

Ridon[®] 3

Active substance: risperidone

Dear patient,

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What *Ridon 3* is and what it is used for
2. Before you take *Ridon 3*
3. How to take *Ridon 3*
4. Possible side effects
5. How to store *Ridon 3*
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1. What *Ridon 3* is and what it is used for

Risperidone is a so-called atypical neuroleptic for the treatment of certain psychiatric disorders.

Ridon 3 is used for the

- treatment of a disease – including short-term exacerbations – with psychotic symptoms such as hearing, seeing or feeling things that are not real, erroneous beliefs, unusual mistrust as well as emotional and social withdrawal; also for further treatment to prevent the occurrence of this disease in stably adjusted patients.
- treatment of a condition with excessive euphoria, the feeling to have unusual energy, to need much less sleep than usual, very rapid speech with rapidly changing ideas and sometimes high irritability.

2. Before you take *Ridon 3*

Do not take *Ridon 3*

- in case of hypersensitivity to risperidone or any of the ingredients of the medicine
- in the presence of elevated prolactin levels not caused by medicines.

Take special care with *Ridon 3*

If you suffer from any of the following diseases, please tell your doctor before taking *Ridon 3*:

- impaired liver and kidney functions
- Parkinson's disease
- certain form of dementia (Lewy-Body dementia)
- seizure disorder (epilepsy)
- certain hormone-dependent tumours (prolactin-dependent tumours)
- severe cardiovascular diseases
- blood count alterations
- diabetes (diabetes mellitus) or presence of risk factors for the occurrence of diabetes.

During treatment with risperidone, particularly at the beginning of treatment, low blood pressure may occur. Risperidone should be used only with caution in patients with known cardiovascular diseases (e.g. certain hereditary heart diseases, considerably lowered pulse, heart failure, heart attack, conduction disturbances, reduced water content in the body, reduced blood content or diseases of the blood vessels supplying the brain), proven potassium or magnesium deficiency in the blood as well as during concomitant intake of medicines that can induce arrhythmias. In case of doubt, please consult your doctor.

In case of long-term treatment with *Ridon 3*, involuntary movements, preferentially of the face, may occur (tardive dyskinesia). In this case, please consult your doctor – if necessary, the dosage must be reduced or *Ridon 3* discontinued.

The occurrence of fever, muscle stiffness, accelerated breathing, heavy sweating and reduced consciousness (neuroleptic malignant syndrome) has been connected with the use of antipsychotic medicines. If such signs occur, a doctor must be consulted immediately – if necessary, *Ridon 3* must be discontinued.

Children and adolescents

No sufficient studies are available regarding the efficacy and tolerability of risperidone in children and adolescents. *Ridon 3* should therefore be prescribed only while specifically considering the benefit-risk ratio in children under 15 years of age.

Elderly patients

Elderly patients with dementia treated with risperidone are at higher risk of perfusion disorders of the brain including stroke and transient hypoperfusion. We ask you and, if necessary, your carers to inform your doctor whether you know from factors that favour the occurrence of a stroke, such as high blood pressure, cardiovascular diseases or perfusion disorders of the brain, so that he/she can assess the benefit and risk of prescribing risperidone in case of dementia. If symptoms such as sudden weakness, feeling of numbness in face, arms or legs, particularly affecting only one side, or slurred speech occur, you should consult your doctor without delay.

Please inform your doctor if you are taking medicines containing furosemide. Furosemide is a medicine for high blood pressure and for the treatment of swelling (oedema) due to accumulation of water in the body. Studies in elderly patients with dementia have shown that treatment with risperidone in combination with medicines containing furosemide may be damaging to your health.

Taking *Ridon 3* with other medicines

Please tell your doctor or pharmacist if you are taking/using, or have recently taken/used, any other medicines, including medicines obtained without a prescription.

In general, interactions are possible with all active substances influencing the central nervous system, such as certain tranquilizers and soporifics, potent analgesics, certain medicines for allergies, medicines for depression and alcohol.

Which other medicines influence the effect of risperidone?

Certain agents for depression (fluoxetine and paroxetine) can enhance the effect of *Ridon 3*.

Certain agents for epilepsy (e.g. carbamazepine) can reduce the effect of *Ridon 3*.

Which effects of other medicines are influenced by risperidone?

Risperidone can enhance the effect of certain other medicines for high blood pressure.

Risperidone can reduce the effect of medicines for Parkinson's disease (such as levodopa).

Cimetidine and ranitidine, two substances to reduce gastric acid, can slightly increase the concentration of risperidone in the blood; however, an influence on the effect of risperidone is improbable.

Erythromycin (an antibiotic), galantamine and donepezil (substances for the treatment of dementia) and amitriptyline (an agent for depression) have no influence on the effect of *Ridon 3*.

