

# Amisulpride Winthrop®

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## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

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### 1. Why am I using Amisulpride Winthrop ?

Amisulpride Winthrop contains the active ingredient amisulpride. Amisulpride Winthrop is used to treat symptoms of schizophrenia. For more information, see Section [1. Why am I using Amisulpride Winthrop?](#) in the full CMI.

### 2. What should I know before I use Amisulpride Winthrop?

Do not use if you have ever had an allergic reaction to Amisulpride Winthrop or any of the ingredients listed at the end of the CMI. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.** For more information, see Section [2. What should I know before I use Amisulpride Winthrop?](#) in the full CMI.

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### 3. What if I am taking other medicines?

Some medicines may interfere with Amisulpride Winthrop and affect how it works. In particular, do not take this medicine, and tell your doctor if you are taking the following medicines: medicines used to treat irregular heart rhythm, other medicines used to treat heart problems, cisapride, sultopride, antibiotics, levodopa, methadone, thioridazine, vincamine, halofantrine, pentamidine and sparfloxacin. A full list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use Amisulpride Winthrop?

- Your doctor will tell you how much Amisulpride Winthrop you should take. The dosage is adjusted for each individual and can range from 50 mg to 800 mg a day, and in some cases up to 1200 mg a day. Amisulpride Winthrop should preferably be taken before meals. More instructions can be found in Section [4. How do I use Amisulpride Winthrop?](#) in the full CMI.

### 5. What should I know while using Amisulpride Winthrop?

Things you should do	
	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are</li></ul>

	<p>using Amisulpride Winthrop.</p> <ul style="list-style-type: none"> <li>● Call your doctor straight away if you have any suicidal thoughts or mental/mood changes</li> <li>● Be careful taking antihistamines, sleeping tablets or tablets to relieve pain as Amisulpride Winthrop can increase drowsiness.</li> </ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"> <li>● Do not stop using this medicine unless your doctor tells you to.</li> <li>● Do not give Amisulpride Winthrop to anyone else.</li> </ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>● Do not drive or operate machinery until you know how Amisulpride Winthrop affects you.</li> <li>● Amisulpride Winthrop may cause drowsiness in some people</li> </ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"> <li>● The effects of alcohol could be made worse while taking Amisulpride Winthrop. It is NOT</li> </ul>

	recommended that you drink alcohol while taking Amisulpride Winthrop.
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• Store below 30°C, in a cool, dry place.</li> </ul>

For more information, see Section [5. What should I know while using Amisulpride Winthrop?](#) in the full CMI.

## 6. Are there any side effects?

Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects: muscle symptoms including pain, weakness, twitching or stiffness, increased levels of an enzyme that measures breakdown of muscle (creatinine phosphokinase) in the blood with impaired consciousness and an unexplained fever, abnormal movements mainly of the face or tongue, fever, unexplained infections, faster breathing, sweating, yellowing of the skin and eyes, light coloured bowel motions, dark coloured urine. After prolonged use in women, medicines of this type can cause: breast pain, milk secretion, an absence of their monthly period, changes in the regularity of their periods. After prolonged use in men, medicines of this type can cause breast enlargement or impotence. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.



# Amisulpride Winthrop\*

Active ingredient: *amisulpride*

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using Amisulpride Winthrop. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Amisulpride Winthrop.**

**Where to find information in this leaflet:**

- [1. Why am I using Amisulpride Winthrop?](#)
- [2. What should I know before I use Amisulpride Winthrop?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Amisulpride Winthrop?](#)
- [5. What should I know while using Amisulpride Winthrop?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using Amisulpride Winthrop?

**Amisulpride Winthrop contains the active ingredient amisulpride.** Amisulpride Winthrop is an antipsychotic medication.

## **Amisulpride Winthrop is used to treat symptoms of schizophrenia.**

Schizophrenia is a condition which affects the way you think, feel and/or act. Schizophrenia may cause symptoms such as hallucinations (e.g. hearing, seeing or sensing things which are not there), delusions, unusual suspiciousness, emotional and social withdrawal. People with schizophrenia may also feel depressed, anxious or tense.

## **2. What should I know before I use Amisulpride Winthrop?**

### **Warnings**

#### **Do not use Amisulpride Winthrop if:**

- you are allergic to amisulpride, or any of the ingredients listed at the end of this leaflet. Signs of an allergic reaction may include a skin rash, itching, shortness of breath or swelling of the face, lips or tongue.
- Always check the ingredients to make sure you can use this medicine.
- you are breastfeeding or plan to breastfeed.
- the packaging is torn or shows signs of tampering or the tablets do not look quite right.

