

REMERON SOLTAB[®]

Consumer Medication Information Leaflet (RiMUP)

Mirtazapine (15mg, 30mg, 45mg)

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What REMERON SolTab is used for

REMERON SolTab is used in the treatment of depression including relapse prevention.

Depression is longer lasting or more severe than "low moods" everyone has from time to time due to the stress of everyday life. It is thought to be caused by a chemical imbalance in parts of the brain. This affects your whole body and can cause emotional and physical symptoms such as feeling low in spirit, loss of interest in activities, unable to enjoy life, poor appetite or overeating, disturbed sleep, often waking up early, loss of sex drive, lack of energy and feeling guilty over nothing.

This medicine corrects this chemical imbalance and may help relieve the symptoms of depression. Your doctor, however, may prescribe it for another purpose. **Ask your doctor if you have any questions about why it has been prescribed for you.** This medicine is only available with a doctor's prescription.

REMERON SolTab is not addictive.

How REMERON SolTab works

Remeron works in the brain to block receptors and corrects the chemical imbalance in the brain which leads to antidepressant effects.

Before you take Remeron SolTab

When you must not take it

Do not take REMERON SolTab:

- if you are allergic to medicines containing mirtazapine
- if you are allergic to any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itching or hives, swelling of the face, lips, mouth, throat or other parts of the body, shortness of breath, wheezing or trouble breathing.

Do not take REMERON SolTab if you are taking another medicine for depression called a monoamine oxidase inhibitor (MAOI) or have been taking an MAOI within the last 14 days.

Taking REMERON SolTab with an MAOI may cause a serious reaction with a sudden increase in body temperature, extremely high blood pressure and severe convulsions. Examples of this type of medicine include phenelzine, tranylcypromine and selegiline. **Ask your doctor or pharmacist if you are not sure if you are or if you have been taking a MAOI medicine.**

Do not take REMERON SolTab if the packaging is torn or shows signs of tampering.

Do not take REMERON SolTab if the expiry date printed on the pack has passed.

If you are not sure whether you should start taking REMERON SolTab, talk to your doctor.

Before you start to take it

Do not give REMERON SolTab to a child or adolescent. The safety of REMERON SolTab in patients under 18 years has not been established.

Tell your doctor if:

1. you are allergic to any other medicines, foods, dyes or preservatives.
2. you are pregnant or plan to become pregnant.

Like most medicines of this kind, REMERON SolTab is not recommended to be used during pregnancy. Your doctor will discuss the risks and benefits of taking REMERON SolTab when pregnant.

3. you are breastfeeding or wish to breastfeed.

It is not known whether REMERON SolTab passes into breast milk.

4. you have or have had any medical conditions, especially the following:

- thoughts of suicide or self-harm
- epilepsy (fits or convulsions)
- liver disease such as jaundice
- kidney disease
- heart disease
- low blood pressure
- any mental illness (e.g. schizophrenia, manic depression)
- diabetes
- glaucoma (increased pressure in the eye)
- problems in urinating due to an enlarged prostate
- unexplainable high fever, sore throat and mouth ulcers
- fructose intolerance
- glucose-galactose malabsorption
- sucrose-isomaltase insufficiency
- phenylketonuria.

If you have not told your doctor about any of the above, tell them before you take REMERON SolTab.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may be affected by REMERON SolTab or may affect how well it works. These include:

- other medicines (e.g. SSRIs, venlafaxine, L-tryptophan, nefazodone) for depression, anxiety, obsessive compulsive disorders or pre-menstrual dysphoric disorder
- Monoamine Oxidase Inhibitors (such as tranylcypromine, phenelzine, and selegiline)
- medicines containing St John's Wort (hypericum perforatum)
- phenytoin or carbamazepine, medicines used to treat epilepsy
- benzodiazepines, medicines used to treat anxiety and sleeping problems
- lithium, a medicine used to treat some psychiatric conditions
- tramadol, a pain killer
- morphine, medicines for severe pain
- cetirizine, medicines for allergies
- warfarin, a medicine used to prevent blood clotting
- linezolid, erythromycin, an antibiotic
- rifampicin, a medicine used to treat

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tuberculosis

- medicines used to treat fungal infections such as ketoconazole
- HIV/AIDS medications
- cimetidine, a medicine used to treat reflux and stomach ulcers
- triptans such as sumatriptan, and zolmitriptan, medicines used to treat migraine.

