

## Consumer Medicine Information

### What is in this leaflet

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

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

Your doctor or pharmacists have more information.

**Keep this leaflet with your medicine.**

You may need to read it again.

### What Risperidone AMNEAL Tablets is used for

Risperidone AMNEAL tablets belong to a group of medicines called antipsychotic agents which improve the symptoms of certain types of mental illness.

It is used for:

\*treatment of sudden (acute) and long-lasting (chronic) schizophrenia and other types of related psychoses. These are disorders related to thought, feeling and/or action

\*short term treatment of acute mania associated with bipolar 1 disorder. This condition is characterised by symptoms such as elevated, expansive or irritable mood, inflated self-esteem, decreased need for sleep, pressured speech, racing thoughts, distractibility or poor judgement including disruptive or aggressive behaviours.

\*treatment of behavioural problems in patients with a decline in mental ability (dementia). These problems include: aggression through words or action, morbid suspiciousness, agitation or wandering

\*treatment of 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.

\*treatment of behavioural symptoms of autism in children and adolescents

Risperidone AMNEAL tablets helps to correct a chemical imbalance in the brain associated with these conditions.

Risperidone AMNEAL tablets have 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. It is only available with a doctor's prescription.

Risperidone AMNEAL tablets are not addictive.

### Before you use Risperidone AMNEAL Tablets

#### When you must not use it

#### Do not use Risperidone AMNEAL tablets

- 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 use it

Risperidone AMNEAL tablets should be used with caution in some patients.

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

- heart or blood vessel problems, including high and low blood pressure. Low blood pressure can result from using Risperidone AMNEAL tablets together with medications to treat high blood pressure. So, if you need to use both Risperidone AMNEAL tablets and medications to reduce blood pressure, consult your doctor. Risperidone AMNEAL tablets should be used with caution, and only after consultation with your doctor, if you have heart problems, particularly irregular heart rhythm, abnormalities in electrical activity of the heart, or if using medications that can change the heart's electrical activity.
- disease of the blood vessels of the brain including stroke
- dehydration
- kidney or liver problems
- Parkinson's disease
- dementia or Lewy body dementia
- epilepsy, seizures
- low blood potassium levels (hypokalaemia)
- breast cancer
- disease of the pituitary gland
- diabetes
- Tardive dyskinesia (a reaction to some medicines with uncontrollable twitching or jerking movements of the arms and legs).
- Neuroleptic Malignant Syndrome (a serious reaction to some medicines with a sudden increase in body temperature, extremely high blood pressure and severe convulsions).

**Tell your doctor if you are pregnant or intend to become pregnant. Your doctor will advise you whether or not you should take Risperidone AMNEAL tablets.**

Shaking, muscle stiffness and difficulty in feeding, all of which are reversible, may occur in newborns, if a mother uses the medicine in the last trimester of her pregnancy

**Tell your doctor if you are breast-feeding.** Risperidone AMNEAL tablets are excreted in breast milk. It is recommended that you do not breast-feed while taking the medicine.

#### Taking other medicines

Risperidone AMNEAL tablets can increase the effect of other medicines which slow your reactions.

**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.**

**Ask your doctor or pharmacist before taking any other medicines. Risperidone AMNEAL tablets can increase the effects of medicines which slow your reactions.**

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

Tell your doctor if you are taking:

- diuretics like frusemide (trade names LASIX, UREMIDE, UREX, FRUSID, or FRUSEHEXAL), a drug used to treat high blood pressure, or to treat swelling of parts of the body caused by the build-up of too much fluid. There is an increased risk of side effects or death in elderly people if frusemide is also taken with Risperidone AMNEAL tablets.
- sleeping tablets, tranquilisers, pain-killers, antihistamines
- carbamazepine, a drug mainly used for epilepsy or trigeminal neuralgia (severe pain attacks in the face) may decrease the level of Risperidone AMNEAL tablets in your blood.
- medicines to treat Parkinson's disease or a tremor
- medicines to treat epilepsy
- medicines to treat depression, panic disorder, anxiety or obsessive-compulsive disorder. For example fluoxetine and paroxetine may increase the level of Risperidone AMNEAL tablets in your blood. So tell your doctor if you start and/or stop taking fluoxetine or paroxetine.
- medicines for your heart or blood pressure
- medicines to treat pre-menstrual dysphoric disorder
- other medicines to treat mental illness or psychotic conditions
- medicines to relieve severe nausea and vomiting.

### Using Risperidone AMNEAL Tablets

#### How much to take

Your doctor will decide the dose suitable for you.

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

#### Important note:

Never take more tablets than your doctor tells you to take. The maximum daily dose of Risperidone AMNEAL tablets is 5 milligrams taken twice a day. Check with your doctor if more than this has been prescribed. The effects of high doses are not yet known.

