

New Zealand Consumer Medicine Information

ARROW - SERTRALINE

Sertraline hydrochloride

What is in this leaflet

This leaflet answers some common questions about ARROW - SERTRALINE.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits.

Your doctor has weighed the risks of you taking ARROW - SERTRALINE against the benefits it is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What ARROW - SERTRALINE is used for

ARROW - SERTRALINE is used to treat depression and conditions called obsessive compulsive disorder (OCD), panic disorder, post-traumatic stress disorder (PTSD), social phobia (social anxiety disorder) and premenstrual dysphoric disorder (PMDD).

PMDD affects some women in the days before their period. PMDD is different from premenstrual syndrome (PMS). The mood symptoms (anger, sadness, tension, etc) in PMDD are more severe than in PMS and affect the woman's daily activities and relationships with others.

ARROW - SERTRALINE belongs to a group of medicines called *selective serotonin reuptake inhibitors (SSRIs)*. They are thought to work by blocking the uptake of a chemical called serotonin into nerve cells in the brain. Serotonin and other chemicals called amines are involved in controlling mood.

Your doctor, however, may prescribe ARROW - SERTRALINE for another purpose.

Ask your doctor if you have any questions about why ARROW - SERTRALINE has been prescribed for you.

ARROW - SERTRALINE should not be used in children and adolescents under the age of 18 years for the treatment of any medical condition other than obsessive compulsive disorder (OCD). The safety and efficacy of ARROW - SERTRALINE for the treatment of medical conditions (other than OCD) in this age group has not been satisfactorily established.

For the treatment of OCD, ARROW - SERTRALINE is not recommended for use in children under the age of 6, as the safety and efficacy in children of this age group has not been established.

This medicine is only available with a doctor's prescription.

There is no evidence that ARROW - SERTRALINE is addictive.

Before you take ARROW - SERTRALINE

When you must not take it

Do not take ARROW - SERTRALINE if:

- 1. you have ever had an allergic reaction to ARROW - SERTRALINE or any of the ingredients listed at the end of this leaflet.** Some of the symptoms of an allergic reaction to ARROW - SERTRALINE may include shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body, rash and itching or hives on the skin.
- 2. you have epilepsy not properly controlled by medication.**
- 3. you are taking another medicine for depression called a monoamine oxidase inhibitor (MAOI) or have been taking it within the last 14 days.** Taking ARROW - SERTRALINE with a MAOI (eg moclobemide, selegiline, phenelzine and tranylcypromine) may cause a serious reaction with a sudden increase in body temperature, extremely high blood pressure and convulsions (fits).
- 4. you are taking phentermine (used to help weight loss), tryptophan (contained in protein-based foods or dietary proteins), medicines used to treat migraine, eg sumatriptan, dextromethorphan (used as a cough suppressant in cold and flu medications), methadone (used to treat drug addiction) and medicines used to treat severe pain such as tramadol, fentanyl or pethidine.** These medicines can cause an exaggerated response to ARROW - SERTRALINE.
- 5. you are taking pimozide (used to treat disturbances in thinking, feeling and behaviour).**

Ask your doctor or pharmacist if you are not sure if you have been taking one of these medicines.

Do not give ARROW - SERTRALINE to children or adolescents under the age of 18 unless the doctor has prescribed it for the treatment of OCD. Do not give ARROW - SERTRALINE to children under 6 years of age for the treatment of OCD.

If you are not sure whether you should be taking ARROW - SERTRALINE, talk to your doctor.

Do not take ARROW - SERTRALINE if:

- the expiry date marked on the packaging has passed, even though the tablets may look all right
- the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Before you start to take it

Tell your doctor if you are allergic to any foods, dyes, preservatives or any other medicines.

Tell your doctor if you have or have had any of the following medical conditions:

- any other mental illness
- epilepsy or seizures
- liver or kidney problems
- heart conditions causing irregular heartbeats
- a tendency to bleed more than normal
- diabetes or high blood sugar
- glaucoma, an eye condition.

Tell your doctor if you are pregnant or intend to become pregnant.

