

Patient Information Leaflet

SCHEDULING STATUS:

S5

ASPEN RISPERIDONE 0,5 mg film coated tablets

Risperidone

Contains sugar: Lactose monohydrate 65,126 mg

ASPEN RISPERIDONE 1 mg film coated tablets

Risperidone

Contains sugar: Lactose monohydrate 88,804 mg

ASPEN RISPERIDONE 2 mg film coated tablets

Risperidone

Contains sugar: Lactose monohydrate 87,804 mg

ASPEN RISPERIDONE 3 mg film coated tablets

Risperidone

Contains sugar: Lactose monohydrate 131,706 mg

ASPEN RISPERIDONE 4 mg film coated tablets

Risperidone

Contains sugar: Lactose monohydrate 175,608 mg

Read all of this leaflet carefully before you start taking/using/are given ASPEN

RISPERIDONE

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- ASPEN RISPERIDONE has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What ASPEN RISPERIDONE is and what it is used for
2. What you need to know before you take/use ASPEN RISPERIDONE
3. How to take/use ASPEN RISPERIDONE
4. Possible side effects
5. How to store ASPEN RISPERIDONE
6. Contents of the pack and other information

1. What ASPEN RISPERIDONE is and what it is used for

ASPEN RISPERIDONE contains the active substance risperidone.

ASPEN RISPERIDONE belongs to a group of medicines called “antipsychotics”. ASPEN RISPERIDONE is used to treat the following conditions:

- Sudden onset or long-term schizophrenic psychoses and related conditions which affect the way you think, feel or act. These conditions may cause symptoms such as hallucinations (when someone sees, hears, smells, tastes or feels things that do not exist), delusions (beliefs that conflict with reality), thought disturbances, poor speech, hostility, emotional and social withdrawal, depression and feelings of guilt or anxiety.
- Behavioural problems in patients with dementia (inability to think and reason clearly).
- Mania, where you may feel very excited, elated, agitated, enthusiastic or hyperactive. Mania occurs in an illness called “bipolar disorder”.
- In the treatment of children aged 5 to 12 years with sub-average intellectual

functioning or mental retardation (delayed progress or development) in whom destructive behaviour disorders such as aggression, impulsivity and self-injurious behaviours are prominent.

2. What you need to know before you take/use ASPEN RISPERIDONE

Do not take ASPEN RISPERIDONE

- If you are hypersensitive (allergic) to risperidone or to any of the other ingredients contained in ASPEN RISPERIDONE.
- If your child is under the age of 5 years as the effects of ASPEN RISPERIDONE has not been tested in this age group.
- If you suffer from Parkinson's disease and/or Lewy Body Dementia (loss of the ability to think or reason clearly due to protein deposits in the nerve cells).

Warnings and precautions

Take special care with ASPEN RISPERIDONE:

- If you are an elderly person with dementia (loss of the ability to think or reason clearly), as there is an increased risk of stroke. You should not take ASPEN RISPERIDONE if you have dementia caused by stroke.
- If you are taking any medicine containing furosemide (used in the treatment of certain heart conditions).
- If you have sugar diabetes or a family history of diabetes as ASPEN RISPERIDONE may worsen diabetes. Report any symptoms of high blood sugar levels such as increased thirst, increased urination, hunger and weakness to your doctor. Diabetic patients must monitor blood sugar levels more closely while taking ASPEN RISPERIDONE.
- If you have heart disease, such as irregular heart rhythm or if you are prone to low blood pressure or if you are using medicines for your blood pressure, as ASPEN RISPERIDONE

may cause low blood pressure. The dose of ASPEN RISPERIDONE may need to be increased more slowly when you start treatment.

