PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

Schedule 4

REMINYL® CR

(galantamine hydrobromide)

8-mg; 16-mg and 24-mg Prolonged Release Capsules

Contains sugar (sucrose).

Read all of this leaflet carefully before you start taking REMINYL CR

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- REMINYL CR 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.

What is in this leaflet

1. What REMINYL CR is and what it is used for
2. What you need to know before you take REMINYL CR
3. How to use REMINYL CR
4. Possible side effects
5. How to store REMINYL CR
6. Contents of the pack and other information

1. What REMINYL CR is and what it is used for

REMINYL CR 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. The capsules are made

in a “controlled release”/ “prolonged-release” form. This means that they release the medicine slowly.

2. What you need to know before you use REMINYL CR

Do not take REMINYL CR:

- if you are hypersensitive (allergic) to galantamine hydrobromide or any of the other ingredients of REMINYL CR. (See section 6);
- if you have severe liver or kidney disease

Warnings and Precautions

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

- A heart condition (such as chest discomfort that is often brought on by physical activity, a heart attack, heart failure, slow or uneven heartbeat);
- changes in ‘electrolyte’ levels (naturally occurring chemicals in the blood, such as potassium).
- An ulcer or a history of ulcers in the stomach or gut;
- A blockage of the stomach or in the gut;
- Seizures or fits (like epilepsy);
- Parkinson’s disease;
- A respiratory disease that affects breathing (such as asthma or obstructive pulmonary disease and pneumonia);
- 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 CR is suitable for you, or if the dose needs to be changed.

Children:

REMINYL CR is not recommended for children.

Other medicines and REMINYL CR

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.) REMINYL CR should not be used with medicines that work in a similar way.

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

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

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

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

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

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

REMINYL CR with food and drink:

REMINYL CR should be taken with meals.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

There are no studies available on the use of REMINYL CR in pregnant woman. REMINYL CR therefore should not be used during pregnancy.

It is not known whether REMINYL CR passes into human milk. Therefore, women on REMINYL CR should not breastfeed.

Driving and using machines

REMINYL CR may make you feel dizzy or sleepy, especially during the first few weeks of treatment. If REMINYL CR affects you, do not drive or use any tools or machinery.

REMINYL CR contains sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking REMINYL CR capsules. It contains sucrose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

4. HOW TO TAKE REMINYL CR

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

You will start treatment with REMINYL CR 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 CR is too strong or too weak, talk to your doctor or pharmacist.

Taking REMINYL CR prolonged release capsules

- The usual starting dose is 8 mg, 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 24 mg, taken once a day.
- Take your dose of REMINYL CR once a day in the morning, with water or other liquids. Try to take REMINYL CR with food.

DO NOT take more than one capsule in a day unless instructed to by your doctor.

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

While you are taking REMINYL CR

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 CR: Each blister packet contains 7 capsules, 1 for each day of the week. The name of each day of the week is printed on the blister. Always choose the capsule next to the right day. It can then be easily seen which capsules have been taken.

Do not share medicines prescribed for you with others.

If you take more REMINYL CR than you should:

The signs of overdose may include:

- Severe nausea and vomiting, abdominal cramps *[or stomach cramps]*, sweating.
- Weak muscles, increased saliva in the windpipe, narrowed airways in the lungs that cause difficulty 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.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre

If you forget to take REMINYL CR

If it is noticed that a dose of REMINYL CR has been forgotten, that dose should be skipped and the treatment should be continued as usual at the next scheduled intake. If multiple doses have been skipped, contact your doctor.

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

4. Possible side effects

REMINYL CR can cause side effects, although not everybody experiences them. If any of the following happens, stop taking REMINYL CR and tell your doctor immediately or go to the casualty department at your nearest hospital.

Skin reactions, including:

- Severe rash with 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.

  These skin reactions need to be seen by a doctor straight away.

Heart problems, including changes in heartbeat (such as a slow beat, extra beats) or palpitations (heartbeat feels fast or uneven). Heart problems may show as an abnormal tracing on an 'electrocardiogram' (ECG), and can be common in people taking REMINYL CR.

Fits (seizures). These are uncommon in people taking REMINYL CR.