There have been reports that babies exposed to ARROW - SERTRALINE and other antidepressants during the third trimester of pregnancy may develop complications after birth.

Tell your doctor if you are breastfeeding or wish to breastfeed

ARROW - SERTRALINE passes into breast milk and may affect your baby.

Your doctor will discuss the risks and benefits of using ARROW - SERTRALINE when pregnant or breastfeeding.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.

You should also tell any health professional who is prescribing a new medication for you that you are taking ARROW - SERTRALINE.

Some medicines may interfere with ARROW - SERTRALINE. These include:

- other medicines for the treatment of depression called monoamine oxidase inhibitors (MAOIs). Taking ARROW - SERTRALINE with, or within 14 days of stopping a MAOI may cause a serious reaction with a sudden increase in body temperature, extremely high blood pressure and convulsions
- other MAOI medicines such as linezolid, an antibiotic used to treat pneumonia and certain skin infections
- other medicines for depression, panic disorder, social anxiety disorder or obsessive illnesses (eg dosulepin, fluoxetine, paroxetine, citalopram, venlafaxine)
- lithium, a medicine used to treat mood swings
- other medicine for premenstrual dysphoric disorder (eg fluoxetine)
- tryptophan (contained in protein-based foods or dietary proteins)
- phentermine (weight-reducing medicines)
- dextromethorphan (used in cold and flu medicines to suppress cough)
- medicines for strong pain management (eg. fentanyl, tramadol or pethidine)
- other medicines used to relieve pain, swelling and other symptoms of inflammation, including arthritis (e.g. aspirin or NSAIDs such as ibuprofen or diclofenac)
- pimozone (used to treat disturbances in thinking, feeling and behaviour)
- St John's wort, a herbal remedy used to treat mood disorders
- clozapine, a medicine used to treat schizophrenia
- medicines for irregular heart beat (eg flecainide)
- warfarin, or other medicines that stop the blood from clotting
- phenytoin, a medicine used to treat epilepsy
- sumatriptan, a medicine used to treat migraine
- diazepam or other medicines that act on the brain or nervous system
- cimetidine, a medicine used to treat reflux and ulcers
- tolbutamide, a medicine used to treat diabetes
- methadone, a medicine used to treat drug addiction
- antibiotics.

These medicines may be affected by ARROW - SERTRALINE or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking ARROW - SERTRALINE.

How to take ARROW - SERTRALINE

Take ARROW - SERTRALINE exactly as your doctor has prescribed.

Follow all directions given to you by your doctor. They may differ from the information contained in this leaflet.

How much to take

For Depression in Adults the usual starting dose of ARROW - SERTRALINE is one 50 mg tablet each day. The dose can be increased gradually up to 200 mg a day if necessary.

For Obsessive Compulsive Disorder in Children (6-12 YEARS) the usual starting dose of ARROW - SERTRALINE is 25 mg per day (half a 50 mg tablet), increasing to one 50 mg tablet a day after one week.

For Obsessive Compulsive Disorder in Adults and Adolescents (13-17 years) the usual starting dose of ARROW - SERTRALINE is one 50 mg tablet each day.

For Panic Disorder in Adults the usual starting dose of ARROW - SERTRALINE is 25 mg per day, increasing to one 50 mg tablet a day after one week.

For Post-Traumatic Stress Disorder in Adults the usual starting dose of ARROW - SERTRALINE is 25 mg per day, increasing to one 50 mg tablet a day after one week.

For Social Phobia (Social Anxiety Disorder) in Adults the usual starting dose of ARROW - SERTRALINE is 25 mg per day, increasing to one 50 mg tablet a day after one week.

The maximum recommended dose of ARROW - SERTRALINE for the conditions listed above is 200 mg per day.

For Premenstrual Dysphoric Disorder (PMDD) the usual starting dose of ARROW - SERTRALINE is one 50 mg tablet each day. If taking throughout the menstrual cycle, the dose may be increased to a maximum of 150 mg a day, increased in a step wise fashion. If taking in the last 14 days of the menstrual cycle, the dose may be increased to a maximum of 100 mg a day.

