Amisulpride Winthrop®

amisulpride

Consumer Medicine Information (CMI)

What is in this leaflet

This leaflet is designed to provide answers to some common questions about this medicine. It does not contain all the available information.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Amisulpride Winthrop against the benefits this medicine is expected to have for you.

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

Keep this leaflet with this medicine.

You may need to read it again.

What Amisulpride Winthrop is used for

The name of your medicine is Amisulpride Winthrop. It contains the active ingredient called amisulpride.

Amisulpride Winthrop belongs to a group of medicines called antipsychotics. 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 (eg 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.

Your doctor may have prescribed Amisulpride Winthrop for another reason.

Ask your doctor if you have any questions about why Amisulpride Winthrop has been prescribed for you.

Before taking it

When you must not take it

Do not take Amisulpride Winthrop if:

- **you have an ALLERGIC REACTION to Amisulpride Winthrop 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.
- **you are breastfeeding or plan to breastfeed**
- **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

- **the packaging is torn or shows signs of tampering or the tablets do not look quite right**
- **the expiry date on the pack has passed.**

Do not take Amisulpride Winthrop if you have or have had any of the following medical conditions:

- 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.

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.

Before you start to take it

Your doctor must know about all the following before you start to take Amisulpride Winthrop.

Tell your doctor if:

1. **you have had an allergic reaction to any medicine which you have taken previously to treat your current condition.**
2. **you are pregnant or intend to become pregnant. Amisulpride Winthrop is not recommended for use in 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.

3. **you suffer from lactose intolerance because Amisulpride Winthrop tablets contain lactose.**
4. **you have kidney or liver disease, Parkinson's disease or fits (seizures).**
5. **you have problems with the heart and blood vessels.**
6. **you have or have a history of blood clots**
7. **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.**
8. **you suffer from dementia**
9. **you have any 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.**
10. **you have risk factors for stroke**

Taking other medicines

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

Some medicines and Amisulpride Winthrop may interfere with each other. 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, an anti-fungal given by injection into the veins
- other antipsychotics such as thioridazine, chlorpromazine, trifluperazine, pimozide, haloperidol, imipramine and lithium
- diuretics
- stimulant laxatives
- glucocorticosteroids
- diagnostics drugs such as tetracosactides
- medicines taken for anxiety or to help you sleep
- medicines taken for depression
- some strong pain killers
- antihistamines, medicines to treat allergies, which cause drowsiness
- some medicines taken to control blood pressure.

If you are unsure about any medicine you are taking, you should check with your doctor or pharmacist. They will have more information on medicines to be careful of while you are taking Amisulpride Winthrop.

How to take it

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.

How to take it

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

When to take it

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

How long do I take it

It is important that you do NOT stop taking Amisulpride Winthrop 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.

If you forget to take it

If you forget to take your medicine, take your dose as soon as you remember. Do not take a double dose to make up for the dose that you missed.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone Australia 13 11 26 or New Zealand 0800 POISON or 0800 764766), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much Amisulpride Winthrop. Show the doctor your pack of tablets. Do this even if there are no signs of discomfort or poisoning.

If you have taken too much Amisulpride Winthrop, the most common signs are drowsiness and slurred speech.

While you are using it

Things you must do

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

Tell all doctors, dentists and pharmacists who are treating you that you are taking Amisulpride Winthrop.

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

Tell your doctor immediately, or go to the nearest hospital, 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.

Things to be careful of

Amisulpride Winthrop may cause drowsiness in some people.

Be careful driving or operating machinery until you know how Amisulpride Winthrop affects you.

Be careful if you are elderly or unwell. Some people may experience side effects such as drowsiness, confusion, dizziness and unsteadiness, which may increase the risk of a fall.

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

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.

Things you must NOT do

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.

Side Effects

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

Like other medicines, Amisulpride Winthrop can cause some side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and may need medical attention. Some of the side effects are dose related, so it is important that you never exceed your prescribed dose.

While you are taking AMISULPRIDE WINTHROP

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

- drowsiness
- weight gain
- dizziness
- increased appetite
- nausea
- vomiting
- constipation
- dry mouth
- insomnia
- anxiety
- agitation.
- problems with orgasm

These are the most common side effects of Amisulpride Winthrop.

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.

Sometimes trembling, noticeable muscle stiffness or spasm, slowness of movement, excess saliva, 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 can occur. This will usually be reduced if your dose of Amisulpride Winthrop is lowered by your doctor or if your doctor prescribes you an additional medicine.

High blood sugar has been reported in patients taking Amisulpride Winthrop. Symptoms of high sugar levels in the blood include passing more urine than normal, persistent excessive thirst, increased appetite with a loss in weight and weakness.

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

- muscle twitching
- abnormal movements mainly of the face or tongue
- fever
- unexplained infections
- faster breathing
- sweating
- muscle stiffness.

If this occurs, stop taking Amisulpride Winthrop immediately and contact your doctor.

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.

Tell your doctor if your monthly periods are absent for six months or more.

After prolonged use in men, medicines of this type can cause breast enlargement or impotence.

Incidences of abnormal liver function have been occasionally reported.

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

Tell your doctor if you notice any symptoms that worry you, even if you think the problems are not connected with the medicine or are not listed in this leaflet.

After taking it

Storage

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.

Keep Amisulpride Winthrop tablets in a cool, dry place where the temperature stays below 30°C.

Do not store Amisulpride Winthrop 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 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.

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

Disposal

If your doctor tells you to stop taking Amisulpride Winthrop or the tablets have passed their expiry date, ask your pharmacist what to do with the amount left over.

Product description

What it looks like

Amisulpride Winthrop tablets are available in three different strengths:

The 100 mg strength is a white, flat faced, breakable tablet, marked "AMI 100".

The 200 mg strength is a white, flat faced, breakable tablet, marked "AMI 200".

The 400 mg strength is a white, film-coated, breakable, oblong tablet, marked "AMI 400".

The 100 mg strength is available in a pack size of 30 tablets.

The 200 mg strength is available in a pack size of 60 tablets.

The 400 mg strength is available in a pack size of 60 tablets.

Ingredients

Active Ingredient

AMISULPRIDE 100 WINTHROP tablets - 100 mg amisulpride per tablet.

AMISULPRIDE 200 WINTHROP tablets - 200 mg amisulpride per tablet.

AMISULPRIDE 400 WINTHROP tablets - 400 mg amisulpride per tablet.

Inactive Ingredients

The tablets also contain:

- sodium starch glycollate type A
- lactose
- microcrystalline cellulose (E 460)
- hypromellose (E 464)
- magnesium stearate (E 470).

The 400 mg tablets also contain:

- polyoxyl 40 stearate
- titanium dioxide (E 171).

Manufacturer

Amisulpride Winthrop is distributed in Australia by:

sanofi-aventis australia pty ltd

12-24 Talavera Road

Macquarie Park

NSW 2113

Australia

Amisulpride Winthrop is distributed in New Zealand by:

sanofi-aventis new zealand limited

Level 8, James & Wells Tower

56 Cawley Street

Ellerslie,Auckland

New Zealand

The Australian Registration numbers for Amisulpride Winthrop are as follows:

AMISULPRIDE 100 WINTHROP : AUST R 125173

AMISULPRIDE 200 WINTHROP : AUST R 125174

AMISULPRIDE 400 WINTHROP : AUST R 125165

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