Proposed Amended Patient Information Leaflet

Information for the Patient about

RISNIA TABLETS

Read all of this leaflet carefully before you start taking RISNIA.

- **Keep this leaflet, you may need to read it again.**
- **If you have further questions, please ask your doctor or pharmacist.**
- **RISNIA 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.**

SCHEDULING STATUS:

S5

PROPRIETARY NAME (AND DOSAGE FORM):

RISNIA 0,5 mg (Tablets)

RISNIA 1 mg (Tablets)

RISNIA 2 mg (Tablets)

RISNIA 3 mg (Tablets)

RISNIA 4 mg (Tablets)

RISNIA 6 mg (Tablets)

WHAT RISNIA TABLETS CONTAIN:

The active ingredient in **RISNIA** tablets is risperidone.

RISNIA 0,5 mg: Each tablet contains risperidone 0,5 mg. Inactive ingredients include lactose monohydrate, corn

starch, microcrystalline cellulose, sodium starch glycollate, red oxide of iron, magnesium stearate, opadry brown, and opacode black.

RISNIA 1 mg: Each tablet contains risperidone 1 mg. Inactive ingredients include lactose monohydrate, corn starch, microcrystalline cellulose, sodium starch glycollate, magnesium stearate, opadry white, and opacode black.

RISNIA 2 mg: Each tablet contains risperidone 2 mg. Inactive ingredients include lactose monohydrate, corn starch, microcrystalline cellulose, sodium starch glycollate, magnesium stearate, opadry orange, and opacode black.

RISNIA 3 mg: Each tablet contains risperidone 3 mg. Inactive ingredients include lactose monohydrate, corn starch, microcrystalline cellulose, sodium starch glycollate, magnesium stearate, opadry yellow, and opacode black.

RISNIA 4 mg: Each tablet contains risperidone 4 mg. Inactive ingredients include lactose monohydrate, corn starch, microcrystalline cellulose, sodium starch glycollate, magnesium stearate, opadry green, and opacode black.

RISNIA 6 mg: Each tablet contains risperidone 6 mg. Inactive ingredients include lactose monohydrate, corn

starch, microcrystalline cellulose, sodium starch glycollate, magnesium stearate, opadry yellow, and opacode black.

WHAT RISNIA IS USED FOR:

RISNIA belongs to a class of medicines called central nervous system depressants.

RISNIA is used to treat symptoms of schizophrenia and can be used over the short- and long-term. **RISNIA** is effective in maintaining improvement in patients who initially responded to treatment. If you have been diagnosed with schizophrenia, your doctor will decide whether you qualify for treatment with **RISNIA**.

RISNIA is also used to treat conduct or behavioural disorders in children (aged 5 to 12 years) with below average intellect or mental retardation.

BEFORE YOU TAKE RISNIA:

Do NOT take RISNIA if:

- You are known to be hypersensitive (allergic) to risperidone or any of the other inactive ingredients.
- You have been diagnosed with Lewy body dementia (see **"Take special care with RISNIA"**).
- You are breastfeeding your baby (see **"Pregnancy and breastfeeding"**).

RISNIA is not for use in children with conduct or other disruptive behaviour disorders who are younger than 5 years of age, since efficacy and safety have not been established in this age group.

Take special care with RISNIA:

RISNIA may cause a condition known as tardive dyskinesia, which is characterised by involuntary movements of the facial muscles or tongue. Although these movements may cease when treatment with **RISNIA** is stopped, this is not always the case. This adverse event is more common in the elderly, especially elderly females; however, it is not possible to predict at the onset of treatment which patients are likely to develop it. A possible predictor for the development of tardive dyskinesia is the occurrence of a tremor, slow movement and abnormal gait. The risk of developing tardive dyskinesia and the likelihood that it will become irreversible are believed to increase as the duration of treatment and the total cumulative dose increase. However, it may also develop after relatively brief periods of treatment at low doses. There is no known treatment for an established case of tardive dyskinesia. The syndrome may remit partially or completely if **RISNIA** is withdrawn. Your doctor will monitor you for this condition.

