

## **Package leaflet: Information for the user**

### **Mirtazapin Alternova film-coated tablets 15 mg**

mirtazapin

**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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

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

#### **1. What Mirtazapin Alternova is and what it is used for**

Mirtazapin Alternova works by increasing the content of the signal substances serotonin and noradrenalin, which are important for the conduction of impulses in the brain. Irregularities in these impulses play a role in the development of depression but the common mode of action is not entirely clear.

Mirtazapin Alternova is used to treat depression.

Your doctor may have prescribed another use. Always follow your doctor's instructions.

#### **2. What you need to know before you take Mirtazapin Alternova**

##### **Do not take Mirtazapin Alternova:**

- If you are allergic to mirtazapine or any of the other ingredients of this medicine (listed in section 6).
- If you are taking a monoamine oxidase inhibitor (MAO inhibitor) or have stopped taking such medicine within the last two weeks.

##### **Warnings and precautions**

Talk to your doctor, pharmacist or nurse before taking Mirtazapin Alternova if you have or have had:

- Epilepsy or brain injury
- Reduced liver or kidney function
- Heart disease (e.g. conduction disorders, convulsions in coronary vessels and cardiac infarction)
- Low blood pressure
- Problems urinating (e.g. because of enlarged prostate)
- Glaucoma
- Diabetes
- Mental illness (e.g. Schizophrenia)

- Alternating periods of exhilaration and depression. Since depression is treated with Mirtazapine Alternova you may enter a panic phase with hyperactivity as a result.
- Akathisia/psychomotor restlessness (inability to sit or stand still)

### **Children and adolescents**

Mirtazapin Alternova should normally not be used for children and adolescents under 18 years due to lacking efficacy in trials and safety concerns. 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 Mirtazapin Alternova for patients under 18 because he/she decides that this is in their best interests. If your doctor has prescribed Mirtazapin Alternova 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 Mirtazapin Alternova. Also, the long-term safety effects concerning growth, maturation and cognitive and behavioural development of Mirtazapin Alternova in this age group have not yet been demonstrated. Besides, significant weight gain has been observed more often in this age group than in adults during treatment with mirtazapine.

Mirtazapin Alternova can in rare case have an effect on the white blood cells such that your resistance to infections is lowered. If you get an infection with symptoms such as fever and a markedly reduced wellbeing or fever with local infection symptoms e.g. pain in neck/throat/mouth or urinary difficulties you should as soon as possible contact your doctor so blood tests can be taken to exclude the possibility of reduced number of white blood cells (agranulocytosis). It is important that you inform about your medical treatment.

If jaundice develops treatment should stop in consultation with your doctor.

In rare cases if Mirtazapin Alternova is taken with other medicines that augment the release of serotonin a syndrome called serotonergic syndrome may occur. The principal symptoms of serotonergic syndrome are fever (above 38°C) and muscle cramps but may also include confusion, irritability and extreme agitation progressing to delirium and coma. Contact your doctor if such symptoms occur, you may need to stop taking the medicine and receive treatment.

Even though mirtazapin is not considered to be addictive abrupt cessation of treatment can lead to withdrawal symptoms such as nausea, headache, dizziness, agitation anxiety and malaise (a feeling of weakness or discomfort). Please contact your doctor for advice on how to reduce the treatment gradually.

### **Thoughts of suicide and worsening of your depression or anxiety disorder**

If you are depressed and/or have anxiety disorders 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. 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 or have an anxiety disorder, and ask them to read this leaflet. You might ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.

### **Other medicines and Mirtazapin Alternova**

Other medicines can influence the effect of Mirtazapin Alternova and/or Mirtazapin Alternova can influence the effect of other medicines. Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

If you have been treated with MAO-inhibitors (another type of anti-depressant) you should let at least 14 days pass until you begin with Mirtazapin Alternova treatment. Treatment with MAO inhibitors can be started two weeks after stopping treatment with Mirtazapin Alternova.

### **It is especially important to inform your doctor if you are taking:**

- Benzodiazepines (drugs that are used to treat anxiety and sleep disorders)
- HIV-protease-inhibitors (drugs used against HIV)
- Ketoconazoles (fungicides, used to treat fungal infections)
- Erythromycin and rifampicin (antibiotics, used to treat bacterial infections)
- Nefazodone (used to treat depression )
- Carbamazepine and phenytoin (used to treat epilepsy)
- Cimetidine (used to treat stomach ulcers, et al.)
- Warfarin (used to prevent blood clotting)
- SSRI (selective serotonin reuptake inhibitors, used to treat depression)
- L-tryptophan and triptans (used to treat migraine)
- Tramadol (pain killer)
- Linezolid (used to treat infection)
- Lithium (used to treat psychiatric disorders)
- St. John's Wort (herbal medicine for depression)
- Antipsychotics
- Antihistamine H1 antagonists (used to treat allergies)
- Opioids (strong pain killers like morphine)

### **Mirtazapin Alternova with food, drink and alcohol**

Mirtazapin Alternova can enhance the negative effect of alcohol e.g. you may get drowsy. You should therefore not consume alcohol while you are under treatment of Mirtazapin Alternova.

### **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.

Mirtazapin Alternova should not be taken during pregnancy unless absolutely necessary.

If you become pregnant during treatment with Mirtazapin Alternova, ask your doctor if you should continue treatment.

If you are breast-feeding you must not take Mirtazapin Alternova.

Make sure your midwife and/or doctor knows you are on Mirtazapin Alternova. 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.

### **Driving and using machines**

Mirtazapin Alternova may impair your concentration and alertness, particularly at the beginning of treatment. You should bear this in mind when driving or working with machinery.

