PATIENT INFORMATION LEAFLET

REMEMBA 5 mg/5 mg dispersible tablet
It is taken orally.

- ***Active ingredient:*** Each dispersible tablet contains 5 mg donepezil hydrochloride and 5 mg memantine hydrochloride.
- ***Excipients:*** Contains sorbitol, colloidal silicon dioxide, microcrystalline cellulose, croscarmellose sodium, sucralose, crospovidone, mint flavor and magnesium stearate.

Read the PATIENT INFORMATION LEAFLET carefully before you start using this medicine. Please read it because it contains important information for you.

- *Keep this user manual. You can need to read again.*
- *If you have other questions, please talk your doctor or pharmacist.*
- *This medicine has been prescribed for you personally, do not give it to others.*
- *During the use of this medicine, tell your doctor that you are using this medicine when you go to the doctor or hospital.*
- *Follow exactly what is written in this instruction. Do not use **high or low** doses other than the dose recommended to you about the drug.*

In this leaflet:

Headings are included.

1. What is REMEMBA and what is it used for?

- REMEMBA is a white, round, biconvex dispersible tablet with “55” imprint on one side, containing 5 mg donepezil hydrochloride and 5 mg memantine hydrochloride.
- REMEMBA is available in opaque PVC/PE/PVdC-Aluminum foil blister packs containing 10 and 28 film-coated tablets.
- REMEMBA is a combination of donepezil, a reversible acetylcholinesterase inhibitor of the piperidine type, and memantine, which belongs to a group of drugs called NMDA receptor antagonists.
- Alzheimer's disease (memory loss due to a disruption in the message signals to the brain) symptoms include memory loss, confusion, and increased behavioral changes. As a result, Alzheimer's patients have difficulty continuing their normal daily activities. REMEMBA is a drug used to treat memory disorders in moderate to severe Alzheimer's patients.
- Only adult patients can use REMEMBA.

2. Things to consider before using REMEMBA

DO NOT use REMEMBA in the following situations.

If,

• You are allergic to memantine hydrochloride, donepezil hydrochloride, piperidine derivatives or any of the ingredients in REMEMBA,

USE REMEMBA CAREFULLY in the following situations.

If,

• You have a stomach or duodenal ulcer,

• You have a seizure or severe spasm (involuntary muscle contraction) or sudden jerks in the face, trunk or arms or legs,

• You have heart disease (irregular or slow heartbeat),

• You have asthma or another long-term lung disease,

• You have liver disease or jaundice,

• You have a history of epileptic seizures,

• You have recently had a myocardial infarction (heart attack) or have a history of congestive heart failure or uncontrolled hypertension (high blood pressure),

• You have difficulty urinating or have kidney disease,

• If you have kidney failure, your doctor should closely monitor your kidney function and adjust the memantine dose accordingly if necessary.
• Avoid concomitant use with amantadine (used to treat Parkinson's disease), ketamine (used for anesthesia), dextromethorphan (usually used to treat cough) and other NMDA (N-methyl-D-aspartate) antagonists.

If you experience any of the effects listed above, do not use REMEMBA and talk to your doctor or pharmacist before you start taking REMEMBA.
Also, if you are pregnant or think you may be pregnant, consult your doctor.
REMEMBA is not recommended for children and adolescents under the age of 18.
If these warnings apply to you, even at any time in the past, please consult your doctor.

Using REMEMBA with food and drink
REMEMBA can be used on an empty or full stomach.
REMEMBA should not be taken with alcohol. Because alcohol can change the effect of the medicine. If you have recently changed or plan to change your diet too much (e.g. switching from a normal diet to a strict vegetarian diet) or if you have renal tubular acidosis (RTA, excess acid-forming substances in the blood due to kidney dysfunction - (weakness of kidney function)) or severe urinary tract infection, you should inform your doctor. The dose of your medicine may need to be adjusted.
Pregnancy
Consult your doctor or pharmacist before using this medication.
There are no adequate studies in pregnant women. Your doctor will decide if you need to use this medication. This medication should not be used during pregnancy unless absolutely necessary, if there is a possibility of pregnancy, or if pregnancy is planned.
If you realise that you are pregnant during your treatment, consult your doctor or pharmacist immediately.
Breastfeeding
Consult your doctor or pharmacist before using the medicine.
If you are breastfeeding your baby, inform your doctor. Breastfeeding women should not use REMEMBA.
Driving and using machines
Alzheimer's disease may cause deterioration in driving performance or reduce the ability to use machines.

REMEMBA may also cause weakness, dizziness and muscle cramps. If any of these effects occur, you should not drive or use machines.

REMEMBA may alter your reaction ability, making it unsafe for you to drive or use machines. Therefore, only do such activities if your doctor allows it.

