Package leaflet: Information for the patient

Mirtazapine Grindeks 15 mg orodispersible tablets
Mirtazapine Grindeks 30 mg orodispersible tablets
Mirtazapine Grindeks 45 mg orodispersible tablets

mirtazapine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What <Invented name> is and what it is used for

<Invented name> contains the active substance mirtazapine which belongs to a group of medicines called antidepressants.
<Invented name> is used to treat depressive illness in adults.
It will take 1 to 2 weeks for <Invented name> to start working. After 2 to 4 weeks, you may start feeling better. You must talk to your doctor if you do not feel better or if you feel worse after 2 to 4 weeks. More information is in section 3 heading “When can you expect to start feeling better”.

2. What you need to know before you take <Invented name>

Do not take <Invented name>
- if you are allergic to mirtazapine or any of the other ingredients of this medicine (listed in section 6). <Invented name>
- if you are taking or have recently taken (within the last two weeks) medicines called monoamine oxidase inhibitors (MAOI).

Warnings and precautions
Talk to your doctor or pharmacist before taking <Invented name>.

Tell your doctor before taking <Invented name>
If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking mirtazapine.

Children and adolescents
<Invented name> should normally not be used for children and adolescents under 18 years because efficacy

was not demonstrated. Also, you should know that patients under 18 have an increased risk of side-effects such as suicide attempt, suicidal thoughts and hostility (predominantly aggression, oppositional behaviour and anger) when they take this class of medicines. Despite this, your doctor may prescribe <Invented name> for patients under 18 because he/she decides that this is in their best interests. If your doctor has prescribed <Invented name> for a patient under 18 and you want to discuss this, please go back to your doctor. You should inform your doctor if any of the symptoms listed above develop or worsen when patients under 18 are taking <Invented name>. Also, the long-term safety effects concerning growth, maturation and cognitive and behavioural development of mirtazapine in this age group have not yet been demonstrated. In addition, significant weight gain has been observed in this age category more often when treated with mirtazapine compared with adults.

Thoughts of suicide and worsening of your depression
If you are depressed you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting antidepressants, since these medicines all take time to work, usually about two weeks but sometimes longer.
You may be more likely to think like this:
- if you have previously had thoughts about killing or harming yourself.
- if you are a young adult (younger than 25 years). Information from clinical trials has shown an increased risk of suicidal behaviour in adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant.

If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital straightaway.

You may find it helpful to tell a relative or close friend that you are depressed and ask them to read this leaflet. You might ask them to tell you if they think your depression is getting worse, or if they are worried about changes in your behaviour.

Also take special care with <Invented name>
- if you have or have ever had one of the following conditions.

Tell your doctor about these conditions before taking <Invented name>, if not done previously:
- seizures (epilepsy). If you develop seizures or your seizures become more frequent, stop taking <Invented name> and contact your doctor immediately;
- liver disease, including jaundice. If jaundice occurs, stop taking <Invented name> and contact your doctor immediately;
- kidney disease;
- heart disease, or low blood pressure;
- schizophrenia. If psychotic symptoms, such as paranoid thoughts, become more frequent or severe, contact your doctor straightaway;
- manic depression (alternating periods of feeling elated/overactivity and depressed mood). If you start feeling elated or over-excited, stop taking <Invented name> and contact your doctor immediately;
- diabetes (you may need to adjust your dose of insulin or other antidiabetic medicines);
- eye disease, such as increased pressure in the eye (glaucoma);
- difficulty in passing water (urinating), which might be caused by an enlarged prostate;
- certain kinds of heart conditions that may change your heart rhythm, a recent heart attack, heart failure, or take certain medicines that may affect the heart's rhythm.

- if you develop signs of infection such as inexplicable high fever, sore throat and mouth ulcers. Stop taking <Invented name> and consult your doctor immediately for a blood test. In rare cases these symptoms can be signs of disturbances in blood cell production in the bone marrow. While rare, these symptoms most commonly appear after 4-6 weeks of treatment.
- if you are an elderly person. You could be more sensitive to the side-effects of antidepressants.

