

## PATIENT INFORMATION LEAFLET

**SCHEDULING STATUS:** S5

**MIRTAZAPINE 15 VIATRIS (film-coated tablets)**

**MIRTAZAPINE 30 VIATRIS (film-coated tablets)**

Mirtazapine

**MIRTAZAPINE 15 VIATRIS** contains sugar (Lactose anhydrous 113,25 mg).

**MIRTAZAPINE 30 VIATRIS** contains sugar (Lactose anhydrous 226,50mg).

### **Read all of this leaflet carefully before you start taking MIRTAZAPINE VIATRIS**

- 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.
- **MIRTAZAPINE VIATRIS** 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 **MIRTAZAPINE VIATRIS** is and what it is used for.
2. What you need to know before you take **MIRTAZAPINE VIATRIS**.
3. How to take **MIRTAZAPINE VIATRIS**.
4. Possible side effects.
5. How to store **MIRTAZAPINE VIATRIS**.
6. Contents of the pack and other information.

## 1. What MIRTAZAPINE VIATRIS is and what it is used for

Mirtazapine belongs to a group of medicines called antidepressants.

**MIRTAZAPINE VIATRIS** is used to treat major depressive illness (persistently depressed mood or loss of interest in activities, causing significant impairment in daily life).

## 2. What you need to know before you take MIRTAZAPINE VIATRIS

### Do not take MIRTAZAPINE VIATRIS:

- If you are hypersensitive (allergic) to mirtazapine or any of the other ingredients of **MIRTAZAPINE VIATRIS** (listed in section 6).
- If you are pregnant or breastfeeding.
- If you are a child and under 18 years old.
- If you are taking or have recently taken (within the last 2 weeks) medicines called monoamine oxidase inhibitors (MAOIs).

### Warnings and precautions

#### Tell your doctor before taking MIRTAZAPINE VIATRIS:

If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking mirtazapine or other medicine(s).

#### Take special care with MIRTAZAPINE VIATRIS:

##### Children and adolescents

**MIRTAZAPINE VIATRIS** should not be used for children and adolescents under 18 years.

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 antidepressants such as **MIRTAZAPINE VIATRIS**.

#### 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 such as **MIRTAZAPINE VIATRIS**, since these medicines all take time to work, usually about 2 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. 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 straight away.

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 MIRTAZAPINE VIATRIS**

If you have, or have ever had one of the following conditions:

- seizures (epilepsy). If you develop seizures or your seizures become more frequent, stop taking **MIRTAZAPINE VIATRIS** and contact your doctor immediately;
- 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 **MIRTAZAPINE VIATRIS**. Stop taking **MIRTAZAPINE VIATRIS** and seek medical attention immediately if you notice any of the symptoms described in section 4 in relation to these skin reactions. If you ever developed any severe skin reactions, treatment with **MIRTAZAPINE VIATRIS** should not be restarted;

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- liver disease, including jaundice. If jaundice occurs, stop taking **MIRTAZAPINE VIATRIS** and contact your doctor immediately;
- kidney disease;
- heart disease, or low blood pressure;
- 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;
- diabetes (you may need to adjust your dose of insulin or other antidiabetic medicines);
- schizophrenia. If psychotic symptoms, such as paranoid thoughts become more frequent or severe, contact your doctor straight away;
- manic depression (alternating periods of feeling elated/overactivity and depressed mood). If you start feeling elated or over-excited, stop taking **MIRTAZAPINE VIATRIS** and contact your doctor immediately;
- eye disease, such as increased pressure in the eye (glaucoma);
- difficulty in passing water (urinating), which might be caused by an enlarged prostate;
- if you develop signs of infection such as inexplicable high fever, sore throat and mouth ulcers. Stop taking **MIRTAZAPINE VIATRIS** 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;
- if you are an elderly person. You could be more sensitive to the side effects of antidepressants such as **MIRTAZAPINE VIATRIS**.

**Other medicines and MIRTAZAPINE VIATRIS**

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

Do not take **MIRTAZAPINE VIATRIS** in combination with:

- monoamine oxidase inhibitors (MAO inhibitors). Also, do not take **MIRTAZAPINE VIATRIS** during the 2 weeks after you have stopped taking MAO inhibitors. If you stop taking **MIRTAZAPINE VIATRIS**, do not take MAO inhibitors during the next 2 weeks either. Examples of MAO inhibitors are moclobemide, tranylcypromine (both antidepressants) and selegiline (used for Parkinson's disease).