Risperidone AMNEAL tablets 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 Schizophrenia and Related Psychoses**  
The usual starting dose of Risperidone AMNEAL tablets are 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, 4 to 6 milligrams per day is usually sufficient but your doctor will determine the dose most suitable for you.

### **For Elderly Patients with Schizophrenia or Related Psychoses**

For older patients a starting dose of 0.5 mg 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 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 acute mania**

The recommended starting dose is 2mg once a day. This dose can be adjusted by dose increases of 1mg when needed every 24 hours. Most people feel better with doses between 2mg and 6mg a day. Your doctor may decide you should take another drug called a mood stabiliser as well as Risperidone AMNEAL Tablets.

### **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 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 Risperidone AMNEAL tablets you need.

Risperidone AMNEAL tablets 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.

### **For Behavioural Disorders Associated with Autism in Children and Adolescents**

For people weighing less than 20kg the usual starting dose is 0.25mg. On day 4 this dose can be increased to 0.5mg.

For people weighing 20kg or more the usual starting dose is 0.5mg. On day 4 this dose can be increased to 1.0mg.

Response should be assessed at day 14; only in patients not achieving sufficient clinical response should additional dose increases be considered. Your doctor will advise you on how much Risperidone AMNEAL tablets you need. When trialled, the maximum dose in patients with autism did not exceed 1.5mg/day in patients less than 20kg, 2.5mg in patients 20kg or more, or 3.5mg in patients more than 45kg.

### **When to take it**

Risperidone AMNEAL tablets 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). You may take

Risperidone AMNEAL tablets either with or between meals.

### **How to take it**

Swallow Risperidone AMNEAL tablets with water or other liquid.

It is very important that you take the correct amount of Risperidone AMNEAL tablets, 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.

As the 0.5 mg risperidone tablets do not have a breakline, they **must not** be broken in half to give a 0.25 mg dose. If you have been prescribed with 0.25 mg dose, consult your doctor or pharmacist for the alternative products.

### **How long to take it**

**Continue taking the tablets for as long as your doctor tells you.**

Risperidone AMNEAL tablets helps control your condition, but does not cure it.

Therefore you must take Risperidone AMNEAL tablets every day.

**Do not stop taking it unless your doctor tells you to - even if you feel better.**

### **If you forget to take**

#### **Risperidone AMNEAL tablets**

- If you forget to take Risperidone AMNEAL tablets, 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 Risperidone AMNEAL tablets 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.

### **If you take too much**

**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 may have taken too much Risperidone AMNEAL tablets. Do this even if there are no signs of discomfort or poisoning.**

You can contact the Poisons Information Centre by dialling:

- Australia: 13 11 26
- New Zealand: 0800 POISON or 0800 764 766.

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

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### **While you are using Risperidone AMNEAL Tablets**

#### **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.**

Risperidone AMNEAL tablets can cause weight gain.

**You should make sure you are not pregnant.**

**Pre-menopausal women should tell their doctor if they do not have a period for more than six months while taking Risperidone AMNEAL tablets.**

**Tell your doctor immediately if you notice any worm-like movements of the tongue, or other uncontrolled movements of the tongue, mouth, cheeks or jaw which may progress to the arms and legs.**

These are symptoms of a condition called tardive dyskinesia, which may develop in people taking antipsychotic medicines, including Risperidone AMNEAL tablets. This condition is more likely to occur during long term treatment with Risperidone AMNEAL tablets, especially in elderly women. In very rare cases, this may be permanent. However, if detected early, these symptoms are usually reversible.

**Tell any other doctors, dentists, and pharmacists who are treating you that you are taking Risperidone AMNEAL tablets.**

**Try to drink plenty of water,** especially if you are elderly and taking frusemide (a diuretic). This will help decrease your risk of certain side effects.

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

**Do not drink alcohol.**

Risperidone AMNEAL tablets can increase the effects of alcohol.

### **Things to be careful of**

**Be careful driving or operating machinery until you know how Risperidone AMNEAL tablets affects you.**

Risperidone AMNEAL tablets may cause dizziness or light-headedness in some people, especially after the first dose. Make sure you know how you react to Risperidone AMNEAL tablets before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy.

**Avoid excessive eating, as there is a possibility of weight gain when taking Risperidone AMNEAL tablets.**

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### **Side effects**

All medicines can have some unwanted side effects. Sometimes they are serious, but most of the time they are not. Your doctor has weighed the risks of using this medicine against the benefits they expect it will have for you.

All medicines can have side effects. You may need medical treatment if you get some of the side effects.

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

**Tell your doctor as soon as possible if you do not feel well while you are taking Risperidone AMNEAL tablets.**

You may need medical treatment if you get some of the side effects.

