

# AGOMELATINE SANDOZ

*Agomelatine-citric acid*

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## Consumer Medicine Information

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### What is in this leaflet

This leaflet answers some common questions about AGOMELATINE SANDOZ. 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 AGOMELATINE SANDOZ against the benefits they expect it will 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.

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### What AGOMELATINE SANDOZ is used for

AGOMELATINE SANDOZ is used to treat depression or to help prevent depression returning.

The symptoms of depression vary from one person to another, but commonly include persistent sadness, loss of interest in favourite activities, feelings of worthlessness, sleep problems, feeling of being slowed down, feelings of anxiety or changes in appetite and weight. Changes in your daily sleep and appetite patterns are examples of disturbances of your 'body clock' that occur commonly in depression.

AGOMELATINE SANDOZ can help regulate your 'body clock' (circadian rhythm) with positive

benefits on mood and sleep in depression.

**Ask your doctor if you have any questions about why this medicine has been prescribed for you.**

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

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

In clinical studies AGOMELATINE SANDOZ had no effect on sexual function.

AGOMELATINE SANDOZ is not recommended for children, adolescents (under 18 years old) or elderly patients aged 75 or older.

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### Before you take AGOMELATINE SANDOZ

#### *When you must not take it*

**Do not take AGOMELATINE SANDOZ if:**

- you suffer from liver disease or you know your liver does not work properly (hepatic impairment)
- your routine blood tests show levels of liver enzymes have increased to more than 3 times the upper limit of normal
- you are currently taking fluvoxamine (a drug used in the treatment of depression) or ciprofloxacin (an antibiotic used to treat infections)

**Do not take AGOMELATINE SANDOZ if you have an allergy to:**

- any medicine containing agomelatine
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin
- add any other specific reactions listed in the PI.

**Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**

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

**If you are not sure whether you should start taking this medicine, talk to your doctor.**

#### *Before you start to take it*

A routine blood test should be performed before treatment to check how your liver is functioning. If you have increased levels of liver enzymes your doctor will decide if AGOMELATINE SANDOZ is right for you.

You may be at risk of liver problems if you are overweight, obese or have diabetes or if you are taking medicines known to affect your liver (ask your doctor if you are unsure which medicines these might be).

Tell your doctor if you have ever experienced or develop an episode of bipolar disorder, mania or hypomania (extreme upward mood swings or irritable mood).

Your doctor should be made aware if you have a history of dementia.

**Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.**

**Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.**

Your doctor can discuss with you the risks and benefits involved.

Talk to your doctor about how much alcohol you drink. People who drink excessive quantities of alcohol should not take AGOMELATINE SANDOZ. Excessive alcohol may cause liver problems and may make depression worse.

Tell your doctor if you are smoking more than 15 cigarettes/day.

**If you have not told your doctor about any of the above, tell them before you start taking AGOMELATINE SANDOZ.**

### *Taking other medicines*

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

Some medicines and AGOMELATINE SANDOZ may interfere with each other. These include:

- propranolol (a medicine sometimes used to treat heart problems)
- rifampicin (an antibiotic used to treat infections).

These medicines may be affected by AGOMELATINE SANDOZ or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

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## How to take AGOMELATINE SANDOZ

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**Follow all directions given to you by your doctor or pharmacist carefully.**

They may differ from the information contained in this leaflet.

**If you do not understand the instructions on the box, ask your doctor or pharmacist for help.**

### *How much to take*

The usual dose of AGOMELATINE SANDOZ is one tablet in the evening at bedtime. In some cases your doctor may prescribe two tablets (50 mg) to be taken together in the evening at bedtime. You should not take more than the maximum recommended dose of 50 mg daily.

**Do not change your dose without the advice of your doctor even if you feel better.**

### *How to take it*

**Swallow the tablets whole with some water.**

AGOMELATINE SANDOZ can be taken with or without food.

### *When to take it*

**Take your medicine in the evening at bedtime.**

### *How long to take it*

Current experience with medications to treat depression shows that treatment for six months or longer provides the best opportunity of long-term recovery from a first episode of depression. For those who have previously had depression, a longer period of treatment will usually be recommended.

