PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

Schedule 4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

REMINYL® CR

(galantamine hydrobromide)

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

Read all of this leaflet carefully before you start taking REMINYL

Keep this leaflet. You may need to read it again.

If you have further questions, please ask your doctor or your pharmacist.

REMINYL 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 REMINYL CONTAINS

- The active substance is galantamine hydrobromide.
- REMINYL comes in the form of tablets and as prolonged release capsules.

The capsules come in three different strengths: 8 mg; 16 mg and 24 mg galantamine.

The capsules contain as inactive ingredients 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).

2. WHAT REMINYL IS USED FOR

REMINYL is used to treat mild to moderately severe dementia of the Alzheimer type.

3. BEFORE YOU TAKE REMINYL

Other Medical Problems:

REMINYL may adversely affect the following:

- some heart disorders;
- stomach ulcer or a history of ulcers;
- acute abdominal pain;
- some disorders of the nervous system (like epilepsy);
- respiratory diseases that interfere with breathing (like asthma);
- a recent operation on the gut or bladder or difficulties passing urine.

If you have any of these medical problems, are taking medications for any of these problems, or are taking aspirin or aspirin-like medicines, please inform your doctor. The treatment may need to be followed more closely and the dose may need to be adapted.

If an operation with general anaesthetic is needed, inform the doctor about the use of REMINYL.

Since people with Alzheimer's disease often lose weight, also while treated with REMINYL, the doctor will regularly check their weight.

<u>Liver and Kidney:</u>

Always tell the doctor about any liver or kidney problem. Depending on the seriousness of the problem, he or she will decide whether treatment with REMINYL is appropriate or the dose needs to be adapted.

Children:

REMINYL is not recommended for children.

Do not take REMINYL:

- if you are hypersensitive (allergic) to galantamine hydrobromide or any of the other ingredients of REMINYL. (See WHAT REMINYL CONTAINS);
- if you have severe liver or kidney disease;
- if you have a rare hereditary problem of galactose intolerance, the Lapp lactase deficiency of glucose-galactose malabsorbtion.

Taking REMINYL with food and drink:

REMINYL should be taken with meals.

Pregnancy and Breastfeeding

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

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

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

Driving and using machinery

REMINYL, as well as the disease itself, can negatively affect the ability to drive or operate machinery. This matter should therefore be discussed with a doctor.

Taking other medicines with REMINYL

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

REMINYL should not be combined with other medicines that act through similar mechanisms in the body. If medicines for diarrhoea, Parkinson's disease or airway spasms are taken, check with the doctor to see if these affect REMINYL.

The doctor must also be informed if medicines for certain heart disorders or high blood pressure (e.g. digoxin or the so called beta-blockers) are used.

If certain medicines are used in the same period as REMINYL, a smaller amount of REMINYL may be needed. Examples are certain antidepressants (such as paroxetine, fluoxetine, amitriptyline or fluvoxamine), quinidine (used for heart rhythm disorders) or the antifungal ketoconazole.

HOW TO TAKE REMINYL

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

REMINYL comes in the form of prolonged release capsules and is to be taken by mouth.

REMINYL Prolonged Release capsules should be taken once a day in the morning, preferably with the morning meal. The capsules should be swallowed whole, together with some liquid. The capsule must not be chewed or crushed.

Be sure to drink plenty of liquids during the treatment with REMINYL to keep hydrated.

REMINYL is started at a low dose and then is slowly increased to the most suitable dose. The doctor will explain what dose to start with and when the dose should be increased.

Prolonged Release Capsules: 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 than you should:

If too much REMINYL has been taken, one or more of the following may occur: severe nausea, vomiting, muscle weakness, abdominal cramps, leakage of urine and faeces, increased saliva**,** eyes watering, sweating, rapid heart rate, serious heart rhythm disorder, slow heartbeat, low blood pressure, breathing difficulties, fainting, seizures or collapse.

In the event of overdosing, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

Information for the doctor in case of overdose

As in any case of overdose, general supportive measures should be used. In severe cases, anticholinergics such as atropine may be used as a general antidote for cholinomimetics. An initial dose of 0,5 to 1,0 mg i.v. is recommended, with subsequent doses based on the clinical response.

Because strategies for the management of overdose are continually evolving, it is advisable to contact a poison control centre to determine the latest recommendations for the management of an overdose.

If you forget to take REMINYL:

If it is noticed that a dose of REMINYL 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.

POSSIBLE SIDE EFFECTS

REMINYL can cause side effects, although not everybody experiences them.

The very common reported side effects (occurring in more than 1 in every 10 people who have taken REMINYL) are nausea and vomiting.

Common side effects (occurring in less than 1 in every 100 people who have taken REMINYL) are:

- 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 pain; upper abdominal pain; indigestion; stomach discomfort; abdominal discomfort, decreased bowel movements, wind.
- Slow heart beat,
- Decreased appetite; weight loss
- 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

Uncommon side effects (occurring in less than 1 in every 100 people who have taken REMINYL) are:

- Change in the sense of taste; excessive sleepiness; tingling, pricking, or numbness of the skin, stiff muscles, seizures, 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 heart beats (palpitations); possible skipped heart beat, rapid or slow heart beat, 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.

Rare side effects (occurring in less than 1 in every 1000 people who have taken REMINYL) are:

- Inflammation of the liver (hepatitis).
- Allergic reaction.

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

STORING AND DISPOSING OF REMINYL

Store at or below 25 °C.

Store all medicines out of the reach of children.

Do not use REMINYL 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).

PRESENTATION OF REMINYL

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.

IDENTIFICATION OF REMINYL

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

- 8 mg galantamine as white opaque capsule with the inscription “G8”, containing white to off-white pellets.
- 16 mg galantamine as pink opaque capsule with the inscription “G16”, containing white to off-white pellets.
- 24 mg galantamine as caramel opaque capsule with the inscription “G24”, containing white to off-white pellets.

REGISTRATION NUMBER/REFERENCE NUMBER

Prolonged Release Capsules:

CR 8 mg - 38/5.3/0311

CR 16 mg – 38/5.3/0312

CR 24 mg - 38/5.3/0313

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

S2

NAME AND ADDRESS OF REGISTRATION HOLDER

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