Important information about some of the ingredients in REMEMBA

Warning for sucralose;

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

Warning for sorbitol;

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

Use with other medicines

If you are using or have just started using any of the following medicines, please inform your doctor or pharmacist. These medicines may be medicines that you have bought from the pharmacy but that your doctor has not prescribed for you. Use of these medicines may make the effects of REMEMBA stronger or weaker in the future.

In particular, inform your doctor if you are taking the following medications:

• Other acetylcholinesterase inhibitor drugs used in the treatment of Alzheimer's disease (e.g., galantamine)

• Painkillers or medicines to treat arthritis (joint inflammation) (e.g. aspirin, non-steroidal anti-inflammatory drugs, such as ibuprofen or diclofenac sodium)

• Anticholinergic medicines (medicines generally used to treat movement disorders or intestinal cramps, such as tolterodine)

• Antibiotics (e.g. erythromycin, rifampin)

• Medicines to treat fungi (e.g. ketoconazole)

• Antidepressants (e.g. fluoxetine)

• Anticonvulsants (substances used to prevent and relieve seizures, such as phenytoin, carbamazepine)

• Medicines to treat heart disease (e.g. quinidine, procainamide, beta-blockers [propanolol and atenolol])

• Hydrochlorothiazide (or any combination with hydrochlorothiazide, diuretics)

• Muscle relaxants (e.g. dantrolene, baclofen, diazepam, succinylcholine)

• Oral anticoagulants (drugs that prevent or delay blood clotting) (e.g., warfarin)

• General anesthetics (e.g., ketamine)

• Over-the-counter medications, such as herbal treatments (St. John's wort)
• Barbiturates (substances generally used to help sleep)
• Dopamine agonists (substances used to treat Parkinson's disease, such as L-dopa, bromocriptine)
• Amantadine (medicine used to treat Parkinson's disease)
• Dextromethorphan (medicine used to treat coughs, colds, and flu)
• Cimetidine, ranitidine (medicine used to treat ulcers)
• Quinine (a drug used to treat malaria)
• Nicotine (found in smoking cessation preparations)
• Neuroleptics (medicine used to treat mental disorders).

If you are going to have an operation that requires general anesthesia, inform your doctor or anesthetist that you are using REMEMBA, as REMEMBA may affect the amount of anesthesia needed.
If you are currently using or have recently used any prescription or non-prescription medication, please inform your doctor or pharmacist about them.

3. How to use REMEMBA?
Instructions for proper use and dose/frequency of administration:
Treatment is started with 5/5 mg/day (single dose daily).

5/5 mg/day should be continued for at least 4–6 weeks to obtain the earliest clinical response to treatment and to reach REMEMBA steady-state concentrations. Your doctor may increase your medication dose to 5/10 mg/day or 5/20 mg/day or 10/10 mg/day or 10/20 mg/day (single dose daily) depending on your response to treatment.

Do not change your medication dose without your doctor's advice.
The maximum recommended daily dose of donepezil hydrochloride is 10 mg, and the maximum recommended daily dose of memantine hydrochloride is 20 mg.

Always follow the instructions given by your doctor and pharmacist about how and how much of your medicine you should take.

Application route and method:

REMEMBA is taken every night before going to bed.

You can apply the tablet in three different ways:

a) Swallow the tablet with a glass of water without breaking it.

b) Drop the tablet into a glass of water (100-200 ml). The tablet will quickly disperse in the water. Stir the dispersed tablet with a spoon. The liquid in the glass will have a cloudy appearance. Drink all of the liquid in the glass.

Then add some water to the residue left in the glass and drink it as well.

c) You can apply the tablet by dispersing it in a tablespoon of water. If there is residue left in the spoon after application, you can add water to the spoon again and swallow the residue.

Dispersible tablets should only be taken with water and should not be mixed with milk or fruit juice.

Different age groups:

Use in children:

REMEMBA is not recommended for use in children under 18 years of age.

Use in the elderly:

REMEMBA can be used in elderly patients at the doses indicated above.

Special use cases:

Kidney failure:

If you have kidney failure, your doctor will decide on a dose that is appropriate for your condition.

In this case, your kidney function should be monitored by your doctor at regular intervals.

In patients with mild kidney failure, no dose adjustment is required. The dose may be increased by the doctor according to the patient's response to treatment. In patients with moderate and severe kidney failure, the daily dose of memantine hydrochloride should be 10 mg.

Liver failure:

If you have liver failure, your doctor will determine the appropriate dose for your condition. REMEMBA is not recommended for patients with severe liver failure.

If you have the impression that the effect of REMEMBA is too strong or weak, talk to your doctor or pharmacist.

If you use more REMEMBA than you should:

If you have used more REMEMBA than you should, talk to a doctor or pharmacist.