Take care when taking **MIRTAZAPINE VIATRIS** in combination with:

- Buprenorphine-containing medicines, antidepressants such as 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 methaemoglobin in the blood) and St. John's Wort - *Hypericum perforatum* (a herbal remedy for depression). In very rare cases **MIRTAZAPINE VIATRIS** alone or the combination of **MIRTAZAPINE VIATRIS** 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.
- warfarin - medicines to prevent blood clotting. **MIRTAZAPINE VIATRIS** can increase the effects of warfarin on the blood. In case of combination it is advised that your doctor monitor your blood carefully.
- 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; alcohol.

In combination with these medicines **MIRTAZAPINE VIATRIS** 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); medicines for HIV/AIDS (such as HIV protease inhibitors) and medicines for stomach ulcers (such as cimetidine).

In combination with **MIRTAZAPINE VIATRIS**, these medicines can increase the amount of **MIRTAZAPINE VIATRIS** in your blood. Inform your doctor if you are using these medicines. It might be needed to lower the dose of **MIRTAZAPINE VIATRIS**, or when these medicines are stopped, to increase the dose of **MIRTAZAPINE VIATRIS** again.

- medicines for epilepsy such as carbamazepine and phenytoin; medicines for tuberculosis such as rifampicin.

In combination with **MIRTAZAPINE VIATRIS**, these medicines can reduce the amount of **MIRTAZAPINE VIATRIS** in your blood. Inform your doctor if you are using these medicines. It might be needed to increase the dose of **MIRTAZAPINE VIATRIS**, or when these medicines are stopped, to lower the dose of **MIRTAZAPINE VIATRIS** again.

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

### **MIRTAZAPINE VIATRIS with food, drink and alcohol**

You may get drowsy if you drink alcohol while you are taking **MIRTAZAPINE VIATRIS**. You are advised not to drink any alcohol when taking **MIRTAZAPINE VIATRIS**.

### **Pregnancy, breastfeeding and fertility**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

You should not take **MIRTAZAPINE VIATRIS** if you are pregnant or breastfeeding your baby (refer to 'Do not take **MIRTAZAPINE VIATRIS**').

### **Driving and using machines**

**MIRTAZAPINE VIATRIS** may decrease your concentration, alertness, judgment and thinking. It is not always possible to predict to what extent **MIRTAZAPINE VIATRIS** may interfere with your daily activities. You should ensure that you do not engage in driving a vehicle or use machinery until you are aware of the measure to which **MIRTAZAPINE VIATRIS** affects you.

### **MIRTAZAPINE VIATRIS contains sugar (lactose)**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

### **3. How to take MIRTAZAPINE VIATRIS**

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

Always take **MIRTAZAPINE VIATRIS** exactly as your doctor or pharmacist has told you.

Check with your doctor or pharmacist if you are not sure.

The usual starting dose is 15 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).

Take **MIRTAZAPINE VIATRIS** at the same time each day. It is best to take **MIRTAZAPINE VIATRIS** as a single dose before you go to bed. However, your doctor may suggest you split your dose of **MIRTAZAPINE VIATRIS**, once in the morning and once at night-time before you go to bed.

However, if you are an elderly person or if you have renal or liver disease, your doctor may adapt the dose.

Take your tablets orally. Swallow your prescribed dose of **MIRTAZAPINE VIATRIS** without chewing, with some water.

It is important that during the first few weeks of the treatment, you talk with your doctor if you have any thoughts about harming yourself.

Your doctor will tell you how long your treatment with **MIRTAZAPINE VIATRIS** will last.

If you have the impression that the effect of **MIRTAZAPINE VIATRIS** is too strong or too weak, tell your doctor or pharmacist.

#### **If you take more MIRTAZAPINE VIATRIS than you should**

In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

#### **If you forget to take MIRTAZAPINE VIATRIS**

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

#### **If you stop taking MIRTAZAPINE VIATRIS**

Your doctor will tell you how long to take the treatment. Do not stop earlier than you are told, even if you feel better.

Do not suddenly stop taking **MIRTAZAPINE VIATRIS**, even when your depression has lifted. If you suddenly stop taking **MIRTAZAPINE VIATRIS** 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.