- If you know of any factors which would favour you having a stroke, such as high blood pressure, cardiovascular disorder or blood vessel problems in the brain as ASPEN RISPERIDONE may be more likely to cause side effects.
- If you have Parkinson's disease as ASPEN RISPERIDONE may worsen symptoms of Parkinson's disease.
- If you have liver or kidney problems or if you are over the age of 65 years as ASPEN RISPERIDONE may need to be started at a lower dose and the dose may need to be increased more slowly.
- If you have epilepsy as ASPEN RISPERIDONE may increase the risk of seizures.
- If you are going to have any surgery, including dental surgery, tell your doctor that you are taking ASPEN RISPERIDONE as ASPEN RISPERIDONE may interfere with certain medicines used during surgery.
- If you have ever experienced involuntary movements of the tongue, mouth and face.
- If you have ever had a condition whose symptoms include high temperature, muscle stiffness, sweating or a lowered level of consciousness (also known as Neuroleptic Malignant Syndrome).
- If you are going to have surgery on the eye for cloudiness of the lens (cataract). Make sure you tell your doctor that you are taking ASPEN RISPERIDONE.
- If you know of any factors which would favour you having a stroke, such as high blood pressure, cardiovascular disorder or blood vessel problems in the brain.
- If you or your care-giver notice a sudden change in your mental state or sudden weakness or numbness of your face, arms or legs, especially on one side, or slurred speech, even for a short period of time, seek medical treatment immediately. These may be signs of a stroke.
- If you have a history of low levels of white blood cells (which may or may not have been caused by other medicines). As dangerously low numbers of a certain type of white blood

cell needed to fight infection in your blood has been seen with patients taking risperidone, as contained in ASPEN RISPERIDONE, your doctor may check your white blood cell counts.

- If you have a condition in which your body over produces a hormone called prolactin or have a tumour that causes increased prolactin levels.
- If you exercise strenuously, are exposed to high heat temperatures or are taking medicines that could increase your body temperature.
- If you are a man and you have ever had a prolonged or painful erection.
- ASPEN RISPERIDONE may cause you to gain weight. Significant weight gain may adversely affect your health.

Other medicines and ASPEN RISPERIDONE

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

Stopping or starting any other medicines may have an effect on ASPEN RISPERIDONE. Do not start or stop taking any other medicines, without speaking to your doctor first. It is important to tell your doctor if you are taking any of the following:

- Medicines containing furosemide (used for heart problems or swelling of parts of your body due to a build-up of too much fluid) (see Take Special Care).
- Alcohol or other medicines that cause sedation (e.g. medicines for hay fever, allergies or colds, medicines to help you sleep, pain medication, muscle relaxants, some prescription medicines and medicines for seizures). Concurrent use may make you feel drowsier.
- Some medicines for epilepsy, depression, other mood disorders or heart problems). Combined use may require the dose of ASPEN RISPERIDONE to be adjusted.
- Medicines for Parkinson's disease, such as levodopa as combined use may oppose the effects of both medicines.

- Tell your doctor if you are taking carbamazepine (used in the treatment of epilepsy), as it

decreases the blood levels of risperidone.

- Tell your doctor if you are taking lithium-containing medicines as risperidone will have an effect on it.
- Medicines that cause a slow heartbeat.
- Medicines that work on the brain such as those used to help you calm down (benzodiazepines) or medicines for pain (opiates), medicines for allergy (some antihistamines), as ASPEN RISPERIDONE may increase the sedative effects of all of these.
- Medicines that may change the electrical activity of your heart, such as medicines for malaria, heart rhythm problems, allergies (antihistamines), some antidepressants or other medicines for mental problems.
- Valproate, carbamazepine and topiramate (used to treat epilepsy).
- Phenothiazine (used to treat serious mental and emotional disorders, including schizophrenia and other psychotic disorders).
 - Tricyclic antidepressants such as imipramine and amitriptyline (used to treat mood disorders and depressive disorders).
 - Fluoxetine, paroxetine, sertraline or venlafaxine (used to treat depression).
 - Paliperidone (used to treat mental conditions).
 - Erythromycin (used to treat bacterial infections).
 - Rifampicin (used to treat tuberculosis (TB)).
 - Donepezil and galantamine (used to treat Alzheimer's).
 - Itraconazole, ketoconazole (used to treat fungal infections).
 - Certain antiretrovirals such as atazanavir, ritonavir (used to treat HIV).
 - Beta-blockers such as atenolol, propranolol and calcium channel blockers such as verapamil (used to treat certain heart conditions).
 - Cimetidine, ranitidine (used to treat certain conditions of the digestive tract).

- Digoxin (used to treat certain heart conditions).
- Lithium (used to treat certain mental conditions).

ASPEN RISPERIDONE with food, drink and alcohol:

ASPEN RISPERIDONE is not affected by food and may be given with meals or on an empty stomach. It is best not to drink alcohol while you take ASPEN RISPERIDONE. Alcohol may add to the sedative effects of ASPEN RISPERIDONE and make you feel more drowsy.

