

# SETRONA

Sertraline Hydrochloride Tablets

## Consumer Medicine Information

### What is in this leaflet

This leaflet answers some common questions about **SETRONA** (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 **SETRONA** against the benefits it is expected to have for you.

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

Keep this leaflet with this medicine. You may need to read it again.

### What SETRONA tablet is used for

**SETRONA** tablets contain the active ingredient sertraline. Sertraline belongs to a group of medicines known as selective serotonin reuptake inhibitors (SSRIs). These medicines are thought to work by increasing the activity of the chemical serotonin in the brain.

**SETRONA** tablets are used to treat the following conditions:

**SETRONA** is used to treat depression and conditions called obsessive compulsive disorder (OCD), panic disorder, social phobia (social anxiety disorder) and premenstrual dysphoric disorder (PMDD).

Depression is longer lasting and/or more severe than the “low moods” everyone has from time to time due to the stress of everyday life. It is thought to be caused by a chemical imbalance in parts of the brain. This imbalance affects your whole body and can cause emotional and physical symptoms such as feeling low in spirit, loss of interest in activities, being unable to enjoy life, poor appetite or overeating, disturbed sleep, often waking up early, loss of sex drive, lack of energy and feeling guilty over nothing. **SETRONA** corrects this chemical imbalance and may help relieve the symptoms of depression.

PMDD affects 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.

Your doctor, however, may have prescribed **SETRONA** for another purpose. Ask your doctor if you have any questions about why **SETRONA** tablets have been prescribed for you.

**SETRONA** is only available with a doctor's prescription

There is no evidence that **SETRONA** is addictive.

**SETRONA** tablets may affect your ability to drive a car or operate machinery.

### Before you take SETRONA

#### When you must not take it

**Do not take SETRONA if**

- You are taking another medicine for depression called a monoamine oxidase inhibitor (MAOI) or have been taking it within the last 14 days. Taking **SETRONA** with a MAOI (eg seligeline, phenelzine, tranylcypromine, moclobemide) may cause a serious reaction with a sudden increase in body temperature, extremely high blood pressure and convulsions (fits).
- You are taking pimozide (medicines used for treating mental illness).

Do not take **SETRONA** tablets if you are allergic to sertraline (see **Side effects**) or any of the inactive ingredients listed at the end of this leaflet (see **Ingredients**)

Some of the symptoms of an allergic reaction to **SETRONA** may include a skin rash, itchiness, difficulty breathing and swelling of the face.

Do not take **SETRONA** tablets after the expiry date printed on the pack. If you take it after the expiry date has passed, it may not work as well. Do not take **SETRONA** if the tablets do not look quite right.

Do not take **SETRONA** tablets if the packaging is torn or shows signs of tampering.

#### Before you start to take it

**Tell your doctor if you have any allergies to:**

- any other medicines
- any other substances, such as foods, preservatives or dyes

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

Your doctor will discuss the risk and benefits of taking **SETRONA** during pregnancy.

The effects of **SETRONA** on the developing baby are not known yet. However, there have been reports that babies exposed to **SETRONA** and other SSRIs antidepressants during the third trimester of pregnancy may develop complications after birth.

Make sure your doctor know you are on **SETRONA**. When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like **SETRONA** 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 doctor immediately.

**Tell your doctor if you are breastfeeding or planning to breastfeed.**

**SETRONA** passes into breast milk and may affect your baby. Side effects have been reported in babies exposed to sertraline during breastfeeding. Your doctor will discuss the risks and benefits of using **SETRONA** when breastfeeding.

**Tell your doctor if you have or have had any medical conditions, especially the following:**

- Liver or kidney problems
- History of a heart attack or have heart problems
- Epilepsy or seizures

- History of bleeding disorders or a tendency to bleed more than normal
- Bipolar disorder (manic depression)
- Syndrome of Inappropriate Antidiuretic Hormone Secretion
- Mental illness, family history of suicide or depression
- Pregnant or intend to become pregnant

**If you have not told your doctor about any of the above, tell them before you use SETRONA tablets.**

#### Taking other medicines

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

Some medicines should not be taken with **SETRONA**. These include:

- medicines called monoamine oxidase inhibitors (MAOI) such as phenelzine (NARDIL), tranylcypromine (PARNATE), moclobemide (AURORIX) and selegiline (ELDEPRYL). Taking **SETRONA** with, or within fourteen days of stopping a MAOI may cause a serious reaction with a sudden increase in body temperature, extremely high blood pressure and convulsions.
- medicines that can increase the effects of **SETRONA** such as tramadol (pain reliever), tryptophan (a complementary medicine), or phentermine (a weight reducing medicine) and sumatriptan (medicine used to relieve migraine attack).
- pimozide (use to treat disturbances in thinking, feeling and behaviour).
- St John's wort, a herbal remedy.

You may respond differently to **SETRONA**, or to some other medicines, if you take them together. These include:

- other medicines for depression, panic disorders, social anxiety disorders or obsessive compulsive disorder.
- medicines for Pre-Menstrual Dysphoric Disorder (e.g. fluoxetine)
- medicine used to treat mental illnesses or mood disorders (e.g. clozapine, lithium)
- medicines for irregular heart beat (e.g. flecainide)
- medicines that can cause abnormal bleeding such as non-steroidal anti-inflammatory drugs (NSAIDs), aspirin, medicines that stop the blood from clotting like warfarin.
- phenytoin (e.g. Dilantin), a medicine used for epilepsy
- diazepam or other medicines to treat sleeping disorders, anxiety or help to relax the muscles (e.g. Serepax, valium)
- tolbutamide (eg Rastinon), a medicine used to treat diabetes
- cimetidine (e.g. Tagamet), a medicines used to treat reflux and ulcers.
- methadone, a medicine used to treat drug addiction

These medicines may be affected by **SETRONA** tablets, or may affect how well

it works. You may need to use different amounts of your medicine or you may need to take different medicines. Your doctor or pharmacist will be able to tell you what to do when taking/being given **SETRONA** tablets with other medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking **SETRONA**. If you have not told your doctor or pharmacist about these things, tell them before you start taking **SETRONA**.

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## How SETRONA is given

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### *How to take it*

**SETRONA** is to be taken by mouth, every morning or evening with or without food. Swallow the tablet whole with a full glass of water.

Take **SETRONA** exactly as your doctor has prescribed.

### *How much to take*

#### *For Major Depression in Adults*

The usual starting dose is one **SETRONA** 50 mg tablet taken once daily. It is possible that your doctor may decide to increase your daily doses, depending on your response to treatment. The maximum daily dose should not exceed 200 mg.

#### *For Obsessive Compulsive Disorder in Children (6-12 years)*

The usual starting dose for **SETRONA** is 25 mg/day (half a 50 mg tablet), increasing to 50 mg/day after one week.

#### *For Obsessive Compulsive Disorder in Adults and Adolescents (13-18 years)*

The usual starting dose for **SETRONA** is one 50 mg tablet each day.

#### *For Panic Disorder in adults*

The usual starting dose for **SETRONA** is 25 mg per day, increasing to 50 mg per day after one week.

#### *For social phobia (social anxiety disorder) in adults*

The usual starting dose for **SETRONA** is 25 mg per day, increasing to 50 mg per day after one week.

The maximum recommended dose of **SETRONA** for the conditions listed above is 200 mg per day.

#### *For Premenstrual Dysphoric Disorder*

The usual starting dose is one **SETRONA** 50 mg tablet each day, either throughout the menstrual cycle (to a maximum of 150 mg daily) or for the last 14 days before the start of your menses (to a maximum of 100 mg daily). However, depending on your condition and how you react to **SETRONA**, your doctor may ask you to take some other dose. The maximum recommended daily dose should not exceed 200 mg.

Your doctor may need to regularly examine you to decide if it is necessary for you to continue taking or stop **SETRONA** tablets.

Your dosage would be different if you have liver problems.

### *When to take it*

Take your **SETRONA** tablets at about the same time each day. Taking your tablets at the same time each day will have the best effect. It will also help you to remember when to take the tablets.

### *How long to take it*

Most medicines for depression and obsessive illness 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 **SETRONA**. Some of your symptoms may improve in 1 or 2 weeks, but it can take up to 4 to 6 weeks to feel any real improvement. Even when you feel well, you will usually have to take **SETRONA** for several months or even longer to make sure the benefits will last. Continue to take it 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 **SETRONA**, or change the dose, without first checking with your doctor.