With AGOMELATINE SANDOZ, some people experience improvements in mood and sleep within two weeks of starting treatment. As people respond

differently to medications, do not become discouraged if you do not notice a difference right away.

Continue taking AGOMELATINE SANDOZ until your doctor advises you to stop. Even when you are feeling better, your doctor would usually continue to give you AGOMELATINE SANDOZ for some time to help to prevent your depression from returning.

### *If you forget to take it*

If you forget to take your AGOMELATINE SANDOZ skip the dose you missed, take your next planned dose at the usual time and continue as normal.

Do not try to make up for missed doses. Simply take one dose per day.

**If you are not sure what to do, 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 the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much AGOMELATINE SANDOZ. Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

**It is important that you do not take more AGOMELATINE SANDOZ tablets than your doctor has prescribed.**

Symptoms of an overdose may include stomach pain, drowsiness, tiredness, agitation, anxiety, dizziness, blue-ish discolouration of the skin or mucous membranes and/or a general feeling of being unwell.

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## While you are taking AGOMELATINE SANDOZ

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### *Your liver function*

**AGOMELATINE SANDOZ is processed by the liver. Before you started taking AGOMELATINE SANDOZ a blood test was required to check your liver function. While you are taking AGOMELATINE SANDOZ you will need further blood tests to check your liver continues to function properly.**

**These tests should be performed:**

- **before the start of treatment and before a dose increase to 50mg (dose should only be increased by your doctor).**

**and then around:**

- **3 weeks,**
- **6 weeks,**
- **12 weeks and**
- **24 weeks.**

These blood test results will help your doctor decide whether AGOMELATINE SANDOZ is suitable for you. AGOMELATINE SANDOZ may sometimes affect the results of these blood tests.

You may also have tests to check that your liver is working properly if you start to take medicines that interfere with how the body processes AGOMELATINE SANDOZ.

Talk to your doctor about how much alcohol you drink.

### *Things you must do*

To make sure you have the best opportunity of long-term recovery from your depression, continue to take AGOMELATINE SANDOZ as long as your doctor recommends you to.

Tell your doctor if you have experienced or develop an episode of bipolar disorder, mania or hypomania (extreme upward mood swings or irritable mood).

Check with your doctor that your liver function tests are done as described in the YOUR LIVER FUNCTION section above.

Seek advice from your doctor immediately if you develop signs or symptoms of potential liver problems (such as dark urine, light coloured faeces, yellow skin or eyes, pain in your upper right abdomen, new-onset and unexplained fatigue). Your doctor may advise you to stop taking AGOMELATINE SANDOZ.

**If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking AGOMELATINE SANDOZ.**

**Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.**

**If you become pregnant while taking this medicine, tell your doctor immediately.**

**Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed. Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.**

Tell your doctor if you feel the tablets are not helping your condition.

**Keep all of your doctor's appointments so that your progress can be checked.**

If you are being treated for depression, be sure to discuss with your doctor any problems you may have and how you feel, especially any feelings of severe sadness or bursts of unusual energy or anger.

**If you have any thoughts about suicide or doing harm to yourself call your doctor immediately and also contact someone you trust.**

All thoughts or talk about suicide or violence towards others or yourself are serious. Such thoughts may even occur after commencing antidepressant treatment, particularly before the full antidepressant effect is seen. Such

thoughts are more likely to occur in young adults under 25 years of age.

**If you or someone you know is showing any of the following common warning signs, either contact your doctor or healthcare professional or go to the nearest hospital for treatment:**

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

**In addition to talking to your doctor, confidential support and counselling services are available (in Australia) from LifeLine by calling 13 11 14.**

You may find it helpful to tell a relative or close friend that you are depressed and ask them to read this leaflet. You might ask them to tell you if they think your depression is getting worse, or if they are worried about changes in your behaviour.

### *Things you must not do*

**You should not take AGOMELATINE SANDOZ together with certain medications (see also under "When you must not take AGOMELATINE SANDOZ") such as: fluvoxamine (another medicine used in the treatment of depression) or ciprofloxacin (an antibiotic).**

**Do not take AGOMELATINE SANDOZ to treat any other complaints unless your doctor tells you to.**

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

### *Things to be careful of*

**Be careful driving or operating machinery until you know how AGOMELATINE SANDOZ affects you.**

Speak to your doctor if you have any concerns.

