

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions about Rispa 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 Rispa Tablets is used for

RISPA belongs 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-term (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) caused by Alzheimer's disease. 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 adolescent.

RISPA 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 it for another use. It is only available with a doctor's prescription.

If you want more information, ask your doctor.

RISPA is not addictive.

Before you use Rispa Tablets

When you must not use it

Do not use RISPA:

- if you know you are allergic to any of its ingredients (see the last section of this leaflet for a list of ingredients) Signs of allergy include skin rash, itching, shortness of breath, and/or swollen face
- if the packaging is torn or shows signs of being tampered with
- if the tablets or the oral solution 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

RISPA should be used with caution in some patients.

1. Tell your doctor if you have or have ever had any medical conditions, especially the following:

- irregular heart rhythm, abnormalities in electrical activity of the heart, high or low blood pressure, or you've had a heart attack or stroke in the past.
- unusual excessive sweating or diarrhoea, dehydration or problems with your body temperature regulation
- kidney or liver problems
- you are prone to dizziness when standing up from lying or sitting position
- Parkinson's disease (a progressive movement and thinking disorder that tends to affect older people)
- dementia or Lewy body dementia Older people suffering dementia may be at increased risk of stroke or death with RISPA
- sugar diabetes
- unusual thirst, tiredness, blurred vision, upset stomach or need to urinate - common signs of high blood sugars
- epilepsy, seizures or fits
- continuous and/or painful erections (called 'priapism')
- involuntary movements or unusual restlessness or difficulty sitting still
- suicidal thoughts or past suicide attempts
- low blood potassium levels (hypokalaemia)
- breast cancer
- cancer of the pituitary gland
- Tardive dyskinesia (a reaction to some medicines with uncontrollable twitching or jerking movements of the tongue, face, mouth, jaw, arms and legs)
- Neuroleptic Malignant Syndrome (a serious reaction to some medicines that causes sudden increase in body temperature, very fast heartbeat, extremely high or low blood pressure and severe muscle stiffness or fits).
- blood clots Tell your doctor if you or someone else in your family has a history of blood clots. Blood clots in the lungs and legs can occur with RISPA. Blood clots in the lungs can result in death.
- low white blood cell count If you have low numbers of some white blood cells, your risk of contracting an infection or developing a fever is increased with RISPA.

2. Tell your doctor if:

- **you have any eye surgery planned.** Your doctor will need to assess whether you are at risk of a surgical complication (called 'Intraoperative Floppy Iris Syndrome'). You may be recommended to stop your RISPA temporarily prior to your eye surgery.
- **you are pregnant or planning to become pregnant.**

Your doctor will advise you whether you should take RISPA.

Newborn babies of mother taking RISPA in their last trimester may be at risk of having difficulty feeding or breathing, shaking, muscle stiffness and/or weakness, sleepiness or agitation.

- **you are breast-feeding.** As RISPA is excreted in breast milk, it is recommended that you do not breast-feed while taking the medicine.
- **you will be in a hot environment or do a lot of vigorous exercise.** RISPA may make you sweat less, causing your body to overheat.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking RISPA.

Taking other medicines

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, strong pain-killers, certain allergy medicines called antihistamines, certain antidepressants and alcohol
- medicines that increase the activity of the central nervous system (psychostimulants such as methylphenidate).
- medicines used to treat bacterial infections such as rifampicin
- medicines to treat fungal infections such as itraconazole and ketoconazole
- medicines to treat HIV/AIDS, such as ritonavir and tipranavir
- other medicines to treat mental illness or psychotic conditions
- medicines to treat depression, panic disorder, anxiety or obsessive-compulsive disorder, such as fluoxetine, paroxetine, sertraline and fluvoxamine
- medicines for your heart or blood pressure
- verapamil, a medicine used to treat high blood pressure and/or abnormal heart rhythm
- frusemide, a medicine used to treat high blood pressure and fluid build-up. There is an increased risk of side effects or death in older people if frusemide is also taken with RISPA.
- carbamazepine, a drug mainly used for epilepsy or trigeminal neuralgia (severe pain attacks in the face)
- medicines to treat Parkinson's disease or a tremor.
- medicines to treat epilepsy

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.

Using Rispa 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 Rispa 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.

Rispa 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 Rispa 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 Rispa 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 Rispa tablets you need.

Rispa 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 Rispa 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

Rispa 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 Rispa tablets either with or between meals.

How to take it

Swallow Rispa tablets with water or other liquid.

It is very important that you take the correct amount of Rispa 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.

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

Therefore you must take Rispa tablets every day.

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

If you forget to take Rispa tablets

- If you forget to take Rispa 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 Rispa 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 Rispa

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.

While you are using Rispa 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.

Rispa 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 Rispa 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 Rispa tablets. This condition is more likely to occur during long term treatment with Rispa 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 Rispa 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.

Rispa tablets can increase the effects of alcohol.

Things to be careful of

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

Rispa tablets may cause dizziness or light-headedness in some people, especially after the first dose. Make sure you know how you react to Rispa 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 Rispa tablets.