- serious skin reactions including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported with the use of <Invented name>. Stop using and seek medical attention immediately if you notice any of the symptoms described in section 4 in relation to these serious skin reactions.
- if you have ever developed any severe skin reactions, treatment with mirtazapine should not be restarted.

Other medicines and <Invented name>
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Do not take <Invented name> in combination with:
- monoamine oxidase (MAO) inhibitors. Also, do not take <Invented name> during the two weeks after you have stopped taking MAO inhibitors. If you stop taking <Invented name>, do not take MAO inhibitors during the next two weeks either.
  Examples of MAO inhibitors are moclobemide, tranylcypromine (both are antidepressants) and selegiline (used for Parkinson's disease).

Take care when taking <Invented name> in combination with:
- antidepressants such as selective serotonin reuptake inhibitors (SSRIs), venlafaxine and L-tryptophan or triptans (used to treat migraine), tramadol (a pain-killer), linezolid (an antibiotic), lithium (used to treat some psychiatric conditions), methylene blue (used to treat high levels of methemoglobin in the blood) and St. John's Wort – Hypericum perforatum preparations (a herbal remedy for depression).
  In very rare cases <Invented name> alone or the combination of <Invented name> with these medicines, can lead to a so-called serotonin syndrome. Some of the symptoms of this syndrome are: inexplicable fever, sweating, increased heart rate, diarrhoea, (uncontrollable) muscle contractions, shivering, overactive reflexes, restlessness, mood changes and unconsciousness. If you get a combination of these symptoms, talk to your doctor immediately.
- the antidepressant nefazodone. It can increase the amount of <Invented name> in your blood. Inform your doctor if you are using this medicine. It might be needed to lower the dose of <Invented name>, or when use of nefazodone is stopped, to increase the dose of <Invented name> again.
- medicines for anxiety or insomnia such as benzodiazepines;
- medicines for schizophrenia such as olanzapine;
- medicines for allergies such as cetirizine;
- medicines for severe pain such as morphine.
  In combination with these medicines <Invented name> can increase the drowsiness caused by these medicines.
- medicines for infections; medicines for bacterial infections (such as erythromycin), medicines for fungal infections (such as ketoconazole) and medicines for HIV/AIDS (such as HIV- protease inhibitors) and drugs for stomach ulcers (such as cimetidine).
  In combination with <Invented name> these medicines can increase the amount of mirtazapine in your blood. Inform your doctor if you are using these medicines. It might be needed to lower the dose of <Invented name>, or when these medicines are stopped, to increase the dose of <Invented name> again.
- medicines for epilepsy such as carbamazepine and phenytoin;
- medicines for tuberculosis such as rifampicin.
  In combination with <Invented name> these medicines can reduce the amount of mirtazapine in your blood. Inform your doctor if you are using these medicines. It might be needed to increase the dose of <Invented name>, or when these medicines are stopped to lower the dose of <Invented name> again.
- medicines to prevent blood clotting such as warfarin.
  <Invented name> can increase the effects of warfarin on the blood. Inform your doctor if you are using this medicine. In case of combination, it is advised that a doctor monitors your blood carefully.

– medicines that may affect the heart's rhythm such as certain antibiotics and some anti- psychotics.

<Invented name> with food and alcohol
You may become drowsy if you drink alcohol while you are taking <Invented name>.
You are advised not to drink any alcohol.
You can take <Invented name> with or without food.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy
Limited experience with mirtazapine in pregnant women does not indicate an increased risk. However, caution should be exercised when used during pregnancy.

If you use <Invented name> until, or shortly before birth, your baby should be supervised for possible adverse effects.