You must stop taking REMINYL CR and get help immediately if you notice any of the side effects above.

The frequently reported side effects are nausea and vomiting.

Allergic reaction

Frequent side effects

- Feeling tired; general feeling of discomfort; feeling weak;
- Falling or injury, back pain, chest pain, fever;
- Dizziness; headache; trembling; feeling faint; abnormally tired;
- Feeling the need to vomit, diarrhoea, abdominal (stomach) pain; upper abdominal pain; indigestion; stomach discomfort; abdominal discomfort, decreased bowel movements, wind;
- Slow heartbeat;
- Decreased appetite; weight loss;
- Seeing, feeling, or hearing things that are not there (hallucinations);
- Muscle spasms;
- Loss of appetite, feeling sad (depression); seeing, feeling, or hearing things that are not real, drowsiness or inability to sleep, confusion, excessive worry;
- Runny nose, inflammation of the airways, upper respiratory tract infection, coughing;
- Increased sweating;
- Infection or blood in the urine, uncontrolled urination;
- Low red blood cells, swelling of the extremities, high blood pressure;
- Change in the sense of taste; excessive sleepiness; tingling, pricking, or numbness of the skin, stiff muscles, muscle twitching, unsteadiness, slow or fast movements, lack of or difficulty in speech, leg cramps, stroke;
- Feeling the need to vomit;
- Inflammation of the stomach or bowel, gastro-intestinal bleeding, blood in the stools, increased saliva, dry mouth, difficulty in swallowing, diarrhoea, hiccup;

- Disturbance in the mechanism of conducting impulses in the heart; sensation of abnormal heartbeats (palpitations); possible skipped heartbeat, rapid or slow heartbeat, heart attack;
- Excessive water loss in the body, increased blood glucose, increased liver enzymes in the blood on laboratory tests;
- Muscle weakness;
- Aggression, feelings of indifference or delusions, inability to think, increased sex drive, thoughts of suicide;
- Increased urination, bladder inflammation, inability to pass urine, passing urine frequently at night, kidney stones;
- Reddening of the face; low blood pressure, low blood pressure on rising, swelling of the limbs;
- Blurred vision;
- Ringing noise in the ears.

<u>Less frequent:</u>

- Inflammation of the liver (hepatitis).

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

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

Reporting of side effects

If you get side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of REMINYL CR

5. How to store REMINYL CR

Store at or below 25 °C.

KEEP ALL MEDICINES OUT OF THE REACH AND SIGHT OF CHILDREN.

Do not use REMINYL CR after the date (month and year) printed after “EXP”,

even if it has been stored properly.

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What REMINYL CR contains

The active substance is galantamine hydrobromide.

The other ingredients are:

gelatin, diethyl phthalate, ethyl cellulose, hypromellose, polyethylene glycol, sugar (59 mg, 117 mg and 176 mg respectively), maize starch and titanium dioxide (E171).

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

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

What REMINYL CR looks like and contents of the pack

REMINYL CR

The 3 different strength capsules can be recognized by their colouring and lettering:

- 8mg galantamine as white opaque capsule with the inscription “GAL 8”
- 16mg galantamine as pink opaque capsule with the inscription “GAL 16”
- 24mg galantamine as caramel –coloured opaque capsule with the inscription “GAL 24”

The 8 mg capsules come in blister packs of 7 or 28 capsules. The 16 mg capsules and 24 mg capsules come in packs of 28, 56 or 84 capsules

Capsules also come in white plastic bottles containing of 30 capsules or 300 capsules.

HOLDER OF CERTIFICATE OF REGISTRATION

JANSSEN PHARMACEUTICA (PTY) LTD

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Registration number(s)

Prolonged Release Capsules: 38/5.3/0311; 0312; 0313

Namibia Reg. No.:
CR 8 mg – 10/5.3/0601
CR 16 mg – 10/5.3/0602
CR 24 mg – 10/5.3/0603
NS 2
Botswana Reg. No.:
CR 8 mg – BOT1202079A-F
CR 16 mg – BOT1202078A-F
CR 24 mg – BOT1202080A-F

Access to the corresponding Professional Information

Included in the carton, accompanying this patient information leaflet.