Do not take more than one tablet each day. If you have taken more than the recommended dose, call your doctor immediately. If you cannot reach your doctor, contact a hospital emergency department immediately. Take the medicine box containing the tablets with you when you go. Symptoms of overdose may include nausea, increased salivation, sweating, slow heartbeat, low blood pressure (feeling faint or dizzy when standing), difficulty breathing, loss of consciousness, seizures or convulsions.

If you forget to use REMEMBA

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

If you forget to take REMEMBA, take the next dose at the usual time. If you forget to take REMEMBA for more than a week, call your doctor before taking the medication.

Effects that may occur when treatment with REMEMBA is terminated

Do not stop taking Rememba unless your doctor tells you to. If you stop taking Rememba, the benefits of your treatment will gradually wear off.

4. What are the possible side effects?

Like all medicines, REMEMBA may cause side effects in people who are sensitive to the ingredients in its content.

Side effects are described in the following categories:

Very common: may occur in at least 1 in 10 patients.

Common: may occur in less than 1 in 10 patients, but more than 1 in 100 patients.

Uncommon: may occur in less than 1 in 100 patients, but more than 1 in 1000 patients.

Rare: may occur in less than 1 in 1000 patients, but more than 1 in 10,000 patients.

Very rare: may occur in less than 1 in 10,000 patients.

Unknown: cannot be estimated from the available data.

If any of the following occur, stop using REMEMBA and IMMEDIATELY contact your doctor or go to the nearest hospital emergency department:

Common

• Allergic reaction (e.g. swelling of the mouth and throat, itching, rash)

• Symptoms manifested by tremors, stiff muscles, a feeling of constant movement in the muscles, movement disorders caused by involuntary contractions in the muscles

Uncommon

• Slow heart rate (bradycardia)

• Heart arrhythmia (heart beating too fast or too slow)

• Heart failure

• Venous thrombosis/thromboembolism (The process of a clot forming in a blood vessel (thrombosis) and then breaking away and traveling to another part of the bloodstream (embolism). The symptoms of thromboembolism depend on where the embolism is located. It can cause pain and numbness in the limbs or extremities; the limbs will be cold and pale, and there will be no pulse. Foot or leg ulcers and gangrene (tissue death) can develop.)

Unknown

• Depression, suicidal thoughts, and suicide

These are all very serious side effects.

If you have any of these, you may need immediate medical attention or hospitalization.

If you notice any of the following, immediately notify your doctor or go to the emergency department of the nearest hospital:

Uncommon

• Seizure or convulsion

• Bleeding in the stomach or intestines. In this case, you may experience effects such as black tarry stools or blood in the rectum,

• Stomach or duodenal ulcer. Symptoms of an ulcer include stomach pain and discomfort between the navel and breastbone.

Rare

• Liver damage such as hepatitis. Symptoms of hepatitis include vomiting or vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the eyes and skin, dark urine (rare),

Very rare

• Fever with muscle stiffness, sweating or decreased levels of consciousness (a condition called neuroleptic malignant syndrome)

• Muscle weakness, tenderness or pain (especially if you feel unwell, have a high temperature or dark urine). These can be caused by abnormal muscle disorders (rhabdomyolysis) that can be life-threatening and lead to kidney problems.

These are all serious side effects. Immediate medical attention may be required. Serious side effects are very rare.

Tell your doctor if you notice any of the following:

Very common

• Headache

• Nausea

• Diarrhea

Common

• Cold

• Dizziness

• Sleepiness

• Loss of appetite

• Agitation

• Muscle cramps

• Incontinence

• Pain

• Rash

• Itching

• Accidents (patients may be prone to falls or accidental injuries)

• Fatigue

• Insomnia (difficulty sleeping)

• Hallucinations (hallucinations, visions)

• Abnormal dreams (including nightmares)

• Aggressive behavior

• Fainting

• Upset stomach

• Constipation

• Headache

• Increased liver function tests

• Dizziness

• Balance disorders

• Shortness of breath

• High blood pressure

• Hypersensitivity

Uncommon

• Slow heart rate

• Increased salivation

• Fungal infections

• Confusion

• Vomiting

• Gait abnormality

• Heart failure

• Venous blood clot (thrombosis/thromboembolism)

Rare:

• Rigidity, tremors or uncontrollable movements, especially of the face, tongue and also limbs.

Unknown:

• Inflammation of the pancreas

• Psychotic reactions

Alzheimer's disease has been associated with depression and suicidal ideation and suicide

These events have been reported in patients treated with the active ingredient memantine in REMEMBA.

If you experience any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. Storage of REMEMBA

Keep REMEMBA out of sight and reach of children and in its packaging.
Store REMEMBA at room temperature below 25ºC and in a dry place.
Use in accordance with the expiration date.
Do not use REMEMBA after the expiration date on the packaging.
If you notice any damage to the product and/or packaging, do not use REMEMBA.
Do not throw away expired or unused medicines! Give them to the collection system determined by the Ministry of Environment and Urbanization.

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