The effect of lithium or valproate (two substances for the treatment of mania), of digoxin (a medicine for the treatment of heart disorders) or topiramate (a medicine for the treatment of seizures or prophylaxis of migraine) is not influenced either by risperidone.

Regarding interaction of *Ridon 3* with medicines containing furosemide in elderly patients with dementia, see section 2. "Take special care with *Ridon 3*" under "Elderly patients".

Caution is required during concomitant use of medicines that - prolong the so-called QT interval in the ECG, e.g. agents for arrhythmias (antiarrhythmics class IA or III), certain antibiotics (such as erythromycin), cisapride, antimalarials, agents for allergies or gastric/intestinal ulcers (antihistamines) or agents for the treatment of specific mental disorders (neuroleptics), or - can lead to potassium or magnesium deficiency (e.g. certain water pills).

For this reason, if you are taking any of the named medicines, please inform your doctor since dose adjustment might be necessary.

Taking *Ridon 3* with food and drink

You should refrain from alcohol during treatment with *Ridon 3*, since alcohol can alter and enhance the effect of *Ridon 3* in an unforeseeable way. The ability to drive and use machines may be further impaired thereby.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking/using any medicine.

Only very little experience is available regarding the use of *Ridon 3* in pregnant women. However, these data do not suggest side effects of risperidone on pregnancy or the health of the unborn or newborn child. For this reason, you may use *Ridon 3* during pregnancy only if your doctor deems it is compellingly necessary while considering the risk for mother and child.

If you want to become pregnant during treatment with risperidone or if you suspect to be pregnant, please inform your doctor without delay, so that he/she can decide on the necessity of further treatment with *Ridon 3* or conversion to another medicine or discontinuation of treatment.

Risperidone, the active substance of *Ridon 3*, passes into mother's milk. If your doctor deems treatment with *Ridon 3* necessary during breast-feeding, weaning should be taken into consideration.

Driving and using machines

Even if used as intended, this medicinal product can alter reactivity to such an extent that the ability to drive, use machines or work in potentially hazardous situations is impaired. This applies to a higher degree in conjunction with alcohol.

Important information about some of the ingredients of *Ridon 3*

This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking *Ridon 3*.

3. How to take *Ridon 3*

Always take *Ridon 3* exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Your doctor will determine the dosage and duration of treatment. It is important that you take *Ridon 3* at regular intervals and that you comply with the dosage directions of your doctor.

If not otherwise prescribed by the doctor, the following dosage guidelines apply

To make it easier for you, the dosage is stated in milligram risperidone. Your doctor will tell you how many film-coated tablets you need.

Treatment of a disease – including short-term exacerbations – with psychotic symptoms such as hearing, seeing or feeling things that are not real, erroneous beliefs, unusual mistrust as well as emotional and social withdrawal
Adults

The daily dose risperidone may be taken all at once or divided into two single doses.

Treatment with *Ridon 3* should start with a low dose and be increased up to the dose mostly appropriate for you. Your doctor decides when and how much the dose is increased.

After a usual starting dose of 2 mg risperidone a day, the optimal maintenance dose is between 4 and 6 mg risperidone daily for most patients. A lower starting and maintenance dose may be appropriate in some patients.

Elderly patients

A lower dosage is recommended for elderly patients; the maximum maintenance dose after titration is 4 mg risperidone a day.

Treatment of a condition with excessive euphoria, the feeling to have unusual energy, to need much less sleep than usual, very rapid speech with rapidly changing ideas and sometimes high irritability.

A starting dose of 2 mg risperidone once daily is recommended in this patient group. If necessary, this dose may be increased by 1 mg risperidone a day after 24 hours at the earliest. The recommended dose range is 3-4 mg risperidone a day.

Patients with impaired kidney and liver function

Irrespective of the indication, starting and subsequent dosages should be halved and patients with impaired kidney or liver function be uptitrated more slowly.

Ridon 3 should be used with caution in this patient group.

Patients with cardiovascular disorders

Careful gradual dosage is important, particularly in this patient group. If lowered blood pressure values occur, dose reduction should be taken into consideration (see also section 2. "Take special care with *Ridon 3*").

Method of use

For oral intake

The film-coated tablets are to be taken with liquid. You may take *Ridon 3* with or without meals.

If you take more *Ridon 3* than you should

In the case of overdose or intoxication with *Ridon 3*, a doctor is always to be asked for advice (e.g. emergency call in the case of poisoning).

An overdose can manifest itself in an increase in the desired and undesired drug effects (drowsiness, tiredness, accelerated heart beat, lowered blood pressure, involuntary movements).

If you forget to take *Ridon 3*

Please do not make up for the omitted dose, but continue treatment at the prescribed dose at the next time scheduled to take the tablets.

If you stop taking *Ridon 3*

This should be done only after consulting your doctor in advance. If this was not possible, you should inform your doctor without delay, so that he/she can decide with you about further action.

