

# Remeron® 15 mg film-coated tablets

# Remeron® 30 mg film-coated tablets

# Remeron® 45 mg film-coated tablets

**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:*

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4. Possible side effects
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**1. What Remeron is and what it is used for**

Remeron is one of a group of medicines called **antidepressants**.

Remeron is used to treat depressive illness.

**2. Before you take Remeron**

**Do not take Remeron**

- if you are **allergic** (hypersensitive) to mirtazapine or any of the other ingredients of Remeron. If so, you must talk to your doctor as soon as you can before taking Remeron.
- if you are taking or have recently taken (within the last two weeks) medicines called monoamine oxidase inhibitors (MAO-Is).

**Take special care with Remeron**

**Use in children and adolescents under 18 years of age**

Remeron should normally not be used for children and adolescents under 18 years. 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 behavior and anger) when they take this class of medicines. Despite this, your doctor may prescribe Remeron for patients under 18 because he/she decides that this is in their best interests. If your doctor has prescribed Remeron 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 Remeron. Also, the long-term safety effects concerning growth, maturation and cognitive and behavioral development of Remeron in this age group have not yet been demonstrated.

**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. 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, 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 behavior.

Also take special care with Remeron

- if you have, or have ever had one of the following conditions. Tell your doctor about these conditions before taking Remeron, if not done previously
  - **seizures** (epilepsy). If you develop seizures or your seizures become more frequent, stop taking Remeron and contact your doctor immediately;
  - **liver disease**, including jaundice. If jaundice occurs, stop taking Remeron 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 straight away;
  - **manic depression** (alternating periods of feeling elated/overactivity and depressed mood). If you start feeling elated or over-excited, stop taking Remeron 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.
- if you develop signs of infection such as inexplicable high fever, sore throat and mouth ulcers. Stop taking Remeron 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.

**Taking other medicines**

Tell your doctor or pharmacist if you are taking (or plan to take) any of the medicines in the following list. Please also tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

**Do not take Remeron** in combination with:

- **monoamine oxidase inhibitors** (MAO inhibitors). Also, do not take Remeron during the two weeks after you

have stopped taking MAO inhibitors. If you stop taking Remeron, 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 Remeron in combination with:**

- **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) and **St. John's Wort - Hypericum perforatum preparations** (a herbal remedy for depression). In very rare cases Remeron alone or the combination of Remeron 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, 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 Remeron in your blood. Inform your doctor if you are using this medicine. It might be needed to lower the dose of Remeron, or when use of nefazodone is stopped, to increase the dose of Remeron 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 Remeron 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). In combination with Remeron these medicines can increase the amount of Remeron in your blood. Inform your doctor if you are using these medicines. It might be needed to lower the dose of Remeron, or when these medicines are stopped, to increase the dose of Remeron again.
- **medicines for epilepsy** such as carbamazepine and phenytoin;
- **medicines for tuberculosis** such as rifampicin. In combination with Remeron these medicines can reduce the amount of Remeron in your blood. Inform your doctor if you are using these medicines. It might be needed to increase the dose of Remeron, or when these medicines are stopped to lower the dose of Remeron again.
- **medicines to prevent blood clotting** such as warfarin. Remeron 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.

**Taking Remeron with food and drink.**

You may get drowsy if you drink alcohol while you are taking Remeron. You are advised not to drink any alcohol. You can take Remeron with or without food.

**Pregnancy and breast-feeding**

Ask your doctor or pharmacist for advice before taking any medicine. Limited experience with Remeron administration to pregnant women does not indicate an increased risk. However, caution should be exercised when used during pregnancy. If you are taking Remeron and you become pregnant or you plan to get pregnant, ask your doctor whether you may continue taking Remeron. If you use Remeron until, or shortly before birth, your baby should be supervised for possible adverse effects. Ask your doctor whether you can breast-feed, while taking Remeron.

**Driving and using machines**

Remeron 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 ingredients of Remeron**

Remeron film-coated tablets contain lactose. If you have been told by your doctor that you have an intolerance for some sugars, contact your doctor before taking this medicinal product.

**3. How to take Remeron**

Always take Remeron exactly as your doctor or pharmacist tells you to. You should check with your doctor or pharmacist if you are not sure.

**How much to take**

**The usual 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 Remeron**

Take Remeron at the same time each day. It is best to take Remeron as a single dose before you go to bed. However your doctor may suggest to split your dose of Remeron - 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 your tablets orally. Swallow your prescribed dose of Remeron without chewing, with some water or juice.

**When can you expect to start feeling better**

Usually Remeron 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 Remeron: 2 to 4 weeks after you have started taking Remeron, 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 Remeron until your symptoms of depression have disappeared for 4 to 6 months.

**If you take more Remeron than you should**

If you or someone else have taken too much Remeron, call a doctor straight away. The most likely signs of an overdose of Remeron (without other medicines or alcohol) are **drowsiness, disorientation and increased heart rate.**

**If you forget to take Remeron**

- If you are supposed to take your dose **once a day**
  - if you have forgotten to take your dose of Remeron, do not take the missed dose. Just skip it. 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 Remeron**

Only stop taking Remeron 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 Remeron, even when your depression has lifted. If you suddenly stop taking Remeron 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 product, ask your doctor or pharmacist.