Do not take more than the maximum doses recommended above for PMDD.

How to take it

Swallow the tablet(s) with a glass of water.

Try to take your tablet(s) at the same time each day, either morning or evening.

ARROW - SERTRALINE can be taken with or without food.

How long to take it

Most medicines for depression and obsessive illnesses take time to work, so do not be discouraged if you do not feel better straight away.

It may take 2 to 4 weeks or even longer to feel the full benefit of ARROW - SERTRALINE.

Even when you feel well, you may need to take ARROW - SERTRALINE for several months or longer. Continue taking ARROW - SERTRALINE until your doctor tells you to stop.

If you have PMDD, your doctor may ask you to take this medicine only at certain times of the month.

Do not stop taking ARROW - SERTRALINE, or change the dose, without first checking with your doctor.

Occasionally the symptoms of depression or other psychiatric conditions may include thoughts of harming yourself or committing suicide. It is possible that these symptoms may continue or increase until the full anti-depressant effect of your medicine becomes apparent (i.e. one to two months).

You or anyone close to you or caring for you should watch for these symptoms and tell your doctor immediately or go to the nearest hospital if you have any distressing thoughts or experiences during this initial period or at any other time.

Contact your doctor if you experience any worsening of your depression or other symptoms at any time during your treatment.

If you forget to take it

Do not take an extra dose to make up for the dose that you missed. Wait until the next day and take your normal dose then.

If you are not sure what to do in this situation, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at your nearest hospital if you think you or anyone else may have taken too much ARROW - SERTRALINE, even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Keep telephone numbers for these places handy.

If you take too many tablets, it may make you feel drowsy, sick in the stomach (nauseous), vomit, have fast or irregular heartbeats, tremors and feel agitated or dizzy. Coma has been reported with overdose.

While you are taking ARROW - SERTRALINE

Things you must do

Tell all doctors, dentists and pharmacists who are treating you that you are taking ARROW - SERTRALINE.

Tell your doctor or pharmacist that you are taking ARROW - SERTRALINE if you are about to be started on any new medicines.

Tell your doctor if you become pregnant while taking ARROW - SERTRALINE.

If you are a woman of child-bearing age, you should avoid becoming pregnant while taking ARROW - SERTRALINE.

Tell your doctor immediately if you have any suicidal thoughts or other mental/mood changes.

A worsening of depressive symptoms including thoughts of suicide or self-harm may occur in the first one or two months of you taking ARROW - SERTRALINE or when the doctor changes your dose. These symptoms should be controlled when the full effect of ARROW - SERTRALINE takes place.

Children, adolescents and young adults under 24 years of age are more likely to experience these effects during the first few months of treatment.

Patients and caregivers should be alert and monitor for these effects.

Signs and symptoms of suicide include:

- thoughts or talk of death or suicide
- thoughts or talk of self-harm or harm to others
- any recent attempts of self-harm
- increase in aggressive behaviour, irritability or agitation
- worsening of depression

All mention of suicide or violence must be taken seriously.

If you or someone you know is demonstrating these warning signs of suicide while taking ARROW - SERTRALINE, contact your doctor or a mental health professional right away.

Children should have regular checkups with the doctor to monitor growth and development.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may interact with other medicines used during surgery and cause unwanted side effects.

If you are about to have any urine tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

Things you must not do

Do not stop taking ARROW - SERTRALINE, or change the dose, without first checking with your doctor.

Do not let yourself run out of tablets over the weekend or on holidays.

Suddenly stopping ARROW - SERTRALINE may cause dizziness, light headedness, numbness, unusual tingling feelings or shakiness.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not take ARROW - SERTRALINE to treat any other complaints unless your doctor says to.

Things to be careful of

Be careful driving or operating machinery until you know how ARROW - SERTRALINE affects you.

Some medicines for depression may affect your ability to drive or operate machinery or do things that could be dangerous if you are not alert.

Although drinking moderate amounts of alcohol is unlikely to affect your response to ARROW - SERTRALINE, your doctor may suggest avoiding alcohol while you are taking ARROW - SERTRALINE.