You are taking the following medicines:

- medicines used to treat irregular heart rhythm such as quinidine, disopyramide, amiodarone and sotalol

- cisapride
- antibiotics such as erythromycin and pentamidine, given as an injection into the veins
- levodopa, a medicine used in Parkinson's disease
- thioridazone, an antipsychotic
- methadone, medicine used to treat pain or addiction

### **Check with your doctor if you:**

- have any other medical conditions, including phaeochromocytoma, a rare tumour of the adrenal glands which sit near the kidneys, tumour of the pituitary gland, a small gland at the base of the brain, breast cancer, liver disease
- take any medicines for any other condition
- you have had an allergic reaction to any medicine which you have taken previously to treat your current condition.
- you are pregnant, think you may be pregnant or intend to become pregnant
- you suffer from lactose intolerance because Amisulpride Winthrop tablets contain lactose.
- you have kidney or liver disease, Parkinson's disease or fits (seizures).
- you have problems with the heart and blood vessels.
- you have, or have a history of blood clots.
- you have hyperglycaemia (high sugar levels in the blood) or a family history of diabetes. Your doctor may recommend monitoring your blood sugar levels while you are taking Amisulpride Winthrop.

- you suffer from dementia.
- you have mental/mood changes or suicidal thoughts. Patients (and caregivers of patients) need to monitor for any worsening of their condition and/or the development of thoughts of suicide, suicidal behaviour or thoughts of harming themselves. Seek medical advice immediately if these symptoms present.
- you have risk factors for stroke.
- you have a history, or family history, of breast cancer
- you have a history of sleep apnoea

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## **Pregnancy and breastfeeding**

Check with your doctor if you are pregnant or intend to become pregnant. Make sure you use a contraceptive to prevent pregnancy during treatment with Amisulpride Winthrop. If you become pregnant while taking this medicine, tell your doctor immediately. Amisulpride Winthrop is not recommended during pregnancy. If you need to take Amisulpride Winthrop during pregnancy you should discuss the benefits and risks of taking it with your doctor. Newborns of mothers who have taken Amisulpride Winthrop during pregnancy need to be carefully monitored.

Talk to your doctor if you are breastfeeding or intend to breastfeed. Amisulpride Winthrop must not be used when breastfeeding.

## Use in children

- Amisulpride Winthrop must not be taken by children up to the age of puberty. There is limited information on the use of Amisulpride Winthrop in adolescents and its use is not recommended from puberty to the age of 18 years. If you are not yet 18 years of age, ask your doctor if Amisulpride Winthrop is right for you.

### 3. What if I am taking other medicines?

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

**Some medicines may interfere with Amisulpride Winthrop and affect how it works. These include:**

- medicines used to treat irregular heart rhythm such as quinidine, disopyramide, amiodarone and sotalol
- other medicines used to treat heart problems such as diltiazem, verapamil, clonidine, digoxin and drugs known as beta blockers (e.g. propranolol)
- intravenous amphotericin B (amphotericin), an anti-fungal given by injection into the veins
- other antipsychotics such as thioridazine, clozapine, chlorpromazine, trifluoperazine, pimozide, haloperidol, imipramine and lithium
- diuretics
- stimulant laxatives
- glucocorticosteroids

- diagnostics drugs such as tetracosactides
- medicines taken for anxiety or to help you sleep (central nervous system depressants)
- anaesthetics (a medicine used during surgery)
- medicines taken for depression
- some strong pain killers
- antihistamines, medicines to treat allergies, which cause drowsiness
- some medicines taken to control blood pressure

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Amisulpride Winthrop.**

## **4. How do I use Amisulpride Winthrop?**

### **How much to take**

- Your doctor will tell you how many Amisulpride Winthrop tablets you should take. The dosage is adjusted for each individual and can range from 50 mg a day up to 800 mg a day. In some cases your doctor may increase the dose to 1200 mg a day.

Amisulpride Winthrop tablets should be taken once or twice a day as advised by your doctor. Your doctor may increase or decrease your dose depending on your condition.

Do not take more than the dose your doctor has recommended.

Follow the instructions provided and use Amisulpride Winthrop until your doctor tells you to stop.

## **When to take Amisulpride Winthrop**

- Amisulpride Winthrop tablets should preferably be taken before meals. Take your prescribed dose at about the same time each day.

## **How to take Amisulpride Winthrop**

- Amisulpride Winthrop tablets should be swallowed whole with a glass of water.

## **If you forget to use Amisulpride Winthrop**

Amisulpride Winthrop should be used regularly at the same time each day. If you miss your dose at the usual time, take your dose as soon as you remember.

