
Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions about RISPA. It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

Ask your doctor or pharmacist if you have any concerns about using RISPA.

Your doctor and pharmacist have more information.

Keep this leaflet with your medicine.

You may need to read it again.

What RISPA is used for

RISPA is used to treat symptoms of schizophrenia and other types of related psychoses. These are disorders related to thought, feeling and/or action. RISPA may be taken for both sudden (acute) and long-lasting (chronic) schizophrenia.

It is also used to treat behavioural problems in patients with a decline in mental ability (dementia). These problems include:

- aggression through words or action
- morbid suspiciousness
- agitation
- wandering.

This medicine can be used to treat conduct and other disruptive behaviours such as aggression, impulsiveness and self-injury in children (over 5 years old), adolescents and adults who are intellectually disabled.

It helps to correct a chemical imbalance in the brain associated with these conditions.

This medicine has been approved for the uses mentioned above. However, your doctor may prescribe this medicine for another use. If you want more information, ask your doctor. RISPA is not addictive.

Before you take it

When you must not use it

Do not use Risperidone:

- if you know you are allergic to any of its ingredients (signs of allergy include skin rash, itching, shortness of breath, and/or swollen face - see the last section of this leaflet for a list of ingredients)
- if the packaging is torn or shows signs of being tampered with
- if the tablets do not look right
- to treat any other complaints unless your doctor says it is safe to do so.

Before you start to take it

RISPA should be used with caution in some patients.

Tell your doctor if you have or have ever had:

- heart or blood vessel diseases, including low blood pressure
- dehydration
- kidney or liver problems
- Parkinson's disease
- dementia or Lewy body dementia
- epilepsy, seizures
- restlessness or difficulty sitting still

- intraoperative iris syndrome (a complication that may occur during cataract extraction)
- suicide
- low blood potassium levels (hypokalaemia)
- low blood sugar
- breast cancer
- disease of the pituitary gland
- diabetes
- disease of the blood vessels of the brain, including stroke
- neuroleptic Malignant Syndrome (a serious reaction to neuroleptics)
- blood clots
- low white blood cell count
- Tardive dyskinesia (a reaction to some medicines with uncontrollable twitching or jerking movements of the arms and legs).

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

Your doctor will advise you whether or not you should take RISPA.

Tell your doctor if you are breast feeding.

This medicine is excreted in breast milk. It is recommended that you do not breast-feed while taking it.

Your doctor will advise you whether or not you should take RISPA.

Other medicines and alcohol

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

- sleeping tablets, tranquillisers, pain killers, antihistamines
- antibiotics like rifampicin
- medicines to treat Parkinson's disease or a tremor
- medicines to treat epilepsy such as carbamazepine
- anti-fungals like itraconazole and ketoconazole
- medicines to treat depression, panic or anxiety disorders, obsessive-compulsive disorder
- medicines for your heart or blood pressure
- medicines to treat pre-menstrual dysphoric disorder
- medicines to relieve severe nausea and vomiting
- other medicines to treat mental illness or psychotic conditions
- diuretics – medicines to treat high blood pressure and fluid build-up (eg. frusemide).

In studies in elderly patients with dementia where risperidone was compared with the dummy pill (placebo), the death rate was 3.1% with the dummy pill and slightly higher at 4% with risperidone.

Taking risperidone with frusemide, a medicine which is used to treat high blood pressure or to treat swelling of parts of the body caused by the build-up of too much

fluid, contributed to this difference, so this combination may be harmful.

Tell your doctor if you are taking frusemide (GenRx Frusemide Lasix, Lasix High Dose, Terry White Chemists Frusemide, Chemmart Frusemide, Uremide, Urex, Urex-M, Urex Forte, Frusid, Frusehaxel Injection, Furosemide Injection Mini Jet or Frusehexal).

RISPA can increase the effect of alcohol and other medicines which slow your reactions. You should not drink alcohol while taking it.

Elderly people

Elderly people should take less Risperidone than is prescribed for other adults (see "How to take it").

Taking it at the wrong time

At the start of treatment, you may have a fall in blood pressure making you feel dizzy on standing up, or your heart may beat faster. These should go away after a few days. Tell your doctor if they continue or worry you.

How to take it

How to take it

RISPA may be taken as a single dose, once a day or it may be taken in divided doses twice a day (in the morning and in the evening). The tablets should be swallowed with a glass of water. You may take your medicine either with or between meals.