When taken during pregnancy, similar drugs (SSRIs) may increase the risk of a serious condition in babies, called persistent pulmonary hypertension of the newborn (PPHN), making the baby breathe faster and appear bluish. These symptoms usually begin during the first 24 hours after the baby is born. If this happens to your baby, you should contact your midwife and/or doctor immediately.

Breast-feeding
Mirtazapine is excreted in breast milk in very small amounts. The decision to continue or stop breastfeeding and to continue or stop treatment with mirtazapine, respectively, must be made taking into account the benefits of breastfeeding for the baby and the benefits of treatment with mirtazapine for the woman.

Driving and using machines
<Invented name> can affect your concentration or alertness. Make sure these abilities are not affected before you drive or operate machinery. If your doctor has prescribed <Invented name> for a patient under 18 years make sure the concentration and alertness is not affected before participation in traffic (e.g. on bicycle).

<Invented name> orodispersible tablets contains aspartame
Each 15 mg orodispersible tablet contains 1.5 mg aspartame.
Each 30 mg orodispersible tablet contains 3 mg aspartame.
Each 45 mg orodispersible tablet contains 4.5 mg aspartame.
Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

3. How to take <Invented name>

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

Recommended dose

The recommended starting dose is 15 or 30 mg every day. Your doctor may advise you to increase your dose after a few days to the amount that is best for you (between 15 and 45 mg per day). The dose is usually the same for all ages. However, if you are an elderly person or if you have renal or liver disease, your doctor may adapt the dose.

When to take <Invented name>
Take <Invented name> at the same time each day.
It is best to take <Invented name> as a single dose before you go to bed. However, your doctor may suggest splitting your dose of <Invented name> – once in the morning and once at night-time before you go to bed. The higher dose should be taken before you go to bed.

Take the orodispersible tablet as follows
Take your tablets orally.
Do not crush the orodispersible tablet. Take out the orodispersible tablet from the blister with dry hands and place it on the tongue. It will rapidly disintegrate and can be swallowed without water.

When can you expect to start feeling better
Usually <Invented name> will start working after 1 to 2 weeks and after 2 to 4 weeks you may start to feel better.

It is important that, during the first few weeks of the treatment, you talk with your doctor about the effects of <Invented name>:
– 2 to 4 weeks after you have started taking <Invented name>, talk to your doctor about how this medicine has affected you.

If you still don't feel better, your doctor may prescribe a higher dose. In that case, talk to your doctor again after another 2 to 4 weeks. Usually you will need to take <Invented name> for at least 6 months, until your symptoms of depression have disappeared.

If you take more <Invented name> than you should
If you have ingested too much of the medicine or if, for example, a child has ingested the medicine by mistake, contact a doctor or a hospital straightaway for an assessment of the risk and advice.
The most likely signs of an overdose of <Invented name> (without other medicines or alcohol) are drowsiness, confusion, and increased heart rate. The symptoms of a possible overdose may include changes to your heart rhythm (fast, irregular heartbeat) and/or fainting which could be symptoms of a life-threatening condition known as *torsade de pointes.*

If you forget to take <Invented name>
If you are supposed to take your dose once a day:
– do not take a double dose to make up for a forgotten dose. Take your next dose at the normal time.

If you are supposed to take your dose twice a day:
– if you have forgotten to take your morning dose, simply take it together with your evening dose.
– if you have forgotten to take your evening dose, do not take it with the next morning dose; just skip it and continue with your normal morning and evening doses.
– if you have forgotten to take both doses, do not attempt to make up for the missed doses. Skip both doses and continue the next day with your normal morning and evening doses.

If you stop taking <Invented name>
Only stop taking <Invented name> in consultation with your doctor.
If you stop too early, your depression might come back. Once you are feeling better, talk to your doctor. Your doctor will decide when treatment can be stopped.
Do not suddenly stop taking <Invented name>, even when your depression has lifted. If you suddenly stop taking <Invented name> you may feel sick, dizzy, agitated or anxious, and have headaches. These symptoms can be avoided by stopping gradually. Your doctor will tell you how to decrease the dose gradually.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you experience any of the following serious side effects, stop taking mirtazapine and tell your doctor immediately.