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

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

## **If you use too much Amisulpride Winthrop**

If you think that you have used too much Amisulpride Winthrop, you may need urgent medical attention.

**You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

Show the doctor your pack of tablets or bottle.

If you have taken too much Amisulpride Winthrop, you may experience:

- drowsiness
- slurred speech
- reduction in irritability or agitation
- dizziness, lightheadedness
- involuntary and uncontrollable movement
- coma

Life-threatening outcomes have been reported in combination with other similar medicines.

## **5. What should I know while using Amisulpride Winthrop?**

### **Things you should do**

**It is very important to continue taking Amisulpride Winthrop because it will help you stay well.**

**While you are taking Amisulpride Winthrop, tell your doctor or pharmacist before you start any new medicine.**

**Call your doctor straight away if you have any of the following suicidal thoughts or mental/mood changes:**

- 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
- depressed mood or worsening of depression

Occasionally, the symptoms of depression may include thoughts of suicide or self-harm. These symptoms may continue to get worse during the early stages of treatment until the effect of the medicine becomes apparent. All mentions of suicide or violence must be taken seriously.

**Call your doctor straight away if you experience the following:**

- lower than normal body temperature (hypothermia)
- muscle stiffness
- muscle pain in the shoulders, thighs or lower back, muscle weakness or trouble moving arms and legs, dark red or brown urine or increased urination (symptoms of rhabdomyolysis)

- dizziness upon standing, exercise intolerance, abnormal sweating, loss of appetite, bloating, diarrhoea, constipation, difficulty swallowing, trouble urinating including incomplete emptying of the bladder, ejaculation difficulties, difficult maintaining erections, blurry vision (symptoms of autonomic instability)

These are all symptoms of Neuroleptic Malignant Syndrome (NMS) which is potentially life threatening.

Remind any doctor, dentist or pharmacist you visit that you are using Amisulpride Winthrop.

## **Things you should not do**

- Do not stop using this medicine unless your doctor tells you. Do not stop taking your Amisulpride Winthrop just because you feel better. It is very important to continue Amisulpride Winthrop because it will help you stay well.
- Do not drive or operate machinery until you know how Amisulpride Winthrop affects you.
- Do not give Amisulpride Winthrop to anyone else. Your doctor has prescribed it for you and your condition.

## **Things to be careful of**

- Be careful if you are elderly or unwell.
- Some people may experience side effects such as drowsiness, confusion, dizziness and unsteadiness. Amisulpride Winthrop may affect your ability to move or balance. This may increase the risk of a fall, sometimes leading to fractures.

- Be careful while taking antihistamines, sleeping tablets or tablets to relieve pain while taking this medicine. Amisulpride Winthrop can increase drowsiness caused by medicines affecting your nervous system.

## **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how Amisulpride Winthrop affects you.**

Amisulpride Winthrop may cause drowsiness in some people

## **Drinking alcohol**

**Tell your doctor if you drink alcohol.**

The effects of alcohol could be made worse while taking Amisulpride Winthrop. It is NOT recommended that you drink alcohol while taking Amisulpride Winthrop.

## **Looking after your medicine**

- Store below 30°C, in a cool, dry place. Keep your tablets in the blister pack until it is time to take them. If you take the tablets out of the blister pack they may not keep well.

There will be an expiry date (month, year) on your Amisulpride Winthrop container. The medicine should not be taken after this date.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

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

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

## **When to discard your medicine**

Amisulpride Winthrop should be discarded after the expiry date on the pack has passed.

## **Getting rid of any unwanted medicine**

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## **6. Are there any side effects?**

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

## Less serious side effects

Less serious side effects	What to do
<p><b>Heart related:</b></p> <ul style="list-style-type: none"><li>• Dizziness. Some people may feel dizzy in the early stages of treatment, especially when getting up from a lying or sitting position. This side effect usually passes after taking Amisulpride Winthrop for a few days.</li><li>• drowsiness</li></ul> <p><b>Gastrointestinal related:</b></p> <ul style="list-style-type: none"><li>• nausea</li><li>• vomiting</li><li>• dry mouth</li></ul> <p><b>Eye related:</b></p> <ul style="list-style-type: none"><li>• blurred vision</li></ul> <p><b>Head and neurology related:</b></p> <ul style="list-style-type: none"><li>• insomnia</li><li>• anxiety</li><li>• agitation</li><li>• problems with orgasm</li></ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● trembling*</li> </ul> <p><b>Muscle related:</b></p> <ul style="list-style-type: none"> <li>● noticeable muscle stiffness or spasm*</li> <li>● slowness of movement*</li> <li>● restlessness, an overwhelming urge to move and either distress or movements such as pacing, swinging of the legs while seated, rocking from foot to foot, or both*</li> </ul> <p><b>Metabolism and nutrition:</b></p> <ul style="list-style-type: none"> <li>● weight gain</li> <li>● increased appetite</li> <li>● excess saliva*</li> <li>● High blood sugar. Symptoms include passing more urine than normal, persistent excessive thirst, increased appetite with a loss in weight and weakness.</li> </ul> <p><b>Other:</b></p>	