4. Possible side effects

Like all medicines, *Ridon 3* can cause side effects, although not everybody gets them.

The evaluation of side effects is based on the following information on frequency:

very common:	more than 1 in 10 treated patients
common:	less than 1 in 10, but more than 1 in 100 treated patients
uncommon:	less than 1 in 10, but more than 1 in 1,000 treated patients
rare:	less than 1 in 10, but more than 1 in 10,000 treated patients
very rare:	less than 1 in 10,000 treated patients, or unknown

Nervous system and psyche

Common: headache, sleeplessness, agitation, anxiety, tiredness
Tiredness, which is generally only mild and transient, more commonly occurs in children and adolescents than in adults.

Uncommon: "extrapyramidal symptoms" (see below)

Rare: somnolence, drowsiness, concentration difficulties

Very rare: "malignant neuroleptic syndrome" (see below), seizures, panic reactions

After longer-term duration of treatment, rhythmic movements particularly of the face and tongue ("tardive dyskinesia") can occur. Please consult your doctor without delay in these cases.

Eye disorders

Rare: visual disturbances

Respiratory tract

Rare: blocked nose

Cardiovascular system

Uncommon: low blood pressure with dizziness and accelerated heart beat, particularly at the beginning of treatment, or when changing from lying to standing, can occur; increase in the blood pressure is also possible.

Gastrointestinal tract

Rare: gastrointestinal complaints (constipation, digestive disorders, nausea/vomiting, abdominal pain)

Urinary tract/sex organs

Rare: continuous penile erection, impaired erection, impaired ejaculation, impaired orgasm, involuntarily passing urine

Endocrine (hormone-forming) system

Risperidone can lead to elevated prolactin levels in the blood, particularly at high dosage. The following can be induced thereby.

Uncommon: menstrual disorders up to absence of the monthly period (amenorrhoea), milk secretion from the breast gland

Rare: enlargement of the male breast gland

Since it cannot be excluded that prolactin favours the development of breast cancer, women at risk should receive *Ridon 3* only with appropriate caution.

Musculoskeletal disorders

Very rare: muscle weakness

Skin disorders

Rare: skin reddening and other allergic reactions

Very rare: itching, skin rash, photosensitivity

Metabolism and nutrition disorders

Very rare: increase in the blood sugar level and exacerbation of existing diabetes and disorders in the water balance due to excessive drinking

Please consult your doctor if symptoms such as excessive thirst or excessive urination occur.

Blood and lymphatic system disorders

Very rare: decrease in the number of white blood cells and/or blood platelets

General disorders

Rare: weakness

Very rare: dysregulation of the body temperature

In addition, weight gain, accumulation of water in the body and increases in liver values have been observed during therapy with risperidone.

Perfusion disorders of the brain

When elderly patients with dementia were treated with risperidone, perfusion disorders of the brain including stroke (even resulting in death) and transient hypoperfusion (TIA) have been observed.

Extrapyramidal symptoms

So-called "extrapyramidal symptoms" uncommonly occur during treatment with risperidone. These are involuntary body movements, trembling, muscle stiffness, excessive secretion of saliva, inability to sit still, but also slowed movements up to immobility are possible. These symptoms are usually mild and reversible after dose reduction and/or during treatment with an anti-parkinsonian agent.

These side effects have very commonly been observed in patients treated with *Ridon 3* because of a condition with excessive euphoria, the feeling of having unusual energy, of needing much less sleep than usual, very rapid speech with rapidly changing ideas and sometimes high irritability.

If these side effects occur, a doctor should be consulted as rapidly as possible; he/she will decide on further action (e.g. dose reduction or termination of treatment with *Ridon 3*).

Malignant neuroleptic syndrome

This life-threatening combination of fever, muscle stiffness, rapid breathing, accelerated heart beat, heavy sweating and reduced consciousness, possibly also undertemperature of the body can very rarely occur. Immediately consult a doctor in such a case.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store *Ridon 3*

Keep out of the reach and sight of children.

Do not use the medicine after the expiry date which is stated on the pack and blister.

6. Further information

What *Ridon 3* contains

The active substance is risperidone.

One film-coated tablet contains 3 mg risperidone.

The other ingredients are

lactose monohydrate, pregelatinized maize starch, microcrystalline cellulose, hypromellose, magnesium stearate (Ph.Eur.), colloidal silicon dioxide, macrogol 4000, colouring agent titanium dioxide (E171), colouring agent quinoline yellow (E104)

What *Ridon 3* looks like and contents of the pack

The film-coated tablets are yellow, oval, have a scoreline and the embossment "3" on one side.

Ridon 3 is available in packs containing 20 film-coated tablets.

Marketing authorisation holder

1 A Pharma GmbH

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Manufacturer

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Last update of information

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Keep out of the reach and sight of children!

1 A Pharma GmbH wishes a speedy recovery!