer than 1 in 10 users):

- colds, sore throat, runny nose,
- reduced appetite, increased appetite
- anxiety, depression, nervous excitement or restlessness (agitation), less interest in sex, nervousness, feeling weird, nightmare, and the grinding of teeth,
- trembling, muscle movement problems (such as exercising more than normal, increased muscle tension, difficulty in walking and stiffness, spasms (contraction of muscles without getting there affects) and involuntary movements of muscles) *, numb and tingling sensation, increased muscular tension, attention disorder, abnormal taste,
- disorders of vision (visual defects),
- tinnitus,
- palpitations,
- flushes,
- yawning,
- stomach problems, congestion (constipation), abdominal pain, vomiting, and gas formation,

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- more sweating than normal, and rash,
- back pain, joint pain, and muscle pain,
- irregular menstruation, problems with getting an erection,
- general feeling of discomfort, chest pain, weakness, fever,
- weight gain,
- injury.

Uncommon side effects (occur in fewer than 1 in 100 users):

- gastrointestinal infections, ear infection,
- tumor,
- hypersensitivity, seasonal allergy,
- low amount of thyroid hormone in the blood,
- suicidal thoughts, suicidal behaviour*, psychotic disorder, different thoughts to normal, worrying for no reason, hallucinations (perception (seeing, hearing, smelling or feeling) things which are not there), aggression, euphoric mood (being extremely happy), paranoia (the feeling of being watched, followed or threatened without this being the case),
- loss of memory (amnesia), a flat feeling, involuntary muscle contractions, fainting, more movement than normal, migraine (episodes of severe, pounding headache), convulsions (episodes of loss of consciousness with contractions of the muscles), dizziness on standing up,
- disorders of co-ordination and speech disorder,
- enlarged pupils,
- earache,
- rapid heartbeat, heart problems,
- bleeding (such as gastric bleeding)*, high blood pressure, blushing and blood in the urine,
- shortness of breath, nosebleeds, respiratory problems and possible wheezing, tarry stools, problems with teeth, inflammation of the oesophagus, conditions affecting the tongue, haemorrhoids, having more saliva than normal, problems with swallowing, belching and problems with moving the tongue,
- swollen eyes, nettle rash, hair loss, itching, purple patches on the skin, problems with blisters on the skin, dry skin, accumulation of fluid in the face (facial oedema) and cold sweats, ,
- a disorder of the joints which usually occurs in elderly people without there being any inflammation (arthrosis/osteoarthritis), contractions of the muscles, muscle cramps* and muscle weakness,
- more frequent urination than normal, problems with urination, not being able to urinate, not being able to retain urine (urinary incontinence), larger quantity of urine and having to urinate at night,

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- sexual disorder, more vaginal bleeding than normal, vaginal bleeding and sexual disorder in women,
- swelling of the legs, shivering, problems with walking and thirst,,
- increase in hepatic enzymes and weight loss.
- **Cases of suicidal thoughts and suicidal behavior have been reported during the years treatment with sertraline or shortly after discontinuation of treatment (see section 2)**

Rare side effects (occur in fewer than 1 in 1,000 users)):