### **Taking it for the first 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.

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

**difficulty thinking or working because of:**

- sleeplessness

- headache
- trembling
- drowsiness, tiredness, difficulty in concentrating

**behavioural changes such as:**

- agitation
- anxiety

**joint or movement changes such as:**

- muscle stiffness
- restlessness in the legs

**other changes such as:**

- weight gain
- indigestion, nausea, abdominal pain, constipation
- excessive thirst
- frequent urination
- unusual secretion of breast milk
- breast swelling
- missed or irregular menstrual periods
- involuntary movements of the tongue, face, mouth, jaws, arms, legs or trunk

These are mild side effects of Risperidone AMNEAL tablets but may require medical attention.

**Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital if you notice any of the following: heart or blood pressure problems such as:**

- 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.
- faster heart rate, slowed heart rate, heart beat irregularities

**body temperature changes such as:**

- fever
- abnormally high body temperature

These may be serious side effects of Risperidone AMNEAL tablets. You may need urgent medical attention.

Serious side effects are uncommon.

**If any of the following happen, stop taking Risperidone AMNEAL tablets 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 Risperidone AMNEAL tablets.
- sudden weakness or numbness of the face, arms, or legs, especially on one side, or instances of slurred speech (these are called mini-strokes)
- in elderly patients with dementia, occurrence of following even for a short period time: sudden weakness or numbness of the face, arms or legs, especially on one side, instances of slurred speech and stroke

These are very 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.

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**After using Risperidone AMNEAL Tablets**

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**Storage**

**Keep Risperidone AMNEAL tablets in a dry place where the temperature stays below 25 degrees C.**

\*Do not store it or any medicines in the bathroom or near a sink.

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.

\*Do not use Risperidone AMNEAL tablets beyond the date (month and year) printed on the pack after the letters "EXP", even if it has been stored properly. Medicines cannot be stored indefinitely.

\*Do not use Risperidone AMNEAL tablets if the appearance of the tablets has changed.

**Disposal**

If your doctor tells you to stop taking Risperidone AMNEAL tablets or if it has passed the expiry date, ask your pharmacist what to do with any that are left over.

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**Product description**

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**What it looks like**

You can identify Risperidone AMNEAL tablets by their colour and shape. This is important because there are 5 types of Risperidone AMNEAL tablets each containing a different amount of Risperidone:

Risperidone AMNEAL tablets 0.5 mg: Brick red coloured, round, biconvex, film coated tablets plain on both sides

Risperidone AMNEAL tablets 1 mg: White to off white capsule shape, biconvex, film coated tablets plain on both sides.

Risperidone AMNEAL tablets 2 mg: Light orange coloured, capsule shape, biconvex, film coated tablets plain on both sides.

Risperidone AMNEAL tablets 3 mg: Light yellow coloured, oval shape, biconvex, film coated tablets with break line on one side and plain on other sides.

Risperidone AMNEAL tablets 4 mg: Green coloured, Capsule shaped, biconvex, film coated tablets plain on both sides.

The tablets are packed in blister packs of 20 tablets & 60 tablets (0.5 mg) and 60 tablets (1mg, 2 mg, 3 mg, 4 mg).

**Ingredients**

Active ingredient:

- Risperidone

Inactive ingredients:

- Lactose
- Maize starch
- Microcrystalline cellulose
- Hypromellose
- Sodium lauryl sulfate
- Silica colloidal anhydrous
- Purified talc
- Magnesium stearate
- Propylene glycol

In order to distinguish between the different tablet strengths, each strength contains different colourings. These are:

\*Risperidone AMNEAL Tablets 0.5 mg also contain titanium dioxide and ferric oxide red.

\*Risperidone AMNEAL Tablets 2 mg also contain titanium dioxide and sunset yellow aluminum lake (CI 15985)

\*Risperidone AMNEAL Tablets 3 mg also contain titanium dioxide and quinoline yellow aluminium lake (CI 47005)

\*Risperidone AMNEAL Tablets 4 mg also contain titanium dioxide, quinoline yellow aluminium lake (CI47005) and indigo carmine aluminium lake (CI73015)

**Name and Address of the Sponsor**

Amneal Pharma Australia Pty Ltd  
12 River Street  
South Yarra VIC 3141  
Australia

**Registration Number**

Risperidone AMNEAL Tablets 0.5 mg  
**(AUSTR 159974)**

Risperidone AMNEAL Tablets 1 mg  
**(AUSTR 159973)**

Risperidone AMNEAL Tablets 2 mg  
**(AUSTR 159976)**

Risperidone AMNEAL Tablets 3 mg  
**(AUSTR 159968)**

Risperidone AMNEAL Tablets 4 mg  
**(AUSTR 159970)**

**Date of Preparation**

November 2015