Pregnancy, breastfeeding

The use of ASPEN RISPERIDONE in pregnancy or during breast-feeding has not been studied. If you are pregnant or breast-feeding your baby please consult your doctor, pharmacist or other healthcare professional for advice before taking ASPEN RISPERIDONE. The following symptoms may occur in new-born babies of mothers who have used risperidone, as contained in ASPEN RISPERIDONE, in the last trimester (last three months of their pregnancy): shaking, muscle stiffness, and/or weakness, sleepiness, agitation, breathing problems, and difficulty in feeding. If your baby develops any of these symptoms contact your doctor.

Driving and using machines

ASPEN RISPERIDONE may cause blurred vision, dizziness or drowsiness.

Make sure you know how you react to ASPEN RISPERIDONE before you drive, use machinery, or do anything else that could be dangerous if you are not alert or able to see clearly.

It is not always possible to predict to what extent ASPEN RISPERIDONE may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which ASPEN RISPERIDONE affects them (see section 4).

ASPEN RISPERIDONE contains lactose monohydrate

ASPEN RISPERIDONE contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus. Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance should not take ASPEN RISPERIDONE.

3. How to take/use ASPEN RISPERIDONE

Do not share medicines prescribed for you with any other person.

Always take ASPEN RISPERIDONE exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Schizophrenia

Your healthcare provider may decide to gradually discontinue you from current injectable treatment while ASPEN RISPERIDONE therapy is initiated.

Adults:

ASPEN RISPERIDONE may be given once or twice daily.

Your healthcare provider may start with ASPEN RISPERIDONE 2 mg/day. Dosing will be individualized, and your healthcare provider may decide to increase your dose. Dosages above 10 mg/day should only be considered if the benefits outweigh the risk. The maximum total daily dose is 16 mg/day.

Elderly patients:

A starting dose of 0,5 mg twice daily is recommended. Your healthcare provider will individualize your dose and may decide to adjust the dose with 0,5 mg twice daily increments to 1 to 2 mg twice daily.

Children:

Not for children under 15 years as efficacy and safety in children under the age of 15 years have not been demonstrated in schizophrenia.

Behavioural disturbances in adult patients with dementia

Your healthcare provider may start you on a dose of 0,25 mg twice daily. Your dose may further be individualized by your healthcare provider by increments of 0,25 mg twice daily, but not more frequently than every other day, if needed. The optimum dose is 0,5 mg twice daily for most patients. Some patients, however, may benefit from doses up to 1 mg twice daily.

The continued use of ASPEN RISPERIDONE must be evaluated and justified on an ongoing basis.

Mania in bipolar disorder

Your healthcare provider may initiate ASPEN RISPERIDONE administered on a once daily schedule, starting with 2 or 3 mg. Dosage adjustments, if indicated, should occur at intervals of not less than 24 hours and in dosage increments of 1 mg per day. Efficacy has been demonstrated in flexible doses over a range of 1 to 6 mg per day.

Experience is lacking in bipolar mania in children and adolescents less than 18 years of age.

Conduct and other disruptive behaviour disorders (DBD) in children 5 to 12 years of age

Patients < 50 kg

A healthcare provider may initiate the patient on a starting dose of 0,01 mg/kg once daily.

This dosage will be may be adjusted by increments of 0,01 mg/kg once daily not more frequently than every other day, if needed. The recommended maintenance dose is 0,02 to 0,04 mg/kg once daily. The mean dose is 0,03 mg/kg once daily.

The continued use of ASPEN RISPERIDONE must be evaluated and justified on an ongoing basis.

Experience is lacking in children aged less than 5 years (see 'Do not Take').

If you have the impression that the effect of ASPEN RISPERIDONE is too strong or too weak, talk to your doctor or pharmacist.

Do not share medicines prescribed for you with any other person.

If you take more ASPEN RISPERIDONE than you should

Symptoms of overdose include drowsiness, sedation, fast heartbeat, tremor, muscle quivering or rigidity, increased salivation or dizziness.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control center.

If you forget to take/use ASPEN RISPERIDONE

If you miss a dose of ASPEN RISPERIDONE, take it as soon as you remember. If it is nearly time for the next dose, skip the missed dose and go back to your normal dosing schedule.

