REMINYL® PROLONGED RELEASE CAPSULES

Galantamine hydrobromide (8mg, 16mg, 24mg)

What is in this leaflet

What REMINYL® is used for

REMINYL® contains the active substance 'galantamine'. It is used to treat mild to moderately severe Alzheimer's disease, a type of dementia that alters brain function.

Alzheimer's disease causes increasing memory loss, confusion and behavioral changes, which make it increasingly difficult to carry out normal daily activities.

How REMINYL® works

Alzheimer's disease symptoms are believed to be due to lack of acetylcholine, a substance responsible for sending messages between brain cells. REMINYL® increases the amount of acetylcholine in the brain and so could improve the symptoms of the disease.

The capsules are made in a 'prolonged release' form. This means that they release the medicine more slowly.

Before you use REMINYL®

- *When you must not use it*

Do not take REMINYL®:

- If you are allergic to galantamine or to any of the other ingredients of this medicine.

Pregnancy

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Breastfeeding

It is not known whether galantamine passes into human milk. You should not breastfeed while you are taking REMINYL®.

Children

REMINYL® is not recommended for children.

- *Before you start use it*

Before you take REMINYL®, your doctor needs to know if you have, or had, any of the following:

- Liver or kidney problem.
- A heart condition.
- An ulcer or a history of ulcers in the stomach or gut.
- A blockage of the stomach or in the gut.
- Seizures [*or fits*] such as epilepsy.
- Problems controlling movements of the body or limbs (extrapyramidal disorder).
- A respiratory disease that affects breathing such as asthma or obstructive pulmonary disease.
- Problems passing urine.

Also, tell your doctor if you recently had an operation on the stomach, gut or bladder.

Your doctor will decide if REMINYL® is suitable for you, or if the dose needs to be changed.

REMINYL® can cause weight loss. Your doctor will check your weight regularly while you are taking REMINYL®.

If you have a liver or kidney problem, your doctor may give you a reduced dose of REMINYL®, or may decide this medicine is not suitable for you.

- *Taking other medicines*

REMINYL® should not be used with medicines that work in a similar way. Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Some medicines can make side effects (such as nausea and vomiting) more likely in people taking REMINYL®. Examples include:

- Ketoconazole (an antifungal).
- Amitriptyline, fluoxetine, fluvoxamine or paroxetine (antidepressants).
- Erythromycin (an antibiotic).
- Quinidine (for uneven heart beat).

Your doctor may give you a lower dose of REMINYL® if you are taking any of these medicines.

Other medicines that can make side effects more likely in people taking REMINYL® include:

- Non-steroidal anti-inflammatory painkillers, which can increase the risk of ulcers.
- Medicine taken for heart conditions or high blood pressure (such as digoxin or beta-blockers).

REMINYL® may affect some anesthetics. If you are going to have an operation under a general anesthetic, tell the doctor that you are taking REMINYL®, well in advance.

How to use REMINYL®

You will start treatment with REMINYL® at a low dose, and then slowly increase this to find the most suitable dose for you. Your doctor will explain what dose to start with and when the dose should be increased. If you are not sure what to do, or find the effect of REMINYL® is too strong or too weak, talk to your doctor or pharmacist.

- *How much to use*

- The usual starting dose is 8mg, taken once a day.
- Your doctor may gradually increase your dose, every 4 weeks or more, until you reach a dose that is suitable for you.
- The maximum dose is 24mg, taken once a day.

- *When to use it*

Take your dose of REMINYL® once a day in the morning with water. Try to take REMINYL® with food.

- *How long to use it*

Continue taking REMINYL® for as long as your doctor recommends.

- *If you forget to use it*

If you forget to take one dose, miss out the forgotten dose completely and take the next dose at the normal time.
Do not take double dose to make up for a forgotten dose.

If you forget to take more than one dose, contact your doctor.

- *If you use too much (overdose)*
If you take too much REMINYL®, contact a doctor or hospital straight away. Take any remaining capsules and the packaging with you. The signs of overdose may include:
  - Severe nausea and vomiting, abdominal cramps, sweating
  - Weak muscles, increased saliva in the windpipe, narrowed airways in the lungs that cause difficulty in breathing
  - Fits (seizures)
  - Low blood pressure, slow or abnormally fast heartbeat, abnormal heart tracing on an ECG (electrocardiogram), abnormal heart rhythm that may cause loss of consciousness

While you are using it
- *Things you must do*
Drink plenty of liquids, to keep yourself hydrated.