Another potentially life-threatening complication of treatment with **RISNIA** is neuroleptic malignant syndrome (NMS) (see **"POSSIBLE SIDE-EFFECTS"**). You should report to your doctor as a matter of urgency if you develop any combination of the following symptoms: fever, muscle rigidity, altered mental status or reduced consciousness, irregular pulse or palpitations, and profuse sweating. This condition may lead to kidney failure and death.

People with Parkinson's disease or dementia with Lewy bodies are at increased risk of developing neuroleptic malignant syndrome when taking **RISNIA** and may have increased sensitivity to it. Such increased sensitivity may result in mental confusion, decreased level of alertness or consciousness, frequent falls as well as extrapyramidal symptoms. Extrapyramidal symptoms include repetitive, involuntary muscle movements (such as lip smacking) or an undeniable urge to be moving constantly. You, or a family member, should report any of these symptoms to your doctor as a matter of urgency.
In addition, elderly patients may have a higher risk of mortality (death). Please discuss these risks with your doctor.

If you are taking water pills (diuretics) with furosemide as the active ingredient, please inform your doctor before starting **RISNIA** (see **"Taking other medicines with RISNIA"**). You may be at increased risk of developing life-threatening complications and you will require careful monitoring during treatment. It is also important that you maintain an adequate fluid intake in such an instance, because dehydration increases your risk of suffering a fatal complication.

RISNIA may increase your blood sugar (glucose) levels (see **"POSSIBLE SIDE-EFFECTS"**). Very high blood glucose levels may result in coma and death. If you have been diagnosed with diabetes mellitus, you (in conjunction with your doctor) will have to monitor your blood glucose levels carefully when starting treatment with **RISNIA**. If you are overweight or if somebody in your family suffers from diabetes, please report to your doctor as soon as possible if you develop excessive or

abnormal thirst, excessive or very frequent urination, excessive eating, and weakness. Your doctor will perform a blood test to evaluate your glucose levels. In some cases, high blood glucose levels may return to normal if **RISNIA** is stopped. However, you may have to keep on taking medicines to lower your blood glucose levels (antidiabetic medicines) despite stopping **RISNIA**.

If you take **RISNIA**, you are at greater risk of suffering a stroke or transient loss of function (similar to stroke).

While taking **RISNIA** you may develop low blood pressure when you stand up after lying or sitting down. People with heart disease should be especially careful and your doctor will slowly increase your dosage of **RISNIA** if and when required. He/she may decide to lower your dosage if you develop low blood pressure. Please report dizziness or light-headedness upon standing up to your doctor as soon as possible.

RISNIA may cause seizures (epileptic fits) in susceptible patients, especially in patients known with epilepsy (see **"POSSIBLE SIDE-EFFECTS"**).

Please report to your doctor if you develop spontaneous flow of milk from the breast (not associated with childbirth or breastfeeding), enlargement of the breasts (male patients), or disturbances of your menstrual cycle or complete absence of menstruation (female patients) (see **"POSSIBLE SIDE-EFFECTS"**). Your doctor will decide on the most appropriate treatment.

RISNIA may cause weight gain and you should refrain from excessive eating while taking it.

Please inform your doctor if you suffer from kidney or liver disease, since it may be necessary to reduce your dosage. Since **RISNIA** tablets are not scored, individual tablets should not be halved.

If you are scheduled to undergo cataract surgery (to remove a cloudy lens of the eye) while you are taking **RISNIA** or if you have previously taken **RISNIA**, please advise your doctor or surgeon before your surgery. You may have an increased risk of developing complications during or after cataract surgery, called intraoperative floppy iris syndrome (IFIS) (see **"POSSIBLE SIDE-EFFECTS"**). This may cause your iris (the coloured part of your eye) to become floppy and lead to your pupil (the black part of your eye) not widening or constricting normally during surgery.

Taking RISNIA with food and drink:

RISNIA can be taken with or without food.