**It is recommended to avoid drinking alcohol while taking any antidepressant including AGOMELATINE SANDOZ.**

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## Side effects

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

This medicine helps most people with depression, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

**Do not be alarmed by the following lists of side effects. You may not experience any of them.**

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

Increases in liver enzymes, and rarely inflammation of the liver, have been observed in some patients treated with AGOMELATINE SANDOZ. When AGOMELATINE SANDOZ was discontinued in these patients, the increases in liver enzymes usually returned to normal levels. This is why your doctor has asked you to have routine blood tests.

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

- headache
- sleepiness (somnolence), difficulty in sleeping (insomnia)
- dizziness
- abnormal dreams
- feeling sick (nausea), vomiting
- diarrhoea, constipation, abdominal pain
- dry mouth
- back pain
- tiredness
- anxiety

- increased level of liver enzymes in your blood
- weight increase
- mania/hypomania (see also under before you start to take AGOMELATINE SANDOZ)
- suicidal thoughts or behaviour
- pins and needles in the fingers and toes (paraesthesia), restless legs syndrome (a disorder that is characterised by an uncontrollable urge to move the legs)
- tremor
- muscle aches or pains
- blurred vision
- ringing in the ears
- eczema, pruritus, urticarial (hives)
- agitation, irritability, restlessness, aggressive behaviour
- nightmares
- confusion
- weight decrease
- migraine
- excessive sweating (hyperhidrosis).

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

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

- serious skin eruption (erythematous rash), face oedema (swelling) and angioedema (swelling of the face, lips, tongue and/or throat that may cause difficulty in breathing or swallowing)
- hepatitis, yellow coloration of the skin or the whites of the eyes (jaundice), hepatic failure (isolated cases of death or liver transplantation have been reported in patients with hepatic risk factors)
- hallucinations
- inability to remain still (due to physical and mental unrest)

- inability to completely empty the bladder.

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

**If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:**

The possibility of a severe liver reaction exists, especially with excessive alcohol consumption and/or with any other medication processed by the liver, e.g. AGOMELATINE SANDOZ.

Symptoms of severe liver reactions may include:

- yellow colouring of the skin or whites of the eyes (jaundice)
- abnormal bleeding or bruising
- confusion, loss of consciousness or hallucinations.

The possibility of a severe allergic reaction exists with any medication. The following are general signs and symptoms of an allergic reaction:

- itching, skin rash or hives
- shortness of breath, wheezing or trouble breathing
- swelling of the face, lips, tongue or other parts of the body which may cause difficulty in swallowing or breathing.

Severe liver reactions and severe allergic reactions are very serious. Medical attention or hospitalisation may be required and should be sought urgently from a doctor or Accident and Emergency at the nearest hospital.

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

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

Other side effects not listed above may also occur in some people.

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## After taking AGOMELATINE SANDOZ

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### *Storage*

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

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

**Keep your tablets in a cool dry place where the temperature stays below 25°C.**

**Do not store AGOMELATINE SANDOZ or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.**

Heat and dampness can destroy some medicines.

**Keep it where children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

### *Disposal*

**If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.**

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## Product description

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### *What it looks like*

AGOMELATINE SANDOZ is a yellow oblong biconvex film-coated tablet.

Each pack contains 28 film-coated tablets.

### *Ingredients*

AGOMELATINE SANDOZ contains 25 mg of agomelatine as the active ingredient.

The tablets also contain the following inactive ingredients:

- silicified microcrystalline cellulose
- mannitol

- povidone
- colloidal anhydrous silica
- crospovidone
- sodium stearyl fumarate
- magnesium stearate
- stearic acid
- hypromellose
- macrogol 6000
- titanium dioxide
- purified talc
- iron oxide yellow.

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

### *Sponsor*

Southern Cross Pharma Pty Ltd  
Suite 2, Level 2  
19-23 Prospect Street  
Box Hill, VIC 3128  
Australia

### *Distributor*

Sandoz Pty Ltd  
100 Pacific Highway  
North Sydney, NSW 2060  
Australia  
Tel 1800 726 369

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