Your doctor will tell you what to do if you are taking any of these medicines.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while taking REMERON SolTab.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

How to take Remeron SolTab

Follow all directions given to you by your doctor and pharmacist.

They may differ from the information contained in this leaflet.

How much to take

Your doctor will tell you how much REMERON SolTab to take each day. Take exactly the amount your doctor tells you.

The usual starting dose is 15mg per day. Your doctor may slowly increase this dose depending on how you respond to REMERON SolTab. The effective dose for most people is usually between 30mg and 45mg per day. Your doctor may have prescribed a different dose.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

When to take it

Take REMERON SolTab at about the same time each day.

Your doctor will tell you when to take your tablets.

The tablet(s) should be taken at the same time each day, preferably as a single night-time dose before going to bed; if recommended by your doctor, REMERON SolTab may be taken in sub-doses equally divided over the day (once in the morning and once at night-time before going to bed).

How to take it

REMERON SolTab can be taken with or without water.

Please read the following instructions carefully.

- To prevent crushing the tablet, do not push against the tablet pocket.
- Each blister contains six tablet pockets, which are separated by perforations (dotted lines). Bend the strip several times along the dotted lines, and then tear off one tablet pocket.
- Carefully peel off the lidding foil, starting in the corner indicated by the arrow.
- Take out the tablet with dry hands and place it on the tongue. The tablet will rapidly disintegrate and can be swallowed with or without water.

Take the tablet immediately after it is removed from the tablet pocket.

Once removed it cannot be stored.

How long to take it

Keep taking REMERON SolTab until your doctor tells you to stop.

For depression, the length of treatment will depend on how quickly your symptoms improve. Most antidepressants take time to work, so do not be discouraged if you don't feel better right away. Some of your symptoms may improve in 1 to 2 weeks but it can take up to 2 – 4 weeks to feel the full benefit of the medicine.

Even when you feel well, you will usually have to take REMERON SolTab for 4 to 6 months or even longer to make sure the benefits will last.

If you forget to take it

ONCE DAILY DOSING

If you forget to take the tablet before you go to bed, do not take the missed dose next morning. It may cause drowsiness or sleepiness during the day. Continue treatment in the evening with your normal dose.

TWICE DAILY DOSING

- **Morning dose forgotten - simply take it together with your evening dose.**
- **Evening dose forgotten - do not take it with the next morning dose. Continue treatment with your normal morning**

and evening doses.

- **Both doses forgotten - do not try to make up for the missed tablets. Continue with your usual morning and evening dose the next day. If you have trouble remembering to take your medicine, ask your pharmacist for some hints.**

If you take too much (overdose)

Immediately telephone your doctor or pharmacist for advice, or go to your nearest hospital if you think you or anyone else may have taken too much REMERON SolTab. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you take too many Remeron SolTab tablets, you may feel drowsy, dizzy, confused, agitated, have increased heart rate or lose consciousness.

While you are taking Remeron SolTab

Things you must do

Tell your doctor immediately if you develop fever, chills, sore throat or mouth ulcers or other signs of frequent infections.

In rare cases REMERON SolTab can cause a shortage of white blood cells, resulting in lowering body resistance to infection. These symptoms may appear after 2 - 6 weeks of treatment.

Tell your doctor immediately or go to the nearest hospital for treatment if you have any suicidal thoughts or other mental/mood changes.

Occasionally, the symptoms of depression or other psychiatric conditions may include thoughts of harming yourself or committing suicide. Until the full antidepressant effect of your medicine becomes apparent, it is possible these symptoms may increase in the first few weeks of treatment.

If you or someone you know is showing warning signs of suicide related behaviour while taking REMERON SolTab, contact your doctor or a mental health professional right away or go to the nearest hospital for treatment.

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These signs include:

- thoughts or talk about death or suicide
- thoughts or talk of self-harm or harm to others

- any recent attempts of self-harm
- increase in aggressive behaviour, irritability or agitation.

All mentions of suicide or violence must be taken seriously.

Tell your doctor if you become pregnant while taking this medicine. Do not stop taking your tablets until you have spoken to your doctor.

Tell your doctor if for any reason you have not taken your medicine exactly as prescribed. Otherwise your doctor may think that it was not effective and change your treatment unnecessarily.