It is very important that you take the correct amount of Risperidone, but this will vary from person to person. Your doctor will adjust the number and strength of the tablets until the desired effect is obtained.

Follow your doctor's instructions carefully and do not change or stop the required dosage without consulting your doctor first.

For Schizophrenia and Related Psychoses

The usual starting dose of RISPA is 1 mg twice a day. This will be gradually increased by your doctor to suit your needs. From then on, the dose can be taken once a day or twice a day according to your doctor's instructions. For long-term treatment, your doctor will determine the dose most suitable for you.

Important note: never take more tablets than your doctor tells you to take.

The effects of high doses are not yet known. Please double check with your doctor if your doctor prescribes more than 5 milligrams twice a day.

RISPA cannot be recommended for use in children with schizophrenia under 15 years at the present time as there is little experience with the product in this group.

For Elderly Patients with Schizophrenia or Related Psychoses

For older patients a starting dose of 0.5 mg (half a 1 mg tablet) twice a day (in the morning and in the evening) is usual. The dose may be increased by 0.5 mg twice daily to 1 to 2 mg twice a day (in the morning and in the evening).

Patients with impaired kidney and liver function.

If you have kidney or liver disease a starting dose of 0.5 mg (half a 1 mg tablet) twice a day (in the morning and in the evening) is usual. The dose may be increased by 0.5 mg

twice daily to 1 to 2 mg twice a day (in the morning and in the evening).

For Behavioural Problems in People with Dementia

The usual starting dose is 0.25 mg twice daily. This may be gradually increased by your doctor to suit your needs.

From then on the dose can be taken once a day or twice a day according to your doctor's instructions. For long-term treatment, 1 mg daily is the usual dose but your doctor will determine the dose most suitable for you.

For Disruptive Behaviour Disorders in Adults and Children

For people who weigh 50 kg or more, the usual starting dose is 0.5 mg (half a 1 mg tablet) once a day. The dose may be increased by 0.5 mg once every two days, to the usual dose of 0.5 to 1.5 mg once a day.

For people who weigh less than 50 kg, the usual starting dose is 0.25 mg once a day. The dose may be increased by 0.25 mg once every two days, to the usual dose of 0.25 to 0.75 mg once a day.

Your doctor will advise you on how much RISPA you need.

This medicine cannot be recommended for use in children with disruptive behaviour disorders under 5 years at the present time as there is little experience with the product in this group.

If you forget to take it

If you forget to take your medicine, take the missed dose as soon as you remember instead of your next dose. Then go back to taking it as you would normally.

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

If you forget to take it for 5 days or more, tell your doctor before starting your medicine again.

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

Overdose

If you think you or anybody else has taken too much RISPA, contact your doctor, pharmacist or the Poisons Information Centre who will advise you what to do.

You can contact the Poisons Information Centre by dialing 13 11 26 in Australia.

Signs of overdose may include drowsiness, sleepiness, excessive trembling, excessive muscle stiffness, increased heart rate, very low blood pressure causing fainting or unconsciousness.

While you are taking it

Things you must do

Always follow your doctor's instructions carefully, and seek your doctor's advice before changing or stopping treatment.

Your doctor will be happy to discuss any questions you may have with your treatment.

Try to eat a moderate diet.

RISPA can cause weight gain.

Pre-menopausal women should tell their doctor if they do not have a period for more than six months while taking this medicine.

Things to be careful of

Do not drink alcohol.

This medicine can increase the effects of alcohol.

Ask your doctor before taking any other medicines. RISPA can increase the effects of medicines which slow your reactions. Always ask your doctor or pharmacist before taking other medicines.

These include herbal treatments and those bought in a pharmacy or supermarket.

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

It may cause dizziness or light-headedness in some people, especially after the first dose.

Make sure you know how you react to it before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy.

Side Effects

All medicines can have side effects. Sometimes they are serious, but most of the time they are not. RISPA is generally well-tolerated and side effects are often hard to distinguish from the disease symptoms. You may need medical treatment if you get some of the side effects.

Tell your doctor as soon as possible if you do not feel well while you are using this medicine.

Below is a list of possible side effects you could get while taking RISPA:

- sleeplessness
- agitation
- anxiety
- headache
- trembling
- excessive saliva
- muscle stiffness
- restlessness in the legs
- fall in blood pressure, particularly on standing. This will be apparent to you as light-headedness or dizziness that passes after a few seconds or after sitting down again
- fast heart rate.

