PACKAGE LEAFLET INFORMATION FOR THE USER

MIRTAPIL®
15mg/ml oral solution
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 effect, talk to your doctor or pharmacist or any other health care professional or directly to the National Drug Organization (284 Mesogeion Av, 15562, Cholargos, Greece. www.eof.gr).

What is in this leaflet

1. WHAT MIRTAPIL® IS AND WHAT IS USED FOR

Mirtapil® is one of a group of medicines called **antidepressants**.
Mirtapil® is used for the treatment of depression.

2. WHAT YOU SHOULD KNOW BEFORE YOU TAKE MIRTAPIL®:

Do not take Mirtapil®:
- if you are allergic (hypersensitive) to mirtazapine or any of the other ingredients of **Mirtapil®**. If so, you must talk to your doctor as soon as you can before taking **Mirtapil®**.
- if you are taking or have recently taken (within the last two weeks) medicines called monoamine oxidase inhibitors (MAO-Is).

Take special care with Mirtapil®

Administration to children and adolescents under 18 years.
Mirtapil® should normally not be used for children and adolescents under 18 years. Also you should know that patients under 18 years have increased risk to side effects as suicide attempts, suicidal thoughts and hostility (predominantly aggression, oppositional behavior, and anger) when they take this class of medicines. Despite this, your doctor may prescribe **Mirtapil®** for patients under 18 because he/she decides that this is in their best interests. If your doctor has prescribed **Mirtapil®** 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 **Mirtapil®**. Also, the long-term safety effects concerning growth, maturation, and cognitive and dehavioural development of **Mirtapil®** 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 to adults.

Thought of suicide and worsening of your depression or stress anxiety
If you have depression and/or stress anxiety, 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 young adult. Information from clinical trials has shown an increased risk of suicidal behavior 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 stress anxiety and ask them to read this leaflet. You might ask them to tell you if they think your depression or stress anxiety is getting worse, or if they are worried about changes in your behavior.

Also take special care with **Mirtapil®**:
- if you have, or have ever had one of the following conditions.
  Tell your doctor about these conditions before taking **Mirtapil®**, if not done previously:
  - **seizures** (epilepsy). If you develop seizures or your seizures become more frequent, stop taking **Mirtapil®** and contact your doctor immediately;
  - **liver disease**, including jaundice. If jaundice occurs, stop taking **Mirtapil ®** 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/over-activity and depressed mood). If you start feeling elated or over-excited, stop taking **Mirtapil ®** and contact your doctor immediately;
  - **diabetes** (you may need to adjust your dose of insulin or other anti-diabetic medicines).
  - **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 **Mirtapil ®** 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 anti-depressants.

Use of other medicines
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicine that is mentioned below.
Please inform your doctor or pharmacist if you are taking any other medicine, even those that you get without prescription.

Do not take Mirtapil® in combination with:
- **monoamine oxidase inhibitors** (MAO inhibitors). Also, do not take **Mirtapil®** during the two weeks after you have stopped taking MAO inhibitors. If you stop taking **Mirtapil®** 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 Mirtapil® in combination with:

- **anti-depressants such as SSRIs, venlafaxine and L-tryptofan, or triptans** (used to treat migraine), **tramadol** (a pain-killer), **linezolid** (an anti-biotic), **lithium** (used to treat some psychiatric conditions), and **St. John's Wort - Hypericum perforatum** (a herbal remedy for depression). In very rare cases **Mirtapil®** alone or in combination 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, diarrhea, (uncontrollable) muscle contractions, shivering, overacting 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 **Mirtapil®** in your blood. Inform your doctor if you are using this medicine. It might be needed to lower the dose of **Mirtapil®** or when use of nefazodone is stopped, to increase the dose of **Mirtapil®** again.
- **medicines for anxiety or insomnia** such as benzodiazepines
- **medicines for schizophrenia** such as olanzapine
- **medicines for allergy** such as cetirizine
- **medicines for severe pain such as morphine.**