Pregnancy and breastfeeding:

You should not take **RISNIA** if you are breastfeeding your baby (see **"Do NOT take RISNIA"**).

The safety of **RISNIA** in pregnant women has not been established. Babies born to mothers who took **RISNIA** during the last three months of pregnancy, may develop withdrawal symptoms after birth, such as increased or decreased muscle tone,

jitteriness, tremor, muscle rigidity, twitching and seizures (epileptic fits), and feeding disorders.

If you are pregnant or breastfeeding your baby while taking RISNIA, please consult your doctor, pharmacist or other healthcare professional for advice.

Driving and using machinery:

RISNIA may impair your mental alertness. You should refrain from driving a car or operating machinery where loss of concentration may lead to accidents.

Important information about some of the ingredients in RISNIA:

RISNIA contains lactose. You should not take **RISNIA** if you have been diagnosed with galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption.

Taking other medicines with RISNIA:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, use of RISNIA with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

In particular, please inform your doctor or pharmacist if you are taking any of the following medicines or substances, since you may require a dosage adjustment or special precaution:

- Furosemide (a water pill).
- Any other medicines that influence brain function.

- Carbamazepine and sodium valproate for epilepsy.
- Phenothiazines for certain psychiatric disorders.
- Medicines for the treatment of depression, such as fluoxetine, paroxetine, venlafaxine, or tricyclic antidepressants.
- Beta-blockers for abnormal heart rate or rhythm.
- Lithium for bipolar disorder.
- Cimetidine or ranitidine to suppress the production of stomach acid.
- Other medicines that may influence heart rate or rhythm. Please speak to your doctor or pharmacist if you are unsure.

You should be very careful when taking **RISNIA** with alcohol, since both **RISNIA** and alcohol suppress brain function.

HOW TO TAKE RISNIA:

Always take RISNIA exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Your doctor will decide the most appropriate dosage for you. **RISNIA** may be taken once or twice daily with or without food. The usual starting dose for patients with schizophrenia is 2 mg per day. Your doctor will decide how and when to increase your dosage if necessary. The usual daily dose is 4 mg to 8 mg. The maximum total daily dose is 16 mg/day. Your doctor may decide to combine **RISNIA** with other medicines.

Elderly patients with schizophrenia usually require lower starting doses (i.e. 0,5 mg twice daily).

For children with conduct and other disruptive behaviour disorders the dosage is calculated based on body weight.

If you suffer from kidney or liver disease, your doctor will adjust your dosage as required.

Since **RISNIA** tablets are not scored, individual tablets should not be halved, but lower dosage strength formulations are recommended.

If you take more RISNIA than you should:

In the event of overdosage, or if someone else has taken your medicine by mistake, you, or this person, may experience any of the side-effects listed below. These may include drowsiness, sedation, low blood pressure, rapid heart rate and movement disorders. **In the event of overdosage, consult your doctor or pharmacist. If neither is available, immediately seek help at the nearest hospital or poison control centre.**

If you forget to take RISNIA:

Always take **RISNIA** exactly as prescribed. If you forget to take **RISNIA**, take it as soon as you remember. However, if it is nearly time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for forgotten individual doses.

POSSIBLE SIDE-EFFECTS:

Not all side-effects reported for RISNIA are included in this leaflet. Should your general health worsen while taking RISNIA, please consult your doctor, pharmacist or other healthcare professional for advice.

One of the most serious side-effects with **RISNIA** is neuroleptic malignant syndrome. Please see **"Take special care with RISNIA"**. You, or a family member, should report any combination of the following symptoms to your doctor as a matter of urgency: fever, muscle rigidity, altered mental status or reduced consciousness, irregular pulse or palpitations, and profuse sweating.