Do not take a double dose to make up for forgotten individual doses.

If you stop taking ASPEN RISPERIDONE

Do not stop taking ASPEN RISPERIDONE unless your doctor tells you to do so. Your doctor may want you to gradually decrease the amount you are taking before stopping or switching to another medicine. This is to prevent withdrawal symptoms and to avoid your condition getting worse.

4. Possible side effects

ASPEN RISPERIDONE can have side effects.

Not all side effects reported for ASPEN RISPERIDONE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ASPEN RISPERIDONE, please consult your healthcare provider for advice.

If any of the following happens, stop taking/using ASPEN RISPERIDONE and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Hypersensitivity reactions that include fever, puffiness or swelling of the eyelids or around the eyes, face, lips or tongue, constriction of the air passages of the lungs and rashes.

These are all very serious side effects. If you have them, you may have had a serious reaction to ASPEN RISPERIDONE. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Experience blood clots in the veins, especially in the legs (symptoms include swelling, pain, and redness in the leg), which may travel through blood vessels to the lungs causing chest pain and difficulty breathing. If you notice any of these symptoms seek medical advice immediately
- Have dementia and experience a sudden change in your mental state or sudden weakness or numbness of your face, arms or legs, especially on one side, or slurred speech, even for a short period of time. These may be signs of a stroke
- Experience fever, muscle stiffness, sweating or a lowered level of consciousness (a disorder called “Neuroleptic Malignant syndrome”) immediate medical treatment may be needed.
- Are a man and experience prolonged or painful erection. This is called priapism.

Immediate medical treatment may be needed

- Experience uncontrolled movements of the tongue, lips, mouth, face, arms or legs, severe muscle stiffness with fever, fast heartbeat, difficulty breathing, increased sweating, severe tiredness or weakness, loss of bladder control or seizures, difficulty in speaking or swallowing, loss of balance control, mask-like face, muscle spasms of face, neck or back, tic-like or twitching movements, tremor, rigidity, restlessness, twisting movements of the body, high body temperature, prolonged or painful erections. Some side effects, such as uncontrolled movements of the mouth, tongue, jaw, arms or legs, may occur after you have stopped taking this medicine. Check with your doctor as soon as possible if you experience any of these effects
- Experience atrial fibrillation (an abnormal heart rhythm), an interruption in conduction between the upper and lower parts of the heart, abnormal electrical conduction of the heart, Prolongation of the QT interval from your heart, Slow heart rate, Abnormal electrical tracing of the heart (electrocardiogram or ECG), A fluttering or pounding feeling in your chest (palpitations).
- Experience jaundice, a condition in which the skin, whites of the eyes and mucous membranes turn yellow because of a high level of bilirubin, a yellow-orange bile pigment.
- Parkinsonism: This condition may include: slow or impaired movement, sensation of stiffness or tightness of the muscles (making your movements jerky), and sometimes even a sensation of movement "freezing up" and then restarting. Other signs of parkinsonism include a slow shuffling walk, a tremor while at rest, increased saliva and/or drooling, and a loss of expression on the face.
- Decrease in the type of white blood cells that help to protect you against infection, decrease in platelets (blood cells that help you stop bleeding), anaemia, decrease in red blood cells, increase in eosinophils (a type of white blood cell) in your blood

- Sudden loss of blood supply to brain (stroke or "mini" stroke)
- Loss of consciousness, low level of consciousness
- Convulsion (fits)
- Glaucoma (increased pressure within the eyeball), problems with movement of your eyes, eye rolling, eyelid margin crusting
- Eye problems during cataract surgery. During cataract surgery, a condition called intraoperative floppy iris syndrome (IFIS) can happen if you take or have taken
- ASPEN RISPERIDONE. If you need to have cataract surgery, be sure to tell your eye doctor if you take or have taken ASPEN RISPERIDONE
- Coma due to uncontrolled diabetes.
- If you experience nausea, vomiting, diarrhoea or oily stools, weight loss, fever, rapid pulse as these may be symptoms of pancreatitis (a disease where the pancreas gets inflamed)
- If you experience cramping pain, vomiting, obstipation, and lack of flatus as these may be symptoms intestinal obstruction which causes blockage of the bowel.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Pneumonia, infection of the chest (bronchitis), common cold symptoms.
- Urinary tract infection.
- Symptoms of high prolactin occur, they may include in men breast swelling, difficulty in getting or maintaining erections, or other sexual dysfunction. In women they may include breast discomfort, leakage of milk from the breasts, missed menstrual periods, or other problems with your cycle.