  In combination with these medicines **Mirtapil®** can increase the drowsiness caused by these medications.
- **medicines for infections:** medicines for bacterial infections (such as erythrocin); medicines for fungal infections (such as ketoconazole) and medicines for HIV/AIDS (such as HIV-protease inhibitors). In combination with **Mirtapil®** these medicines can increase the amount of **Mirtapil®** in your blood. Inform your doctor if you are taking these medicines. It might be needed to lower the dose of **Mirtapil®** or when these medicines are stopped, to increase the dose of **Mirtapil®** again.
- **medicines for epilepsy** such as carbamazepine and phenytoin
- **medicines for tuberculosis** such as rifampicin
  In combination with **Mirtapil®** these medicines can reduce the amount of **Mirtapil®** in your blood. Inform your doctor if you are using these medicines. It might be needed to increase the dose of **Mirtapil®**, or when these medicines are stopped to lower the dose of **Mirtapil®**.
- **medicines to prevent blood clotting** such as warfarin
  Mirtapil® 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.

Mirtapil® with food and alcohol
You may get drowsy if you drink alcohol while you are taking **Mirtapil®**.
You are advised not to drink alcohol.
You can take **Mirtapil®** with or without food.

Pregnancy and breast-feeding
Ask for your doctor's or pharmacist's advice before taking any medicine.
Limited experience with **Mirtapil®** administration to pregnant women does not indicate an increased risk. However, caution should be exercised when used during pregnancy.
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 doctor immediately.
If you use **Mirtapil®** until or shortly before birth, your baby should be supervised for possible adverse effects.

Ask your doctor if you can breast-feed while you are taking **Mirtapil®**.

Driving and using machines
Mirtapil® can affect your concentration or alertness. Make sure these abilities are not affected before you drive or operate machinery.

Important information about some of the excipients of Mirtapil®
If you have been told by your doctor that you have intolerance in certain substances, contact your doctor before taking this medicinal product. you may find the excipients of this product in the end of this leaflet.

3. HOW TO TAKE MIRTAPIL®:

Always take **Mirtapil®** exactly as your doctor or pharmacist has told you. If you have any doubts, ask your doctor or pharmacist.

How much to take:
The recommended starting dose is 15 or 30mg daily. Your doctor may advice you to increase your dose after a few days to the amount that is best for you (between 15 and 45mg daily). 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.

Ehen to take Mirtapil®:
→ Take **Mirtapil®** at the same time each day.
It is best to take **Mirtapil®** as a single dose before you go to bed. However, your doctor may suggest to split the dose of **Mirtapil®** – one in the morning and one in the evening before you go to bed. The higher dose should be taken before you go to bed.

When can you expect to start feeling better
Usually **Mirtapil®** will start working after one to two weeks and after two to four weeks you may start to feel better.
It is important that, during the first two weeks of treatment, you talk with your doctor about the effects of **Mirtapil®**.
→ Two to four weeks after started taking **Mirtapil®**, 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 need to take **Mirtapil®** until the symptoms of depression have disappeared for 4 to 6 months.

If you take more Mirtapil® than you should:
→ If you or someone else has taken too much **Mirtapil®** call a doctor straight away.
The most likely signs of an overdose of **Mirtapil®** (without other medicines or alcohol) are **drowsiness, disorientation and increased heart rate.**

If you forget to take Mirtapil®:
If you are supposed to take your dose **once daily:**
- Do not take a double dose to make up for a forgotten **Mirtapil®** dose. Just ignore it and take your next dose of **Mirtapil®** at the scheduled time.

If you are supposed to take your dose twice a day:
- If you have forgotten to take your morning dose, simply take it 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 are supposed to take the oral solution **twice a day:**
- If you Εάν ξεχάσατε την πρωινή δόση σας απλά πάρτε τη μαζί με τη βραδινή δόση σας.

- Εάν ξεχάσατε τη βραδινή δόση σας, μην την πάρετε μαζί με την επόμενη πρωινή δόση. Απλά παραλείψτε την και συνεχίστε με την κανονική πρωινή και βραδινή δόση σας.
- Εάν ξεχάσατε και τις δύο δόσεις, δεν πρέπει να προσπαθήσετε να καλύψετε τις ξεχασμένες δόσεις. Παραλείψτε τις και συνεχίστε την επόμενη μέρα με την κανονική πρωινή και βραδινή δόση σας.