Other serious side-effects that you, or a family member, should report to your doctor immediately include:

- Allergic reactions, presenting with swelling of the face, lips, or throat, skin rash or hives, nausea with or without vomiting, and difficulty breathing. Severe allergic reactions may result in death if not treated promptly.
- Fever or chills, cough or hoarseness, lower back or flank pain, painful or difficult urination or a sore throat, since this may be due to infection because of low white blood cell counts.
- Pinpoint red spots on the skin, bleeding from the gums, blood in the urine and easy bruising, since this may be due to low platelet counts.
- Any alteration in consciousness.
- Reduced consciousness combined with loss of function on one side of the face or body or inability to communicate (see **"Take special care with RISNIA"**).

- Extremely elevated (happy) mood, reduced need for sleep, excessive talkativeness, and irresponsible behaviour.
- Epileptic fit or seizure (see **"Take special care with RISNIA"**), or fainting spell.
- Sudden loss of vision.
- Severely painful red eye with blurred vision with or without nausea and vomiting.
- Cessation of breathing.
- Severe stomach pain or cramping accompanied by distension of the stomach, nausea, and vomiting, since this may indicate bowel obstruction or inflammation of the pancreas.
- Yellow discolouration of the skin or white of the eyes (jaundice).
- A painful, red, swollen skin lesion accompanied by fever or chills.
- Dark or red-coloured urine, decreased urine production, general weakness, muscle stiffness or aching, muscle tenderness, or muscle weakness, since a combination of these symptoms may indicate muscle damage.

If you develop any of the following side-effects, please report to your doctor as soon as possible:

- Extreme tiredness or weakness accompanied by chest pain or palpitations and pallor, since these symptoms may be due to low red blood cell counts.
- Bruising of the skin, since this may be due to low platelet counts.
- Fever or chills.

- Excessive thirst and excessive eating combined with frequent urination and weakness, since this may be due to high blood sugar levels (see **"Take special care with RISNIA"**).
- Tremor, muscle rigidity, excessive production of saliva, slow or reduced movement, extreme and upward deviation of the eyes, an unpleasant sensation of “inner” restlessness, and sustained muscle contractions causing twisting and repetitive movements or abnormal postures.
- Tardive dyskinesia (please see **"Take special care with RISNIA"**).
- Aggravation of Parkinson’s disease (see **"Take special care with RISNIA"**).
- A reduced sense of touch or sensation, pins and needles, or a lowered level of consciousness with drowsiness, listlessness, and apathy.
- Increased muscle tone, balance disorder, unresponsiveness to stimuli, abnormal movements or inability to move as normal, involuntary muscle contraction, or speech disorder.
- Blurred vision or any loss of vision.
- Feeling faint or dizzy after standing up (please see **"Take special care with RISNIA"**).
- Palpitations or slow or fast heart rate.
- Chest pain.
- Shortness of breath, tightness of the chest, or wheezing.
- Fever, coughing, chest pain, tiredness and the production of yellow, brownish or green phlegm.
- Ear ache.

- Red eyes, painful eyes, eye discharge, eye rolling, swelling of the eyelids, crusting of the eyelids, sensitivity to light, or problems with movement of your eyes.
- Eye problems during or after cataract surgery called intraoperative floppy iris syndrome (see **"Take special care with RISNIA"**).
- Pain or a burning sensation when passing urine or pain over the bladder.
- Stomach pain or discomfort situated just below the chest or rib cage accompanied by heartburn or acid reflux, or difficulty swallowing.
- Difficulty in passing stool, pain when passing stool, or leakage of stool.
- Reddening and blistering of the skin with exposure to sunlight.
- Sustained and painful twisting or frequent jerking of neck muscles.
- Inability to pass urine.
- Continuous painful erection in the absence of sexual arousal.
- Spontaneous flow of milk from the breast (not associated with childbirth or nursing), or absence of menstruation (please see **"Take special care with RISNIA"**).

Please report any of the following side-effects to your doctor if they continue or become bothersome:

- Excessive thirst.
- Anxiety or nervousness, excessive sleepiness, headache, sleeplessness, agitation, impaired concentration, memory problems, dizziness, mood or mental changes, including aggressive behaviour, depression, confusion, lack of emotional reactivity, or lack of facial expression of emotion.
- Dry eyes or increased tearing of the eyes.