- Increased or decreased appetite, loss of appetite resulting in malnutrition and low body weight.
- Sleeplessness, anxiety, agitation, sleep disorders, depression.
- Headache, dizziness, tremors.
- Akathisia: This is a condition where you feel inner restlessness the inability to sit still.
- Dystonia: This is a condition involving slow or sustained involuntary contraction of muscles. While it can involve any part of the body (and may result in abnormal posture), dystonia often involves muscles of the face, including abnormal movements of the eyes, mouth, tongue or jaw.
- Sleepiness, drowsiness, lack of energy.
- Impairment of voluntary movement.
- Blurred vision.
- Increased heart rate.
- Difficulty in breathing, nose bleeds, cough nasal congestion.
- Vomiting, diarrhoea, constipation, nausea, abdominal pain, indigestion, dry mouth, abdominal discomfort.
- Skin rash and redness of the skin.
- Joint pain, back pain, pain in arms and legs, muscle spasms, muscle pain.
- Involuntary urination.
- Fever, tiredness, water retention.
- Weight gain.
- Glucose in the urine.

Less frequent side effects:

- Sinus infection, viral infection, ear infection, inflammation of the tonsils, bacterial skin infection, ear infection, eye infection, localised infection, hardening of the skin, urinary tract infection, nail infection, abscess under the skin, inflammation of the stomach and intestines.

- Confusion.
- Decreased sex drive.
- Listlessness.
- Nervousness.
- Toothache.
- Hardened faeces in the rectum.
- Inability to reach an orgasm.
- Impaired concentration,
- Nightmares,
- Mania (periods of great excitement).
- Little to no feeling in otherwise emotionally-charged contexts.
- Excessive sleepiness.
- Abnormal coordination.
- Shaking of the head.
- Disturbance in attention.
- Unclear speech.
- Reduced sense of touch, numbness.
- Taste distortion.
- Dangerously excessive intake of water.
- Inability to regulate body temperature.
- Low blood sugar.
- Loss of appetite.
- Inflammation and swelling of the conjunctiva (the thin, inner layer of the eye).
- Eye discharge, dry eye, increase in tears in the eye, sensitivity to light, reduced clarity of vision, crusting of the eyelid, eye movement disorder.
- Ear pain, ringing in the ears, sensation of loss of balance.
- Low blood pressure, flushing, high blood pressure.
- Breathing with a whistling/rattling sound in the chest (wheezing).

- Abnormal lung sounds.
- Fast, irregular breathing.
- Runny nose.
- Sleep apnoea (pauses in breathing during sleep).
- Skin lesions, itching of the skin, acne, skin discoloration, dandruff, dry skin, thickening of the skin.
- Muscle weakness, neck pain, swelling and stiffness of the joints, chest muscle pain, buttock pain.
- Painful urination, urinary incontinence, urinary retention, abnormal daytime urinary frequency.
- Absence of menstruation, erectile dysfunction, ejaculation disorder, development of breasts in men, leakage of milk from the breasts, sexual dysfunction, breast pain, breast discomfort, vaginal discharge, breast discharge
- Orgasmic dysfunction.
- Delayed menstruation, delayed ejaculation, infrequent menstruation.
- Swelling of the face (water retention), thirst, chills.
- Increased or decreased body temperature.
- Falls.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to:

SAHPRA: <https://www.sahpra.org.za/health-products-vigilance/>

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

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

5. How to store ASPEN RISPERIDONE

Store all medicines out of reach of children.

Store at or below 25 °C, protected from light.

Keep the blister strip in the unit carton until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What ASPEN RISPERIDONE contains

The active substance is risperidone.