Although these effects are generally not harmful, contact your doctor if they bother you too much.

The following may occur less often:

- drowsiness, tiredness, difficulty in concentrating, somnolence, usually mild and short lasting may occur more often in children than in adults
- blurred vision
- dizziness
- indigestion, nausea, abdominal pain, constipation
- sexual function disturbances
- some loss of bladder control
- blocked nose
- weight gain
- excessive thirst
- blockage of the bowel
- unusual secretion of breast milk
- breast swelling
- missed or irregular menstrual periods
- during a long treatment, twitching of the tongue, face, mouth and jaws can occur.

Should this happen contact your doctor:

- in the early stages of treatment, in some people, blood pressure may decrease slightly and the heart beat increase resulting in dizziness. This usually goes

away after a few days. (See Taking it for the first time)

- after taking RISPA for a long time, some women may experience breast enlargement or get a discharge from the breasts. They may also experience irregular or heavy periods or absence of their periods. In men, breasts may enlarge slightly.

The following may occur rarely:

- oversensitivity (allergy). (See When you must not use it)
- in extremely rare cases, significant changes in body temperature may occur. This rise or fall in temperature is caused by a combination of several factors such as extreme cold or heat. Call your doctor if this happens
- in elderly patients with dementia, sudden weakness or numbness of the face, arms or legs, especially on one side, instances of slurred speech and stroke have been seen. If any of these should occur, even if for a short period of time, seek medical attention right away
- in very rare cases, high blood sugar has been reported. The symptoms of high blood sugar may be the need to urinate more often or feeling thirsty all the time. Contact your doctor if you experience any of these symptoms.

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

- Rash, itching or hives on the skin; shortness of breath, wheezing or difficulty breathing; swelling of the face, lips tongue or other parts of the body. If you have them, you may have had a serious allergic reaction to RISPA.
- Sudden weakness or numbness of the face, arms, legs, especially on one side, or instances of slurred speech (these are called mini-strokes).
- In elderly patients with dementia, occurrence of the following even for a short period of time: sudden weakness or numbness of the face, arms, or legs, especially on one side, instances of slurred speech and stroke.

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

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

Other side effects not listed above may occur in some consumers.

Do not hesitate to report any other side effects to your doctor or pharmacist.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After using it

Keep your medicine 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.

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

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

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

Do not store RISPA 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.

Disposal

Once you have finished using RISPA, ask your pharmacist what to do with any unused medicine.

Product description

What it looks like

RISPA comes in 5 strengths of tablets:

- RISPA 0.5 mg - red, round tablets marked "R" on one side and scored on the other. Blister packs of 20 tablets.
- RISPA 1 mg - white, oblong scored tablets marked "R" "1" on the scored side. Blister packs of 60 tablets.
- RISPA 2 mg - orange, oblong scored tablets marked "R" "2" on the scored side. Blister packs of 60 tablets
- RISPA 3 mg - yellow, oblong scored tablets marked "R" "3" on the scored side. Blister packs of 60 tablets
- RISPA 4 mg - green, oblong scored tablets marked "R" "4" on the scored side. Blister packs of 60 tablets

Ingredients

The active ingredient in RISPA is risperidone:

- each RISPA 0.5 mg tablet contains 0.5 mg of risperidone
- each RISPA 1 mg tablet contains 1 mg of risperidone
- each RISPA 2 mg tablet contains 2 mg of risperidone
- each RISPA 3 mg tablet contains 3 mg of risperidone
- each RISPA 4 mg tablet contains 4 mg of risperidone.

The tablets also contain:

- lactose monohydrate
- microcrystalline cellulose
- maize starch
- colloidal anhydrous silica
- magnesium stearate
- hypromellose
- titanium dioxide
- macrogol 400
- iron oxide red CI77491 (0.5 mg, 2 mg tablets)
- quinoline yellow CI47005 (2 mg, 3 mg tablets)
- indigotin CI73015 (4 mg tablets)

Sponsor

Arrow Pharma Pty Ltd
15 – 17 Chapel Street
Cremorne VIC 3121

Australian registration numbers

0.5 mg Tablet: AUST R 127880

1 mg Tablet: AUST R 127882

2 mg Tablet: AUST R 127884

3 mg Tablet: AUST R 127886

4 mg Tablet: AUST R 127888

This leaflet was revised in July 2017