**4. Possible side effects**

Like all medicines, Remeron can cause side effects, although not everybody gets these side effects. Some side effects are more likely to occur than others. The possible side effects of Remeron are listed below and can be divided as:

- **Very common:** affects more than 1 user in 10
- **Common:** affects 1 to 10 users in 100
- **Uncommon:** affects 1 to 10 users in 1,000
- **Rare:** affects 1 to 10 users in 10,000
- **Very rare:** affects less than 1 user in 10,000
- **Not known:** 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
- 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 Remeron and tell your doctor straight away.**
- abnormal sensation in the skin e.g. burning, stinging, tickling or tingling (paresthesia)
- restless legs
- fainting (syncope)
- sensations of numbness in the mouth (oral hypoesthesia)
- 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 Remeron and tell your doctor straight away.**
- muscle twitching or contractions (myoclonus)

**Not known:**

- signs of infection such as sudden unexplainable high fever, sore throat and mouth ulcers (agranulocytosis)
- **Stop taking Remeron and contact your doctor straight away for a blood test.** In rare cases Remeron can cause disturbances in the production of blood cells (bone marrow depression). Some people become less resistant to infection because Remeron can cause a temporary shortage of white blood cells (granulocytopenia). In rare cases Remeron 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 Remeron and tell your doctor straight away.**

- a combination of symptoms such as inexplicable fever, sweating, increased heart rate, diarrhea, (uncontrollable) muscle contractions, shivering, overactive reflexes, restlessness, mood changes and unconsciousness. In very rare cases these can be signs of serotonin syndrome.

**Stop taking Remeron and tell your doctor straight away.**

- thoughts of harming or killing yourself
- **Contact your doctor or go to a hospital straight away.**
- abnormal sensations in the mouth (oral paresthesia)
- swelling in the mouth (mouth edema)
- hyponatremia
- inappropriate anti-diuretic hormone secretion

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 Remeron**

Keep out of the reach and sight of children. Do not use Remeron after the expiry date which is stated on the carton and the blister or bottle. The expiry date refers to the last day of that month. Remeron should be stored at 2-30°C. Store in the original package in order to protect from light and moisture. Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

**6. Further information**

**What Remeron contains**

- The active substance is mirtazapine.
  - Remeron 15 mg film-coated tablets contain 15 mg mirtazapine per film-coated tablet.
  - Remeron 30 mg film-coated tablets contain 30 mg mirtazapine per film-coated tablet.
  - Remeron 45 mg film-coated tablets contain 45 mg mirtazapine per film-coated tablet.
  - The other ingredients are:
    - Tablet core: maize starch, hypromellose, magnesium stearate, silica, colloidal anhydrous, lactose monohydrate
    - Tablet coating: hypromellose, Macrogol 8000, titanium dioxide (E171)
- The tablet core of Remeron 15 mg film-coated tablets also contains yellow iron oxide (E172)

**What Remeron looks like and contents of the pack**

Remeron are film-coated tablets. Remeron 15 mg film-coated tablets are oval, biconvex, yellow, scored and coded with 'Organon' on one side and with 'TZ/3' on the other side. The tablet can be divided into equal halves. Remeron 30 mg film-coated tablets are oval, biconvex, red-brown, scored and coded with 'Organon' on one side and with 'TZ/5' on the other side. The tablet can be divided into equal halves. Remeron 45 mg film-coated tablets are oval, biconvex, white and coded with 'Organon' on one side and with 'TZ/7' on the other side. Remeron 15 mg film-coated tablets are packed in blisters or bottles. For Remeron 15 mg film-coated tablets in blisters the following pack sizes are available: 30, 60, 90 and 100 tablets; 14, 28, 56 and 70 tablets; for Remeron 15 mg film-coated tablets in bottles a pack size of 250 tablets is available (not all pack sizes may be marketed). Remeron 30 mg film-coated tablets are packed in blisters or bottles. For Remeron 30 mg film-coated tablets in blisters the following pack sizes are available: 10, 20, 30, 50, 60, 90, 100, 200 and 500 tablets; 14, 28, 56 and 70 tablets; for Remeron 30 mg film-coated tablets in bottles a pack size of 250 tablets is available (not all pack sizes may be marketed). Remeron 45 mg film-coated tablets are packed in blisters or bottles. For Remeron 45 mg film-coated tablets in blisters the following pack sizes are available: 10, 20, 30, 50, 100, 200 and 500 tablets; 14, 28, 56 and 70 tablets; for Remeron 45 mg film-coated tablets in bottles a pack size of 250 tablets is available (not all pack sizes may be marketed).

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This leaflet was revised in October 2008.

**THIS IS A MEDICAMENT**

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
  - Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament. The doctor and the pharmacist are the experts in medicines, their benefits and risks.
  - Do not by yourself interrupt the period of treatment prescribed.
  - Do not repeat the same prescription without consulting your doctor.
  - Keep all medicaments out of reach of children.
- Council of Arab Health Ministers &  
Union of Arab Pharmacists