### *If you forget to take it*

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, then go back to taking it as you would normally.

Do not double a dose to make up for the dose you have missed.

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

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

### *If you take too much (Overdose)*

**Immediately telephone your doctor or the Poisons Information Centre, or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else has taken too much of SETRONA tablets. Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention. Keep these telephone numbers handy (Australian Poisons Information Centre - 13 11 26).

If you take too many **SETRONA** tablets, you may feel drowsy, sick in the stomach, have a fast heart beat, have tremors, feel agitated or dizzy. Coma has also been reported with the overdose.

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## While you are using SETRONA tablets

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### *Things you must remember*

Take **SETRONA** exactly as your doctor tells you to.

Try not to miss any doses and take the medicine even if you feel well.

Visit your doctor regularly for check ups.

Tell all doctors, dentists and pharmacists who are treating you that you are taking **SETRONA**.

If you are about to be started on any new medicine, tell your doctor or pharmacist that you are taking **SETRONA**.

If you plan to have surgery make sure you tell your doctor, dentist or anaesthetist that you are taking **SETRONA**.

If you become pregnant or intend to become pregnant while taking **SETRONA**, you should make an appointment to see your

doctor and have your treatment reviewed. It is important that you do not stop taking **SETRONA** suddenly. **SETRONA** is a medicine that can have withdrawal side effects if stopped suddenly. Withdrawal symptoms (e.g. feeding difficulty, vomiting, tremor, irritability, unstable temperature) have also been reported rarely in the newborn baby after maternal use in the last 3 months of pregnancy.

If you take this medicine during late pregnancy, the newborn may be at increased risk of developing troubled breathing, bluish skin, fits, changes in body temperature, feeding difficulties, vomiting and cough (signs of persistent pulmonary hypertension).

Your doctor will discuss the risks and benefits of taking **SETRONA** during pregnancy.

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

**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 SETRONA or when the doctor changes your dose. These symptoms should be controlled when the full effect of SETRONA takes place.**

**Adolescents or 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 of talk of death or suicide, self-harm or harm to others
- Any recent attempts of self-harm
- Increase in aggressive behaviour, irritability or agitation
- Worsening of depression

**All mentions of suicide or violence must be taken seriously.**

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

**Tell your doctor immediately if you develop symptoms and signs of serotonin syndrome.**

**Signs and symptoms of serotonin syndrome include:**

- Incoordination
- Trembling, abrupt contraction of muscles
- Confusion
- Agitation
- Sweating
- Fever
- Shivering
- Diarrhoea.

Tell your doctor if you develop symptoms and signs of hyponatraemia (decreased level of sodium in blood), such as:

- Headache
- Difficulty in concentration

- Memory impairment
- Confusion
- Weakness
- Unsteadiness

In cases of sudden and/or severe hyponatraemia, symptoms such as hallucination (seeing, feeling or hearing things that are not there), fainting, seizure, coma, respiratory arrest, and death have also been reported.

Risk of developing hyponatraemia is greater if you:

- are elderly
- are on diuretics (fluid or water tablets)
- have Syndrome of Inappropriate Antidiuretic Hormone Secretion

### **Things you must not do**

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not use **SETRONA** tablets to treat any other complaints unless your doctor tells you to.

Do not stop taking **SETRONA** tablets, or lower the dose, without first checking with your doctor.

Suddenly stopping **SETRONA** may cause dizziness, lightheadedness, numbness, feeling sick, unusual tingling feelings, shakiness or anxiety.

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

Do not use **SETRONA** 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 **SETRONA** 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.

If you are to switch to another medicine for depression from the MAOI group such as Aurox, Nardil or Parnate, you should wait at least 14 days after stopping **SETRONA** before starting the MAOI medicine.

All the above precautions are important even after you have stopped taking **SETRONA**. The effects of **SETRONA** may last for some days after you have stopped taking it.

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## **Side effects**

**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking SETRONA.**

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 side effects.

