PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S5

PROPRIETARY NAME AND DOSAGE FORM

REMERON® 15 mg Tablet

REMERON® 30 mg Tablet

Read all of this leaflet carefully before you are given REMERON

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- REMERON 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.

1. WHAT REMERON CONTAINS

Each REMERON 15 mg tablet contains as active ingredient 15 mg mirtazapine and each 30 mg tablet contains as active ingredient 30 mg mirtazapine.

The inactive ingredients are maize starch, hydroxypropyl cellulose, magnesium stearate, colloidal silicon dioxide, lactose monohydrate, hydroxypropyl methylcellulose, polyethylene glycol, titanium dioxide and red and yellow iron oxide colouring agents.

2. WHAT REMERON IS USED FOR

This medicine belongs to a group of medicines known as antidepressants.

REMERON is used to treat depression in adults.

It may take up to 4 weeks before you experience an improvement.

3. BEFORE TAKING 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 2 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 not be used for children and adolescents under 18 years, as 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 have taken this class of medicines.

Thoughts of suicide and worsening of your depression

If you are depressed you may have thoughts of harming or killing yourself. These thoughts may be increased when first starting REMERON, since REMERON takes 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 straightaway.

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.

Tell your doctor 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 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 straightaway.
- **bipolar disorder** (alternating periods of feeling elated or 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

- **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
- if you are an elderly person. You could be more sensitive to the side effects of antidepressants
- 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.

  Infrequently these symptoms can be signs of disturbances in blood cell production in the bone marrow. Although infrequent these symptoms most commonly appear after 4 to 6 weeks of treatment.

Tell your doctor about these conditions before taking REMERON, if not done previously.

Taking REMERON with food and drink

You are advised not to drink any alcohol. You may become drowsy if you drink alcohol while you are taking REMERON.

You can take REMERON with or without food.

Pregnancy and Breastfeeding

Safety in pregnancy and lactation has not been established.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

You should not breastfeed your baby if you are on treatment with REMERON.

Driving and using machinery

REMERON may decrease alertness, judgement, thinking and powers of concentration. Potentially dangerous tasks that require your continual attention, like driving a car or operating machinery, should be avoided during treatment with REMERON.

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 REMERON.

Taking REMERON with other medicines

Always tell your healthcare professional if you are taking any other medicine. This includes complementary or traditional medicines.

Do not take REMERON in combination with:

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

Tell your doctor if you are using any of the following medicines:

- antidepressants such as selective serotonin reuptake inhibitors (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* preparations (a herbal remedy for depression). 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, 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.

- medicines for anxiety or insomnia, medicines for schizophrenia, medicines for allergies and medicines for severe pain. 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) and medicines for stomach ulcers (such as cimetidine). 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.
- medicines that may affect the heart's rhythm such as certain antibiotics and some anti-psychotics.

4. HOW TO TAKE REMERON

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

Always take REMERON exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

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

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 you 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.

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.

Two to four weeks after you have started taking REMERON, talk to your doctor about how this medicine has affected you.

- If you still do not feel better, your doctor may prescribe a higher dose. In that case, talk to your doctor again after another 2 to 4 weeks.

- You will usually need to take REMERON until after your symptoms of depression have disappeared for 4 to 6 months.

If you forget to take REMERON

If you are supposed to take REMERON once a day:

- Do not take the missed dose; just skip it and 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 take more REMERON than you should

- In the event of an overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.
- The most likely signs of an overdose of REMERON (without other medicines or alcohol) are drowsiness, disorientation and increased heart rate. The symptoms of a possible overdose may include changes to your heart rhythm (fast, irregular heartbeat) and/or fainting which could be symptoms of a life-threatening condition known as Torsade de Pointes.

Effects when treatment with REMERON is stopped

- 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 improved. 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 REMERON, ask your doctor or pharmacist.

5. POSSIBLE SIDE EFFECTS

REMERON can have side effects.

Not all side effects reported for REMERON are included in this leaflet. Should your general health worsen while taking REMERON, or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Less frequent:

- feeling elated or emotionally ‘high’ (mania); stop taking REMERON and tell your doctor straightaway.
- yellow colouring of eyes or skin; this may suggest disturbance in liver function (jaundice). Stop taking REMERON and tell your doctor straight away.
- 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.

- epileptic attack (convulsions). Stop taking REMERON and tell your doctor straight away.
- a combination of symptoms such as fever, sweating, increased heart rate, diarrhoea, (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 straightaway.
- thoughts of harming or killing yourself. Contact your doctor or go to a hospital straight away.
- severe skin reactions (Stevens-Johnson syndrome, dermatitis bullous, erythema multiforme, toxic epidermal necrolysis).

Tell your doctor if you notice any of the following:

Some side effects are more likely to occur than others. The other possible side effects of REMERON include:

Frequent:

- increase in appetite and weight gain
- drowsiness or sleepiness
- headache
- dry mouth
- lethargy
- dizziness
- shakiness or tremor
- nausea
- diarrhoea
- vomiting
- constipation
- rash or skin eruptions (exanthema)
- pain in 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 (oedema)
- tiredness
- vivid dreams
- confusion
- feeling anxious
- sleeping problems.

Less Frequent

- abnormal sensation in the skin e.g. burning, stinging, tickling or tingling (paraesthesia)
- restless legs
- fainting (syncope)
- sensations of numbness in the mouth (oral hypoaesthesia)
- low blood pressure
- nightmares
- feeling agitated
- hallucinations
- urge to move
- muscle twitching or contractions (myoclonus)
- aggression
- abdominal pain and nausea; this may suggest inflammation of the pancreas (pancreatitis)
- in 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 anaemia), a shortage of blood platelets (thrombocytopenia) or an increase in the number of white blood cells (eosinophilia)

- abnormal sensations in the mouth (oral paraesthesia)
- swelling in the mouth (mouth oedema)
- low blood sodium (hyponatraemia)
- increased creatine kinase blood levels
- difficulty in passing urine (urinary retention)
- muscle pain, stiffness and/or weakness, darkening or discolouration of the urine (rhabdomyolysis).
- increased prolactin hormone levels in blood (hyperprolactinemia, including symptoms such as enlarged breasts and/or milky nipple discharge)
- sleepwalking

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.

Tell your doctor if any side effect becomes troublesome or persists. It is also important to tell your doctor or pharmacist if you experience other unusual or unexpected symptoms during treatment with REMERON.

6. STORING AND DISPOSING OF REMERON

Store at or below 30 °C. Store in the original package in order to protect from light and moisture.

Keep all medicines out of the reach of children.

Return all unused medicine to your pharmacist.

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

7. PRESENTATION OF REMERON

REMERON 15 mg or 30 mg Tablets are presented in press-through strips of 10 tablets (3 strips per carton). Each carton pack contains 30 tablets.

8. IDENTIFICATION OF REMERON

REMERON 15 mg Tablets are yellow, coated, oval, biconvex tablets coded TZ over 3 on both sides of a score on one side and MSD on the reverse.

REMERON 30 mg Tablets are red-brown, coated, oval, biconvex tablets coded TZ over 5 on both sides of a score on one side and MSD on the reverse.

9. REGISTRATION NUMBERS

REMERON 15 mg: 32/1.2/0481

REMERON 30 mg: 32/1.2/0482

10. NAME AND ADDRESS OF REGISTRATION HOLDER

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11. DATE OF PUBLICATION

Date on the registration certificate:

- REMERON 15 mg: 30 July 1998
- REMERON 30 mg: 30 July 1998

Date of the most recent revision: 30 October 2020

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