#### **4. Possible side effects**

**MIRTAZAPINE VIATRIS** can have side effects.

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

If any of the following happens, stop taking **MIRTAZAPINE VIATRIS** and tell your doctor immediately or go to the casualty department of your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat (angioedema), which may cause difficulty in swallowing or breathing,
- skin rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **MIRTAZAPINE VIATRIS**. 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:

*Frequent*

- skin rash with fever

*Less frequent*

- signs of infection such as sudden unexplainable high fever, sore throat and mouth ulcers (agranulocytosis)
- feeling elated or emotionally 'high' (mania)
- hallucinations
- convulsions (fits)
- inability to sit or keep still
- muscle twitching or contractions
- abnormal physical weakness or lack of energy
- inflammation of the pancreas which may cause abdominal pain and nausea
- aggression

*Frequency unknown*

- thoughts of harming or killing yourself;
- a skin reaction known as 'erythema multiforme' (itchy reddish purple patches on the skin, especially on the palms of the hands or soles of the feet, 'hive-like' raised swollen areas on the skin, tender areas on the surfaces of the mouth, eyes and genitals, which may be accompanied by fever and tiredness);
- reddish patches on the torso which are target-like macules or 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);
- jaundice (yellowing of skin and/or eyes);

• **MIRTAZAPINE VIATRIS** can cause disturbances in the production of blood cells (bone marrow depression). Some people become less resistant to infection because **MIRTAZAPINE VIATRIS** can cause a temporary shortage of white blood cells (granulocytopenia). **MIRTAZAPINE VIATRIS** can also cause a shortage of red and white blood cells, as well as blood platelets (aplastic anaemia), a shortage of blood platelets (thrombocytopenia) or an increase in the number of white blood cells (eosinophilia). 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*

- abnormal dreams
- confusion
- anxiety
- trouble falling or staying asleep (insomnia)
- nightmares
- drowsiness, sleepiness
- dizziness
- headache
- involuntary shaking (tremor)
- lack of energy and enthusiasm
- memory loss
- increase in appetite and weight gain
- dry mouth
- constipation
- nausea, vomiting
- diarrhoea

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- thirst
- low blood pressure when you stand up from sitting or lying position
- joint pain, muscle pain, back pain

*Less frequent side effects*

- increased sweating
- tiredness
- moving or spinning sensation (vertigo)
- abnormal sensation in the skin e.g. burning, stinging, tickling or tingling (paraesthesia)
- sensations of numbness in the mouth (oral hypoaesthesia)
- fluid retention (swollen ankles, feet or legs)
- elevated levels of certain enzymes as revealed by blood tests

*Unknown frequency*

- a bitter or bad taste in the mouth
- increase in liver enzymes
- condition that occurs when the level of sodium in the blood is too low (hyponatraemia)
- sleepwalking
- 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. These can be signs of serotonin syndrome.
- slowed or slurred speech
- your salivary glands produce more saliva than usual
- general swelling throughout the body
- difficulty urinating and completely emptying the bladder
- priapism (prolonged erection of the penis)

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- a breakdown of muscle tissue that releases a damaging protein into the blood (rhabdomyolysis)
- increased prolactin hormone levels in blood (hyperprolactinemia, including symptoms of enlarged breasts and/or milky nipple discharge).

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 or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of **MIRTAZAPINE VIATRIS**.

## **5. How to store MIRTAZAPINE VIATRIS**

Store at or below 25 °C.

Protect from light and moisture.

Store in the original container.

Do not use after the expiry date indicated on the outer container.

Return all unused medicine to your pharmacist.

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

**STORE ALL MEDICINES OUT OF REACH OF CHILDREN.**

## **6. Contents of the pack and other information**

### **What MIRTAZAPINE VIATRIS contains**

Each film-coated tablet contains 15 or 30 mg mirtazapine.

The other ingredients are: Colloidal anhydrous silica, hydroxypropylcellulose, lactose anhydrous, magnesium stearate and maize starch.

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*Film-coating*

**MIRTAZAPINE 15 VIATRIS:** Opadry Yellow 39F52901 consisting of: Hypromellose, lactose monohydrate, macrogol 4000, titanium dioxide, quinoline yellow CI 47005, iron oxide yellow CI 77492.

**MIRTAZAPINE 30 VIATRIS:** Opadry Buff OY-LS-37200 consisting of: hypromellose, lactose monohydrate, macrogol 4000, titanium dioxide, iron oxide yellow CI 77492, iron oxide red CI 77491, iron oxide black CI 77499.

**What MIRTAZAPINE VIATRIS looks like and content of the pack**

**MIRTAZAPINE 15 VIATRIS:** A normal convex, yellow film-coated tablet debossed “MR scoreline 15” on one side and “G” on the other.

**MIRTAZAPINE 30 VIATRIS:** A normal convex, buff film-coated tablet debossed “MR scoreline 30” on one side and “G” on the other.

Aluminium/Clear PVC/PVDC blister strips in packs of – 10, 14, 20, 28, 30, 50, 100, 250 & 500 tablets.

White or grey polypropylene securitainers with polyethylene caps containing – 10, 14, 20, 28, 30, 50, 100, 250 & 500 tablets.

Not all pack sizes may be marketed.

**Holder of Certificate of Registration**

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