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● increased sensitivity to the sun or symptoms of sunburn (such as redness, itching, swelling, blistering) which may occur more quickly than normal</li> </ul> <p><b>Rare</b></p> <ul style="list-style-type: none"> <li>● sleep walking</li> <li>● sleep eating</li> </ul> <p>* These symptoms will usually be reduced if your dose of Amisulpride Winthrop is lowered by your doctor or if your doctor prescribes you an additional medicine.</p>	

## **Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● muscle symptoms including pain, weakness, twitching or stiffness</li> <li>● increased levels of an enzyme that measures breakdown</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<p>of muscle (creatine phosphokinase) in the blood with impaired consciousness and an unexplained fever</p> <ul style="list-style-type: none"> <li>● abnormal movements mainly of the face or tongue</li> <li>● fever</li> <li>● unexplained infections</li> <li>● faster breathing</li> <li>● sweating</li> <li>● yellowing of the skin and eyes, also called jaundice</li> <li>● light coloured bowel motions</li> <li>● dark coloured urine or increased urination</li> <li>● lower than normal body temperature (hyperthermia)</li> <li>● dizziness upon standing, exercise intolerance, abnormal sweating, loss of appetite, bloating, diarrhoea, constipation, difficulty swallowing, trouble urinating</li> </ul>	

<b>Serious side effects</b>	<b>What to do</b>
<p>including incomplete emptying of the bladder, ejaculation difficulties, difficult maintaining erections, blurry vision</p> <p>After prolonged use in women, medicines of this type can cause:</p> <ul style="list-style-type: none"> <li>• breast pain</li> <li>• milk secretion</li> <li>• an absence of their monthly period</li> <li>• changes in the regularity of their periods</li> </ul> <p>Tell your doctor if your monthly periods are absent for six months or more.</p> <p>After prolonged use in men, medicines of this type can cause breast enlargement or impotence.</p> <p>Incidences of abnormal liver function have been occasionally reported.</p>	

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## **Reporting side effects**

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems).

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

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## **7. Product details**

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

### **What Amisulpride Winthrop contains**

<b>Active ingredient (main ingredient)</b>	amisulpride  Amisulpride 100 Winthrop tablets - 100 mg amisulpride per tablet.
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	<p>Amisulpride 200 Winthrop tablets - 200 mg amisulpride per tablet.</p> <p>Amisulpride 400 Winthrop tablets - 400 mg amisulpride per tablet.</p>
<p><b>Other ingredients (inactive ingredients)</b></p>	<p>The tablets also contain:</p> <ul style="list-style-type: none"> <li>● sodium starch glycollate type A</li> <li>● lactose monohydrate</li> <li>● microcrystalline cellulose (E 460)</li> <li>● hypromellose (E 464)</li> <li>● magnesium stearate (E 470)</li> </ul> <p>The 400 mg tablets also contain:</p> <ul style="list-style-type: none"> <li>● PEG-40 stearate</li> <li>● titanium dioxide (E 171)</li> </ul>
<p><b>Potential allergens</b></p>	<p>Tablets: Sugars as lactose</p>

**Do not take this medicine if you are allergic to any of these ingredients.**

**What Amisulpride Winthrop looks like**

100 mg - white, flat faced, breakable tablet, marked "AMI 100". Available in a pack size of 30 tablets (AUST R 125173).

200 mg - white, flat faced, breakable tablet, marked "AMI 200". Available in a pack size of 60 tablets (AUST R 125174).

400 mg - white, film-coated, breakable, oblong tablet, marked "AMI 400". Available in a pack size of 60 tablets (AUST R 125165).

## **Who distributes Amisulpride Winthrop**

Amisulpride Winthrop is distributed in Australia by:

sanofi-aventis australia Pty Ltd

12-24 Talavera Road

Macquarie Park NSW 2113

Australia

Freecall: 1800 818 806

Email: [medinfo.australia@sanofi.com](mailto:medinfo.australia@sanofi.com)

This leaflet was prepared in February 2023

amisulpride-winthrop-ccds16-cmiv17-10feb23

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