Uncommon (may affect up to 1 in 100 people):
– feeling elated or emotionally ‘high’ (mania)

Rare (may affect up to 1 in 1,000 people):
– yellow colouring of eyes or skin; this may suggest disturbance in liver function (jaundice)

Not known (frequency cannot be estimated from the available data):
– signs of infection such as sudden unexplainable high fever, sore throat and mouth ulcers (agranulocytosis). In rare cases mirtazapine can cause disturbances in the production of blood cells (bone marrow depression). Some people become less resistant to infection because mirtazapine can cause a temporary shortage of white blood cells (granulocytopenia). In rare cases mirtazapine can also cause a shortage of red and white blood cells, as well as blood platelets (aplastic anemia), a shortage of blood platelets (thrombocytopenia) or an increase in the number of white blood cells (eosinophilia)
– epileptic attack (convulsions)
– a combination of symptoms such as inexplicable fever, sweating, increased heart rate, diarrhoea, (uncontrollable) muscle contractions, shivering, overactive reflexes, restlessness, mood changes, unconsciousness and increased salivation. In very rare cases these can be signs of serotonin syndrome
– thoughts of harming or killing yourself
– severe skin reactions:
  - reddish patches on the trunk that look like targets or are circular, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis)
  - widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome)

Other possible side effects of mirtazapine are:

Very common (may affect more than 1 in 10 people):
– increase in appetite and weight gain
– drowsiness or sleepiness
– headache
– dry mouth

Common (may affect up to 1 in 10 people):
– lethargy (an abnormal state of sleepiness)
– dizziness
– shakiness or tremor
– nausea
– diarrhoea
– vomiting
– constipation
– rash or eczema (exanthema)
– pain in your joints (arthralgia) or muscles (myalgia)
– back pain

– feeling dizzy or faint when you stand up suddenly (orthostatic hypotension)
– swelling (typically in ankles or feet) caused by fluid retention (oedema)
– tiredness
– vivid dreams
– confusion
– feeling anxious
– sleeping problems
– memory problems, which in most cases resolved when treatment was stopped

Uncommon (may affect up to 1 in 100 people):
– abnormal sensation in the skin e.g. burning, stinging, tickling or tingling (paraesthesia)
– restless legs
– fainting (syncope)
– sensations of numbness in the mouth (oral hypoaesthesia)
– low blood pressure
– nightmares
– feeling agitated
– hallucinations
– urge to move

Rare (may affect up to 1 in 1,000 people):
– muscle twitching or contractions (myoclonus)
– aggression
– abdominal pain and nausea; this may suggest inflammation of the pancreas (pancreatitis)

Not known (frequency cannot be estimated from the available data):
– abnormal sensations in the mouth (oral paraesthesia)
– swelling in the mouth (mouth oedema)
– swelling throughout the body (generalized oedema)
– localized swelling
– hyponatraemia
– inappropriate anti-diuretic hormone secretion
– severe skin reactions (dermatitis bullous, erythema multiforme)
– sleep walking (somnambulism)
– speech disorder
– increased creatine kinase blood levels
– difficulty in passing urine (urinary retention)
– muscle pain, stiffness and/or weakness, darkening or discolouration of the urine (rhabdomyolysis)
– increased prolactin hormone levels in blood (hyperprolactinemia, including symptoms of enlarged breasts and/or milky nipple discharge)
– prolonged painful erection of the penis

Additional side effects in children and adolescents
In children under 18 years the following adverse events were observed commonly in clinical trials: significant weight gain, hives and increased blood triglycerides.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V*. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store <Invented name>

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and the blister after “EXP”. The expiry date refers to the last day of that month.

This medicine does not require any special temperature storage conditions. Store in the original package in order to protect from moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What <Invented name> contains
The active substance is mirtazapine.
Each <Invented name> orodispersible tablet contains 15 mg, 30 mg or 45 mg mirtazapine.