Your doctor will need to see you regularly, to check that this medicine is working and to discuss how you are feeling.

REMINYL® can cause serious skin reactions, heart problems and seizures *[or fits]*. You must be aware of these side effects while you are taking REMINYL®. See "Side Effects – Look out for serious side effects".

- *Things you not must do*
Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give REMINYL® to anyone else, even if they have the same symptoms or condition as you.

- *Things to be careful of*
Driving and using machines
REMINYL® may make you feel dizzy or sleepy, especially during the first few weeks of treatment. If REMINYL® affects you, do not drive or use any tools or machinery.

Side effects
Like all medicines, this medicine can cause side effects, although not everybody gets them.
Look out for ***serious side effects***.
You need to look out for serious side effects while you are taking REMINYL®.

Skin reactions, including:
- Severe rash blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome).
- Red rash covered with small pus-filled bumps that can spread over the body, sometimes with a fever (acute generalized exanthematous pustulosis).
- Rash that may blister, with spots that look like small targets.

The first appearance of skin rash need to be seen by a doctor straight away.

Heart problems including changes in heart beat (such as a slow beat, extra beats) or palpitations (heart beat feels fast or uneven). Heart problems may show as an abnormal tracing on an 'electrocardiogram' (ECG).

Seizures *[or* ***Fits]*****.**

Stop taking REMINYL® and see a doctor immediately if you notice any of these side effects. Your doctor may decide that REMINYL® is not suitable for you.

Other side effects
- Nausea or vomiting. These side effects are more likely to happen in the first few weeks of treatment or when the dose is increased. They tend to disappear gradually as the body gets used to the medicine and generally only lasts for a few days. If you have these effects, your doctor may recommend that you drink more liquids, and may prescribe a medicine to stop you being sick
- Allergic reaction
- Decreased appetite
- Not enough water in the body (dehydration)
- Depression
- Seeing, feeling, or hearing things that are not there (hallucinations)
- Feeling dizzy or fainting
- Headache
- Muscle tremors or spasms
- Feeling tired or low energy
- Feeling sleepy
- Change in the sense of taste
- Tingling or numb feeling of the skin (pins and needles)
- Blurred vision
- Ringing in the ears
- Flushing
- Low or high blood pressure
- Diarrhea
- Abdominal pain or discomfort
- Indigestion
- Inflamed liver
- Excessive sweating
- Muscle weakness
- Weight loss
- Increased level of liver enzymes in the blood
- Falls
- Wounds
- Problems controlling movements of the body or limbs (extrapyramidal disorder)

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.moh.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and disposal of REMINYL®
- *Storage*
Do not use REMINYL® after the expiry stated on the pack.

Keep out of reach of children.

Do not store above 30°C.

- *Disposal*
Return old medicines to your pharmacist.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product description

- *What it looks like*

  The capsules come on 3 different strengths, which can be recognized by their color and lettering:
  - *8mg capsules:* White opaque, size 4 hard gelatin capsules with the inscription "G 8", containing white to off-white pellets.
  - *16mg capsules:* Pink opaque, size 2 hard gelatin capsules with the inscription "G 16", containing white to off-white pellets.
  - *24mg capsules:* Caramel opaque, size 1 hard gelatin capsules with the inscription "G 24", containing white to off-white pellets.

- *Ingredients*
  - Active ingredient
    Galantamine hydrobromide.

  - Inactive ingredients
    Diethyl phthalate, ethyl-cellulose, gelatin, hypromellose, macrogol, maize starch, titanium oxide and sucrose.

    The 16mg capsules also contain red ferric oxide (E172).

    The 24mg capsules also contain red ferric oxide (E172) and yellow ferric oxide (E172).

- *MAL numbers*
  REMINYL® 8mg, 16mg and 24mg:
  MAL20091915AZ
  MAL20091916AZ
  MAL20091917AZ

  Not all strengths are marketed.

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Janssen Cilag SPA
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Date of revision
14/7/2023 (MY PI based on CCDS v23Oct2020)

Serial number
NPRA (R1/2) 13072023/134