The other ingredients for ASPEN RISPERIDONE 0,5 mg are:

FD&C blue/indigo carmine aluminium lake (C.I. 73015), FD&C yellow/sunset yellow FCF aluminium lake (C.I. 15985), hypromellose, iron oxide yellow (C.I. 77492), lactose monohydrate, macrogol, magnesium stearate, microcrystalline cellulose, pregelatinised starch, silica colloidal anhydrous, sodium lauryl sulphate, sodium starch glycollate, titanium dioxide (C.I. 77891)

Contains sugar: Lactose monohydrate 65,126 mg

The other ingredients for ASPEN RISPERIDONE 1 mg are:

Hypromellose, lactose monohydrate, macrogol, magnesium stearate, microcrystalline cellulose, pregelatinised starch, silica colloidal anhydrous, sodium lauryl sulphate, sodium starch glycollate, titanium dioxide (C.I. 77891)

Contains sugar: Lactose monohydrate 88,804 mg

The other ingredients for ASPEN RISPERIDONE 2 mg are:

FD&C yellow/sunset yellow FCF (C.I. 15985), hypromellose, iron oxide yellow (C.I. 77492), lactose monohydrate, macrogol, magnesium stearate, microcrystalline cellulose, pregelatinised starch, silica colloidal anhydrous, sodium lauryl sulphate, sodium starch glycollate, titanium dioxide (C.I. 77891)

Contains sugar: Lactose monohydrate 87,804 mg

The other ingredients for ASPEN RISPERIDONE 3 mg are:

FD&C blue/indigo carmine aluminium lake (C.I. 73015), FD&C yellow/sunset yellow FCF aluminium lake (C.I. 15985), hypromellose, lactose monohydrate, macrogol, magnesium stearate, microcrystalline cellulose, pregelatinised starch, quinoline yellow aluminium lake (C.I. 47005), silica colloidal anhydrous, sodium lauryl sulphate, sodium starch glycollate, titanium dioxide (C.I. 77891)

Contains sugar: Lactose monohydrate 131,706 mg

The other ingredients for ASPEN RISPERIDONE 4 mg are:

FD&C blue/indigo carmine aluminium lake (C.I. 73015), hypromellose, lactose monohydrate, macrogol, magnesium stearate, microcrystalline cellulose, pregelatinised starch, quinoline yellow aluminium lake (C.I. 47005), silica colloidal anhydrous, sodium lauryl sulphate, sodium starch glycollate, titanium dioxide (C.I. 77891)

Contains sugar: Lactose monohydrate 175,608 mg

What ASPEN RISPERIDONE looks like and contents of the pack

ASPEN RISPERIDONE 0,5 mg: Red brown colour, normal round, scored biconvex film-coated tablets. Tablets might be embossed with either “PhI” or “A 27” on one side.

ASPEN RISPERIDONE 1 mg: White colour, normal round, scored biconvex film-coated tablets. Tablets might be embossed with either “PhI” or “A 28” on one side.

ASPEN RISPERIDONE 2 mg: Peach colour, normal round, scored biconvex film-coated tablets.

Tablets might be embossed with either “Phl” or “A 29” on one side.

ASPEN RISPERIDONE 3 mg: Yellow colour, normal round, film-coated tablets. Tablets might be embossed with either “Phl” or “A 30” on one side.

ASPEN RISPERIDONE 4 mg: Green colour, normal round, scored biconvex film-coated tablets.

Tablets might be embossed with either “Phl” or “A 31” on one side.

28 or 30 film-coated tablets are packed in a clear polyvinyl chloride/polyvinylidene chloride blister strip sealed with an aluminium foil backing. The blister strips are packed into a cardboard unit carton together with a leaflet.

Not all pack sizes are necessarily marketed.

Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead, 2191

Hotline: 0800 122 912

This leaflet was last revised in

14 February 2022

Registration number

ASPEN RISPERIDONE 0,5 mg: 41/2.6.5/0339

ASPEN RISPERIDONE 1 mg: 41/2.6.5/0340



ASPEN RISPERIDONE 2 mg: 41/2.6.5/0341

ASPEN RISPERIDONE 3 mg: 41/2.6.5/0346

ASPEN RISPERIDONE 4 mg: 41/2.6.5/0347

Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

<https://www.sahpra.org.za/pi-pil-repository/>

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

Namibia: NS3	
0,5 mg	10/2.6.5/0535
1 mg	10/2.6.5/0536
2 mg	10/2.6.5/0537
3 mg	10/2.6.5/0538
4 mg	10/2.6.5/0539

ZA_ASRSPTAB_2202_00