If you stop taking Mirtapil®
Only stop taking **Mirtapil®** 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 **Mirtapil®,** even when your depression has lifted. If you suddenly stop taking **Mirtapil®** 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, **Mirtapil®** can cause side effects, although not everybody gets them.
Some of the side effects are more possible to occur than others. Possible side effects when you use **Mirtapil®** are mentioned below and may occur according to frequency as follows:

- **Very common:** may affect more than 1 in 10 people
- **Common:** may affect 1 to 10 people out of 100
- **Uncommon:** may affect 1 to 10 people out of 1.000
- **Rare:** may affect 1 to 10 people out of 10.000
- **Very Rare:** may affect less than 1 person out of 10.000
- **Unknown:** frequency cannot be estimated from the available data

Very common:
- increase in appetite and weight gain
- drowsiness or sleepiness
- headache
- dry mouth

Common:
- lethargy
- dizziness
- shakiness or tremor
- nausea
- diarrhea
- vomiting
- rash or skin eruptions (exanthema)
- pain in your joints (arthralgia) or muscles (myalgia)
- back pain (osfyalgia)
- feeling dizzy or faint when you stand up suddenly (orthostatic hypotension)
- swelling (typically in ankles or feet) caused by fluid retention (edema)
- tiredness
- vivid dreams
- confusion
- feeling anxious
- sleeping problems

Uncommon:
- feeling elated or emotionally “high” (mania).
  Stop taking **Mirtapil®** immediately in such case and consult with your doctor as soon as possible.

- abnormal sensation in the skin e.g. burning, stinging, tickling or tingling (paraesthesia)
- restless leg syndrom
- fainting (syncope)
- sensations of numbness in the mouth (oral hyperesthesia)
- low blood pressure
- nightmares
- feeling agitated
- hallucinations
- urge to move

Rare:
- yellow coloring of eyes or skin; this may suggest disturbance in liver function (jaundice). Stop taking **Mirtapil®** immediately in such case and consult with your doctor as soon as possible.
- muscle twitching or contractions (myoclonus)

Not known:
- signs of infection such as sudden unexplained high fever, sore throat and mouth ulcers (agranulocytosis). Stop taking **Mirtapil®** immediately in such case and talk to your doctor in order to do the proper blood testing.
  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)
  Stop taking **Mirtapil®** immediately in such case and consult with your doctor as soon as possible.
- 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.
  Stop taking **Mirtapil®** immediately in such case and consult with your doctor as soon as possible.
- thoughts of harming or killing yourself. Contact your doctor or go immediately to the hospital.
- abnormal sensation in the mouth (oral paresthesia)
- swelling in the mouth (mouth edema)
- hyponatraemia
- inappropriate anti-diuretic hormone secretion

If any side effect becomes serious or if you see any side effect that is not mentioned in this leaflet, please inform your doctor or pharmacist.

5. HOW TO STORE MIRTAPIL®

Keep this medicine out of sight and reach of children.

Do not use **Mirtapil®** after the expiry date, which is stated on the carton and the bottle after EXP. The expiry date refers to the last day of the month mentioned. After first opening store the solution for six weeks.

Do not through away any medicines via wastewater or household waste.

Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. CONTENT OF THE PACK AND OTHER INFORMATION

What Mirtapil® contains:
- Active substance is mirtazapine. Each ml of solution contains 15mg of mirtazapine.
- Other ingredients are: Maltitol liquid, Glycerol, Citric acid monohydrate, Orange flavour, L-methionine, Sodium benzoate, Saccharin sodium, Water purified.

What Mirtapil® looks like and content of the pack:
Mirtapil® is packed in an amber glass bottle of 66 ml, with a child-proof safety cap and a dosimetric pipet (ml) and a leaflet.

Marketing Authorization Holder:
TARGET PHARMA LTD. 54 Menandrou st., 104 31 Athens - Greece, Tel.: +30 210 5224830, Fax: +30 210 5224838, Email: info@targetpharma.gr, http://www.targetpharma.gr

Manufacturer:
RAFARM AEBE.

This medicine is subjected to medical prescription

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