### **Mirtazapin Alternova contains lactose**

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

### **3. How to take Mirtazapin Alternova**

Always take this medicine 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 15-30 mg daily. The dose can be increased to 45 mg daily.  
The tablet can be divided into equal doses.

Mirtazapin Alternova should not be used for adolescents below the age of 18 (please refer to section 2 *Children and adolescents*) for more information.

In cases of reduced kidney- or liver-function the dose should be adjusted/lowered by the doctor.

The tablets should be swallowed whole with  $\frac{1}{2}$  a glass of liquid. The entire daily dose can be taken just before bedtime, but the dose can also be divided in 2 daily doses (one dose in the morning and one dose in the evening before bedtime). It can take up to 2-4 weeks before you begin to feel the effect of the treatment.

#### **If you take more Mirtazapin Alternova than you should**

Contact your doctor, hospital or pharmacy if you have taken more Mirtazapin Alternova than described in this information or by your doctor.

#### **If you forget to take Mirtazapin Alternova**

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

#### **If you stop taking Mirtazapin Alternova**

After long-term treatment with Mirtazapin Alternova you must not immediately stop taking your medicine as this may cause problems in the form of nausea, headache and malaise (a feeling of discomfort). The dose should therefore be reduced gradually if you stop the treatment.

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

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

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

#### **Serious side effects**

**The following side effects are very serious and may require immediate treatment. If any of the following side effects occur, stop taking the medicine straight away and seek urgent medical advice.**

#### **Rare side effects (may affect up to 1 in 1,000 people):**

Pancreatitis.

#### **Frequency not known (cannot be estimated from the available data):**

Inappropriate antidiuretic hormone secretion (too much water in the body causing symptoms such as nausea, vomiting, headache and stomach cramps, and in severe cases convulsions, loss of consciousness and death), convulsions (insults), serotonin syndrome (a form of poisoning with symptoms such as confusion, trembling,

sweating, fever and pounding heartbeat), Stevens Johnson's syndrome (a potentially life-threatening skin condition with inflammation and rash, particularly involving hands, feet and mouth, nose, eyes and genitals accompanied by fever), toxic epidermal necrolysis (a potentially life-threatening condition with severe skin peeling all over the body).

Cases of suicidal ideation and suicidal behaviours have been reported during mirtazapine therapy or early after treatment discontinuation (see section 2).

### **Other side effects**

#### **Very common side effects** *(may affect more than 1 in 10 people):*

Increased appetite and weight gain, drowsiness (especially in the first weeks of treatment), dry mouth, headache.

#### **Common side effects** *(may affect up to 1 in 10 people):*

Abnormal dreams, confusion, anxiety, insomnia, lethargy, dizziness, shaking, orthostatic hypotension (drop in blood pressure when you stand up), generalised or local oedema (resulting in weight gain), nausea, diarrhoea, vomiting, rash, joint pain, muscle pain, back pain, swelling of feet, ankles and hands, fatigue.

#### **Uncommon side effects** *(may affect up to 1 in 100 people):*

Nightmares, mania, agitation, hallucinations, psychomotor restlessness (including inability to sit or stand still and involuntary movements), pins and needles, restless legs, fainting, low blood pressure, decreased oral sensitivity.

#### **Rare side effects** *(may affect up to 1 in 1,000 people):*

Acute bone marrow depression (suppression of the bone marrow function resulting in changes in blood cells and blood platelets), aggression, sudden muscle contractions, effects on the liver (elevated liver enzymes).

#### **Frequency not known** *(cannot be estimated from the available data):*

Hyponatraemia (decreased sodium levels in blood), numbness or tingling in the mouth, speech difficulties, mouth oedema, increased salivation, blisters on skin, erythema multiforme (acute rash with red patches in the face and mouth and on arms and legs, often accompanied by fever) and somnambulism.

### **Additional side effects in children and adolescents**

Weight gain, nettle rash and increased levels of fat (triglycerides) in the blood were common side effects in clinical trials with children.

### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. 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 Mirtazapin Alternova**

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

There are no special storage conditions for Mirtazapin Alternova.

Do not use this medicine after the expiry date, which is stated on the carton. The expiry date refers to the last day of that month.

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 further information**

### **What Mirtazapin Alternova contains**

- The active substance is mirtazapine. Each tablet contains 15 mg mirtazapine.
- The other ingredients are lactose monohydrate, corn starch, hydroxypropyl cellulose, anhydrous colloid silica, magnesium stearate, hypromellose and macrogol 8000. Colouring agents: titanium dioxide (E171), yellow iron oxide (E172), quinoline yellow (E104), sunset yellow FCF (E110).

### **What Mirtazapin Alternova looks like and contents of the pack**

#### *Appearance*

Yellow, oblong and biconvex tablets with a score.

#### *Contents of the pack*

Blister: 14, 28, 30, 56, 60, 70, 90 and 100 tablets.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

#### *Marketing Authorisation Holder*

Alternova A/S, Lodshusvej 11, 4230 Skælskør, Denmark

#### *Manufacturer*

Combino Pharm S.L, C/Fructuós Gelabert 6-8, E-08970 Sant Joan Despi., Barcelona, Spain

or

Combino Pharm Malta Ltd., HF 60 Hal Far Industrial Estate, Hal Far BBG 07, Malta,

or

Viminco A/S, Lodshusvej 11, 4230 Skælskør, Denmark

**This medicinal product is authorised in the Member States of the EEA under the following names:  
Denmark, Sweden: Mirtazapin Alternova**

**This leaflet was last revised in 11.03.2015.**