– The other ingredients are mannitol (E421); cellulose, microcrystalline; crospovidone; silica, colloidal anhydrous; hydroxypropylcellulose, low-substituted; aspartame (E951); orange flavour; magnesium stearate.

What <Invented name> looks like and contents of the pack
<Invented name> 15 mg are white to off-white, round with beveled edge orodispersible tablet, embossed with '15' on one side. The size of tablet is 7.5 mm in diameter.
<Invented name> 30 mg are white to off-white, round with beveled edge orodispersible tablet, embossed with '30' on one side. The size of tablet is 9 mm in diameter.
<Invented name> 45 mg are white to off-white, round with beveled edge orodispersible tablet, embossed with '45' on one side. The size of tablet is 11 mm in diameter.

Mirtazapine Grindeks 15 mg and 30 mg are available in blisters containing 28, 30, 50, 56, 60 or 100 orodispersible tablets.
Mirtazapine Grindeks 45 mg are available in blisters containing 30 or 100 orodispersible tablets.

Not all pack sizes may be marketed.

Marketing Authorization Holder

[To be completed nationally]

Manufacturers

[To be completed nationally]

This medicine is authorised in the Member States of the European Economic Area under the following names:

Austria	Mirtazapin Grindeks 15 mg, 30 mg, 45 mg Schmelztabletten
Belgium	Mirtazapine Grindeks 15 mg, 30 mg, 45 mg comprimés orodispersibles
Bulgaria	Миртазапин Гриндекс 15 mg, 30 mg, 45 mg таблетки, диспергиращи се в устата

	Mirtazapine Grindeks 15 mg, 30 mg, 45 mg orodispersible tablets
Croatia	Mirtazapin Grindeks 15 mg raspadljive tablete za usta
	Mirtazapin Grindeks 30 mg raspadljive tablete za usta
	Mirtazapin Grindeks 45 mg raspadljive tablete za usta
Czech Republic	Mirtazapine Grindeks
Denmark	Mirtazapin Grindeks
Estonia	Mirtazapine Grindeks
Finland	Mirtazapine Grindeks 15 mg, 30 mg, 45 mg suussa hajoavat tabletit
France	MIRTAZAPINE GRINDEKS 15 mg, comprimé orodispersible
	MIRTAZAPINE GRINDEKS 30 mg, comprimé orodispersible
	MIRTAZAPINE GRINDEKS 45 mg, comprimé orodispersible
Germany	Mirtazapin Grindeks 15 mg, 30 mg, 45 mg Schmelztabletten
Greece	Mirtazapine/Grindeks
Hungary	Mirtazapine Grindeks 15 mg, 30 mg, 45 mg szájban diszpergálódó tabletta
Ireland	Mirtazapine Grindeks 15 mg, 30 mg, 45 mg orodispersible tablets
Italy	Mirtazapina Grindeks
Latvia	Mirtazapine Grindeks 15 mg, 30 mg, 45 mg mutē disperģējamās tabletes
Lithuania	Mirtazapine Grindeks 15 mg burnoje disperguojamosios tabletės
	Mirtazapine Grindeks 30 mg burnoje disperguojamosios tabletės
	Mirtazapine Grindeks 45 mg burnoje disperguojamosios tabletės
Norway	Mirtazapine Grindeks
Poland	Mirtazapine Grindeks
Portugal	Mirtazapina Grindeks 15 mg, 30 mg, 45 mg comprimidos orodispersíveis
Slovenia	Mirtazapin Grindeks 15 mg, 30 mg, 45 mg orodisperzibilne tablete
Spain	Mirtazapina Grindeks 15 mg, 30 mg, 45 mg comprimidos bucodispersables
Sweden	Mirtazapine Grindeks 15 mg, 30 mg, 45 mg munsönderfallande tabletter

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