Tell your doctor if you feel the tablets are not helping your condition.

Be sure to keep all of your appointments with your doctor so that your progress can be checked.

You may need to have blood tests from time to time.

Before starting any new medicine, tell your doctor or pharmacist that you are taking REMERON SolTab.

Tell all doctors, dentists and pharmacists who are treating you that you are taking REMERON SolTab.

Things you must not do

Do not drive or operate machinery until you know how REMERON SolTab affects you.

REMERON SolTab may cause drowsiness, dizziness or sleepiness in some people and affect alertness and concentration. If any of these occur, do not drive, operate machinery or do anything else that could be dangerous.

Do not suddenly stop taking REMERON SolTab, or lower the dose, without first checking with your doctor. Do not let yourself run out of medicine over the weekend or on holidays. Do not stop taking REMERON SolTab, even if you feel better, unless advised by your doctor.

Suddenly stopping REMERON SolTab may cause nausea, headache, dizziness, anxiety, agitation.

Your doctor may want to gradually reduce the amount of REMERON SolTab you are taking before stopping completely.

Do not use REMERON SolTab to treat any other conditions unless your doctor tells you to.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours or if they have the same condition as you.

Things to be careful of
Be careful when drinking alcohol while taking REMERON SolTab.

Combining REMERON SolTab and alcohol can make you sleepier and less alert. Your doctor may suggest you avoid alcohol while being treated with this medicine.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking REMERON SolTab.

REMERON SolTab helps most people with depression, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects. **Ask your doctor or pharmacist any questions you may have.**

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Tell your doctor if you notice any of the following and they bother you:

Very common (affects more than 1 user in 10):

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

Common (affects 1 to 10 users in 100):

- 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 (affects 1 to 10 users in 1000):

- 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 (affects 1 to 10 users in 10,000):

- 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)
- aggression

Not known (cannot be estimated from available data):

- signs of infection such as sudden unexplainable high fever, sore throat and mouth ulcers (agranulocytosis)

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- 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, 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 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)
 - swelling throughout the body (generalized oedema)
 - localized swelling
 - hyponatremia
 - severe skin reactions (Stevens-Johnson syndrome, dermatitis bullous, erythema multiforme, toxic epidermal necrolysis)
 - Speech disorder
- Other side effects not listed above may also occur in some patients. Tell your**

doctor if you notice anything else that is making you feel unwell.

Ask your doctor or pharmacist if you don't understand anything in this list.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting)”

Storage and disposal of REMERON SolTab

Storage

Keep your tablets in their blister pack until it is time to take them. The tablets will not keep if you take them out of their blister.

Store below 30°C in a dark, dry place.

Do not store REMERON SolTab, or any other medicine, in a bathroom or near a sink. Do not leave it in the car or on window sills. Heat and dampness can destroy some medicines.

Keep this medicine where young children cannot reach it.

A locked cupboard at least one-and-a half metres above the ground is a good place to store medicines.

Disposal

Return any unused medicine to your pharmacist.

Product Description

What it looks like

REMERON SolTab is available in three strengths: 15 mg, 30 mg and 45 mg.

They are round, white, flat faced bevelled edge tablets marked with a code on one side (15 mg TZ/1, 30 mg TZ/2, 45 mg TZ/4) and an orange odour. The medicine is packed in child-resistant blisters.

Pack size: blister packs of 6, 18, 30 tablets (not all pack sizes may be marketed).

Ingredients

REMERON SolTab contains 15mg or 30 mg or 45 mg of mirtazapine as the active ingredient.

REMERON SolTab also contains the following inactive ingredients: sugar spheres# (containing sucrose and starch), hypromellose, povidone, Eudragit E 100, magnesium stearate, mannitol (E421), crospovidone, sodium bicarbonate, citric acid anhydrous, cellulose microcrystalline, aspartame (E951)##, orange flavour SN 027512. # REMERON SolTab contains sugar spheres containing sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take this medicine.

Aspartame may be harmful for people with phenylketonuria.

MAL No.:

MAL05023178ACR (15 MG)

MAL05023176ACR (30 MG)

MAL05023179ACR (45 MG)

Manufacturer

CIMA Labs Inc, 10000 Valley View Road, Eden Prairie, MN 55344, United States.

Product Registration Holder

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