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 or pharmacist as soon as possible if you do not feel well while you are taking RISPA

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

- **difficulty thinking, working or carrying out your usual daily activities because of:**
 - headache
 - trembling, muscle weakness, unsteadiness on your feet, lack of coordination or slow, shuffling walk (symptoms of Parkinsonism).
 - lack of energy, drowsiness or excessive sleeping during the day, sleeplessness or difficulty in concentrating
 - difficulty speaking
 - blurred vision
 - fainting
 - dizziness
 - any problems with confusion or unsteadiness
 - pains in parts of your body, e.g. in the neck, back, ear, hands or feet
 - falling
- **muscle, joint, nerve or movement changes such as:**
 - shaking or trembling
 - fatigue or weakness
 - muscle stiffness
 - restlessness in the legs or difficulty sitting still
 - uncontrolled muscle spasms, twitching, jerky or writhing movements
 - muscle aches or pain
 - joint swelling or pain
 - walking abnormally or with difficulty
 - abnormal posture, such as rigid body movements and persistent abnormal positions of the body
- **behavioural changes such as:**
 - irritability or agitation
 - unusual anxiety or nervousness
- **other changes such as:**
 - cold or "flu-like" symptoms e.g. cough, blocked or runny nose, sneezing, sore throat
 - feeling of tension or fullness in the nose, cheeks and behind your eyes, sometimes with a throbbing ache, fever, stuffy nose and loss of the sense of smell (signs of sinusitis)
 - tiredness, headaches, being short of breath when exercising, dizziness and looking pale (signs of decreased red blood cells)
 - fever, chills, shortness of breath, cough, phlegm and occasionally blood (signs of pneumonia)
 - nosebleeds
 - discharge with itching of the eyes and crusty eyelids
 - unexplained weight gain
 - unexplained increase or decrease in appetite
 - indigestion, stomach discomfort or pain, diarrhoea or constipation
 - nausea or vomiting
 - dry mouth or excessive thirst
 - drooling
 - difficulty swallowing
 - acne

- dry skin
- rash, red skin or itchy skin
- thickening of the skin resulting in warts, corns, calluses
- skin infection
- swelling of any part of your body, e.g. hands, ankles or feet
- inability to or feeling burning pain when passing urine
- some loss of bladder control
- bedwetting
- frequent daytime urination in children
- sexual function disturbances
- problems with ejaculation
- breast abnormalities
- breast discomfort or swelling or unusual secretion of breast milk
- missed or irregular menstrual periods
- dizziness on standing up, especially when getting up from a sitting or lying down position
- shortness of breath
- chest pain or discomfort
- an increase of CPK (creatine phosphokinase) in your blood, an enzyme which is sometimes released with muscle breakdown. These can only be detected by blood tests that your doctor may ask to be done.

These are mild side effects of RISPA 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:

- **Signs of heart or blood pressure problems including:**
 - fainting, blurry vision, lightheadedness or dizziness particularly on standing that persists despite sitting or lying down again
 - very fast heart rate, slowed heart rate, heart rhythm irregularities
- **Signs of lung problems including:**
 - sudden shortness of breath, trouble breathing, wheezing or gasping when you breathe, light-headedness or dizziness
- **signs of high blood sugar or diabetes such as:**
 - unusual thirst, tiredness, upset stomach or need to urinate more often than usual
- **body temperature changes such as:**
 - fever
 - unexplained high body temperature, excessive sweating or rapid breathing
 - severe muscle stiffness or fits
- **involuntary movements of the tongue, face, mouth, jaw, arms, legs or trunk**
- **severe or life-threatening rash with blisters and peeling skin that may start in and around the mouth, nose, eyes, and genitals and spread to other areas of the body (Stevens-Johnson syndrome or toxic epidermal necrolysis)**
- **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, or legs, especially on one side, or instances of slurred speech (these are called mini-strokes)**

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 patients.

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.

Storage using Rispa Tablets

Storage

Keep Rispa 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 Rispa 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 Rispa tablets if the appearance of the tablets has changed.

Disposal

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

Product description

What it looks like

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

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

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

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

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

Rispa 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 monohydrate
- Maize starch
- Microcrystalline cellulose
- Hypromellose
- Sodium lauryl sulfate
- colloidal anhydrous silica

- Purified talc
- Magnesium stearate
- Propylene glycol

Contains sugars as lactose.

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

*Rispa Tablets 0.5 mg also contain titanium dioxide and Iron oxide red.

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

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

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

Name and Address of the Sponsor

Arrotex Pharmaceuticals Pty Ltd
15 – 17 Chapel street
Cremorne, VIC 3121
Australia

Registration Number

Rispa Tablets 0.5 mg (**AUSTR 159974**)

Rispa Tablets 1 mg (**AUSTR 159973**)

Rispa Tablets 2 mg (**AUSTR 159976**)

Rispa Tablets 3 mg (**AUSTR 159968**)

Rispa Tablets 4 mg (**AUSTR 159970**)

Date of Preparation

November 2023