**Ask your doctor or pharmacist any questions you may have.**

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

- Nausea (feeling sick), vomiting (being sick), indigestion, loose stools (diarrhoea), dry mouth, abdominal pain, increased or decreased appetite, constipation
- Headache, dizziness, lack of sleep or drowsiness, excessive sweating, inability to concentrate, nervousness, yawning, teeth grinding

- Tingling and numbness in hands and feet
- Decreased sexual performance including failure of ejaculation in males, decreased or increased sexual desire, impotence, lack of orgasm in female patients
- Mental confusion or agitation, excessive excitement, hallucinations
- Increased tendency to bleed or abnormal bleeding, predominantly of the skin and mucous membranes (including nasal, vaginal and gastrointestinal bleeding).
- Urinary disturbances
- Puffiness of face, fever, blushing, weight loss or gain, vague feeling of being unwell
- Ringing in the ears
- Increased production of the hormone prolactin, which may result in abnormal production of breast milk or breast enlargement
- High or low blood pressure
- Vision disturbances
- Menstrual irregularities
- Unusually overactive
- Shaking and tremors
- Unusual hair loss or thinning
- Swelling of hands, ankles or feet
- Increased sensitivity of the skin to sun
- Symptoms of agitation, anxiety, confusion, dizziness, feeling tense and restless, feeling of tiredness, drowsiness, or lack of energy, headache, irritability, nausea, trouble sleeping and tingling or numbness of the hands and feet after stopping **SETRONA**.

### **Laboratory abnormalities**

- Lowered sodium content of the blood
- Increased blood cholesterol, and sugar
- Abnormal liver function test
- Decreased blood uric acid levels

These are the more common side effects of **SETRONA** tablets. These side effects are usually mild and occur at the start of treatment.

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

- Symptoms of an allergic reaction may include rashes, hives, itching, difficulty breathing, shortness of breath or swelling of face, lips, tongue, hands/feet, fainting, high temperature.
- Severe skin reactions with blisters, sores or ulceration
- Marked behavioural changes including excessive excitement; abnormal body movements; combination of unresponsive body rigidity (inability to move or talk), high fever and profuse sweating.
- Seizures or fits
- Palpitations, fainting or chest pains
- Symptoms of sudden fever with sweating, fast heart beat and muscle stiffness, which may lead to loss of consciousness
- Marked changes in behaviour, emotions or mood including thoughts of suicide and self-harm, attempts at suicide.

These are very serious side effects. You may need urgent medical attention or

hospitalisation. All these side effects are very rare.

**Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell.**

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

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## **After using it**

### **Storage**

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

If you take the tablets out of the box or the blister pack they may not keep well.

Keep your **SETRONA** in a cool, dry place where it stays below 25°C.

Do not store it, or any other medicine, in the bathroom or near a sink.

Do not leave it in the car on hot days.

Heat and dampness can destroy some medicines.

Keep this medicine where young children cannot reach it.

### **Disposal**

If your doctor tells you to stop taking **SETRONA** or you find that they have passed their expiry date, ask your pharmacist what to do with any tablets that are left over.

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## **Product description**

### **What it looks like**

Setrona 50 mg tablets are available in a pack of 30 tablets.

SETRONA 50 mg are white film coated caplet shaped tablets debossed with '50' on one side and a break-line on the other.

Setrona 100 mg tablets are available in a pack of 30 tablets.

SETRONA 100 mg are white film coated caplet shaped tablets debossed with '100' on one side and a breakline on the other.

### **Ingredients**

#### **Active ingredient:**

Setrona 50 mg tablets - 50 mg of sertraline (as hydrochloride)

Setrona 100 mg tablets - 100 mg of sertraline (as hydrochloride)

#### **Inactive ingredients:**

Microcrystalline cellulose, calcium hydrogen phosphate dihydrate, sodium starch glycollate, hypromellose, magnesium stearate, and OPADRY complete film coating system OY-S-58910 WHITE (PI 11503).

### **Australian Registration No.**

**Setrona** 50 mg tablets - AUST R 116623

**Setrona** 100 mg tablets - AUST R 116636

### **Sponsor**

**SETRONA** is supplied in Australia by:  
Sun Pharma ANZ Pty Ltd.  
Macquarie Park NSW 2113  
Australia

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