If you are feeling drowsy or are uncoordinated, be careful that you do not fall over.

ARROW - SERTRALINE, like other medicines in this class, may increase your risk of bone fracture.

You should wait at least 14 days after stopping ARROW - SERTRALINE before starting medicines for depression or obsessive illnesses from the MAOI group, such as moclobemide, selegiline, phenelzine, tranylcypromine.

All of the above precautions are important even after you have stopped taking ARROW - SERTRALINE.

The effects of ARROW - SERTRALINE may last for some days after you have stopped taking it.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking ARROW - SERTRALINE.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if...

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- headache, dizziness, shakiness, muscle stiffness or weakness, decrease or loss of touch or other senses
- dry mouth or excessive saliva, increased sweating, feeling sick, diarrhoea, indigestion, vomiting, stomach pain, constipation, haemorrhoids
- tiredness, hot flushes, fever, feeling unwell
- weight increase or loss
- sleeping difficulties, sexual problems, sleepiness
- vision disturbance
- menstrual irregularities
- difficulty in passing urine, or increased frequency
- unusually overactive, restlessness or difficulty sitting still
- shaking or tremors
- swollen or enlarged lymph glands
- problem with swallowing
- problem with speech.

Tell your doctor as soon as possible if...

Tell your doctor as soon as possible if you notice any of the following:

- agitation, nervousness, anxiety, frightening dreams, sleep walking, yawning, abnormal thinking, teeth grinding, loss of appetite, impaired concentration, loss of memory, symptoms of agitation, anxiety, dizziness, headache, nausea and tingling or numbness of the hands and feet after stopping ARROW - SERTRALINE
- uncontrollable muscle spasms affecting the eyes, head, neck and body
- uncontrollable movements of the body, shuffling walk
- palpitations, fainting or chest pain
- irregular heartbeats
- breathlessness
- abnormal bleeding
- sudden onset of severe headache.

Go to hospital if...

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital, if you notice any of the following:

- fits or seizures
- signs of allergy such as rash or hives, swelling of the face, lips or tongue, wheezing or difficulty breathing
- symptoms of sudden fever with sweating, fast heart beat and muscle stiffness, which may lead to loss of consciousness
- thoughts of suicide or attempting suicide or self harm.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Some of these side effects (e.g., changes in thyroid function, liver function or glucose control) can only be found when your doctor does tests from time to time to check your progress.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

After taking ARROW - SERTRALINE

Storage

Keep your tablets where young children cannot reach them.

A locked cupboard at least 1½ metres above the ground is a good place to store medicines.

Keep ARROW - SERTRALINE in a cool, dry place where the temperature stays below 25°C. Protect from light. Do not store it or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep your tablets in their blister pack until it is time to take them.

Disposal

If your doctor tells you to stop taking ARROW - SERTRALINE, or the tablets have passed their expiry date, ask your pharmacist what to do with any left over.

Product description

What it looks like

ARROW - SERTRALINE tablets come in two strengths:

ARROW - SERTRALINE 50 mg - White to off white, capsule shaped, biconvex, film-coated tablets with break line on one side and "50" and "BL" embossed on either side of the breakline.

ARROW - SERTRALINE 100 mg – White to off-white, capsule shaped, biconvex, film coated tablets with "BL" and 100 embossed on one side.

A box contains 30 or 90 tablets.

Ingredients

ARROW - SERTRALINE contains either 50 mg or 100 mg of sertraline as the active ingredient.

It also contains:

- calcium hydrogen phosphate
- hypolose
- microcrystalline cellulose
- sodium starch glycollate
- magnesium stearate.

The film coating contains hypromellose, macrogol, polysorbate and titanium dioxide.

ARROW - SERTRALINE does not contain gluten, lactose or sugar.

Supplier

ARROW - SERTRALINE is distributed in New Zealand by:

Teva Pharma (New Zealand) Limited
PO Box 128 244
Remuera
Auckland 1541
Telephone: 0800 800 097

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