- diverticulitis (inflammation in a deviated bulge in the wall of an organ), swollen lymph nodes, decrease in platelet count *, decrease in white blood cell count *,
- severe allergic reaction, hormonal problems *,
- high cholesterol levels, problems with the control of the sugar content in the blood (diabetes, mellitus), too little sugar in the blood, too much sugar in the blood *, low blood sodium *,
- physical symptoms as a result of stress or emotions, strange anxiety-inducing dreams*, dependency on medicines, sleepwalking and too early release of semen (ejection),
- coma, abnormal movements, difficulty with moving, hearing, seeing, tasting, smelling and feeling with greater intensity, sudden severe headache (which can indicate a severe disorder which is called reversible cerebral vasoconstriction syndrome (RCVS) in which the blood vessels in the brain suddenly constrict and cause a headache and other complaints)* and disorders of hearing, vision, taste, smell and touch,
- spots in front of the eyes, increased pressure in the eyeball (green cataract and glaucoma), double vision, light is painful to the eyes, blood in the eyes, different size pupils*, abnormalities of vision* and problems with tears,,
- alopecia, feeling of light-headedness, fainting and a feeling of discomfort in the chest; these can be signs of changes in the electrical activity of the heart (seen on an electrocardiogram or a film of the heart), an abnormal rhythm of the heart*, a low heartbeat, poor circulation in the arms and legs,
- rapid breathing, worse scar formation in lung tissue (interstitial lung disease)*, a blockage in the throat, speech problems, slow breathing and hiccups,
- mouth ulcers and inflammation of the adrenal glands resulting in symptoms of severe pain in the upper abdomen radiating to the back as well as nausea and vomiting (pancreatitis)*, blood in the stools, ulcers on the tongue and a sore mouth,,
- disturbed function of the liver, severe problems with the function of the liver* and yellow skin and yellow whites of eyes (jaundice)*,
- reactions of skin to sunlight*, accumulation of fluid in the skin (cutaneous oedema*), abnormal hair growth, abnormal smell of skin and alopecia, ,
- breakdown of muscle tissue *, bone disorders,
- faltering flow of urine and less urine,

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- discharge from breasts, dry vaginal region, genital discharge, painful red penis and foreskin, enlargement of the breasts* and long-term erection,,
- hernia and lower tolerance of medicines,
- increase in the levels of cholesterol in the blood, abnormal laboratory results*, abnormal sperm and problems with coagulation*,
- dilation of the blood vessels.

Not known: frequency can not be determined with the available data:

- tetanus*,
- bedwetting *.
- partial loss of vision

* Side effect reported after placing on the market.

Extra side effects in children and adolescents up to the age of 18

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 unwell

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 shivering (See section 3: If you stop taking Sertraline).

In patients who use this kind of medicine, a higher risk of bone fractures is seen.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system listed in Appendix V*](#)

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Sertraline

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

This medicinal product does not require any special storage conditions.

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Store in the original package. Do not remove the tablets from the blister pack until you are ready to take the medicine.

Do not use this medicine after the expiry date which is stated on the pack. The expiry date refers to the last day of that month.

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 Sertraline contains

The active substance is sertraline. Each film-coated tablet contains sertraline hydrochloride equivalent to 50 mg or 100 mg sertraline.

The other ingredients are:

- Tablet core: Cellulose, microcrystalline (E460), Methylcellulose (E461), Silica, colloidal anhydrous (E550), Magnesium Stearate
- Tablet coating: Hypromellose (E464), Hydroxypropylcellulose (E463), Macrogol 8000 (E1521), Titanium Dioxide (E171).

In addition, the film-coated tablets contain:

- Sertraline 50 mg tablets: Indigo carmine (E132), lake.
- Sertraline 100 mg tablets: Ferric Oxide (Yellow Iron Oxide) (E172).

What Sertraline looks like and contents of the pack

Sertraline 50 mg film-coated tablets are bluish purple oval scored tablets engraved "APO" on one side, "SE" bisect "50" on the other side.

Sertraline 100 mg film-coated tablets are yellow oval scored tablets engraved "APO" on one side, "SER" bisect "100" on the other side.

The tablet can be divided into equal doses.

Sertraline 50 mg and 100 mg film-coated tablets are supplied in blister packs of 30, 60 or 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Apotex Europe BV

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Archimedesweg 2
2333 CN Leiden
Nederland

50 mg: RVG 112794
100 mg: RVG 112795

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

Nederland	Sertraline Apotex 50 mg / 100 mg filmomhulde tabletten
België	Sertraline Apotex 50 mg / 100 mg filmomhulde tabletten / comprimés pelliculés / Filmtabletten
Tsjechië	Sertralin Apotex 50 mg / 100 mg potahované tablety
Luxemburg	Sertraline Apotex 50 mg / 100 mg comprimés pelliculés
Polen	Sertraline Apotex
Spanje	Sertralina Apotex 50 mg / 100 mg comprimidos recubiertos con película EFG

Deze bijsluiter is voor het laatst goedgekeurd in september 2020.