- Ringing in the ears or a feeling that the environment is moving or spinning.
- Runny nose, cough, sore throat, or bleeding from the nose.
- Pain over the sinuses and runny or blocked nose with production of phlegm.
- Finding it difficult to produce voice sounds.
- Hyperventilation (rapid breathing) or swelling of the nasal passages.
- Constipation, indigestion, nausea, diarrhoea, inflammation of the lips and dryness of the mouth or reduced production of saliva.
- Vomiting, stomach pain, and toothache.
- Any skin rash or itching, discolouration of a nail with or without brittleness, increased pigmentation (dark discolouration of the skin), increased sweating, oily skin or acne, red discolouration of the skin, red skin rash, skin lesions, thickening of the skin, dandruff, or hair loss.
- Joint pain, back pain, muscle pain, pain in the arms or legs, muscle weakness, neck pain, pain in the chest, buttock pain, swelling of a joint or joints, or joint stiffness.
- Frequent urination or other problems with urination, including leakage of urine, bed wetting, painful urination or excessive daytime urination.
- Painful menstruation or heavy periods, sexual dysfunction or decreased libido, or other disturbances in menstrual cycle, including light periods.
- Erectile dysfunction, ejaculatory dysfunction, or orgasmic dysfunction.
- Breast discomfort or breast enlargement in male patients.
- Weight gain or weight loss, or increased or decreased appetite.
- Weakness, fatigue, listlessness or diminished energy, generally feeling unwell, sluggishness, chest discomfort, feeling abnormal, thirst, chills,

coldness of the hands or feet, generalised swelling, withdrawal syndrome, high body temperature or low body temperature.

Other side-effects due to **RISNIA** include:

- High blood pressure (hypertension), or low blood pressure.
- Flushing.
- Swelling of the feet or hands.
- Falls.

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

STORAGE AND DISPOSING OF RISNIA:

Store at or below 25 °C.

Keep the blisters in the outer carton until required for use.

KEEP ALL MEDICINES OUT OF REACH AND SIGHT OF CHILDREN.

Do not use after the expiry date stated on the packaging material. Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems, for example toilets.

PRESENTATION OF RISNIA:

RISNIA 0,5 mg: Blister strips of 10 tablets, packed in 30’s.

RISNIA 1 mg: Blister strips of 10 tablets, packed in 30’s.

RISNIA 2 mg: Blister strips of 10 tablets, packed in 30’s.

RISNIA 3 mg: Blister strips of 10 tablets, packed in 30’s.

RISNIA 4 mg: Blister strips of 10 tablets, packed in 30's.

RISNIA 6 mg: Blister strips of 10 tablets, packed in 30's.

IDENTIFICATION OF RISNIA:

RISNIA 0,5 mg: Brown coloured, circular, biconvex, film-coated tablets debossed "0.5" on one side and plain on the other side.

RISNIA 1 mg: White, round, film-coated tablets debossed "1" on one side and plain on the other side.

RISNIA 2 mg: Orange, round, film-coated tablets debossed "2" on one side and plain on the other side.

RISNIA 3 mg: Yellow, round, film-coated tablets debossed "3" on one side and plain on the other side.

RISNIA 4 mg: Green, round, film-coated tablets debossed "4" on one side and plain on the other side.

RISNIA 6 mg: Yellow, capsule-shaped, biconvex, film-coated tablets debossed "6" on one side and plain on the other side.

REGISTRATION NUMBERS:

RISNIA 0,5 mg: 42/2.6.5/0792

RISNIA 1 mg: 42/2.6.5/0793

RISNIA 2 mg: 42/2.6.5/0794

RISNIA 3 mg: 42/2.6.5/0795

RISNIA 4 mg: 42/2.6.5/0796

RISNIA 6 mg: 42/2.6.5/0797

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATES OF REGISTRATION:

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RSA

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