SCHEDULING STATUS

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

COGNIMET 10, 10 mg memantine hydrochloride (film coated tablets 10 mg)

Read all of this leaflet carefully before you start taking COGNIMET 10 tablets.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- **COGNIMET 10** 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.

Supervision by a caregiver, who needs to read and refer to this leaflet as and when necessary, is recommended when COGNIMET 10 is prescribed.

1. WHAT COGNIMET 10 CONTAINS

The active substance is memantine hydrochloride.

Each film coated tablet contains 10 mg memantine hydrochloride.

The tablet contains lactose monohydrate.

The other ingredients are colloidal silicon dioxide, corn starch, magnesium stearate, povidone and talc.

The film coating contains Opadry™ grey (hypromellose, iron oxide black, macrogol 400 and titaniFum dioxide).

2. WHAT COGNIMET 10 IS USED FOR

COGNIMET 10 is one of a group of medicines known as anti-dementia medicines.

It is used to treat adults with (moderately severe to severe) Alzheimer's disease, a brain disease that causes deterioration of memory, language, thinking and other skills and that worsens

gradually over time.

The efficacy of **COGNIMET 10** beyond treatment for six months, has not been established.

3. BEFORE YOU TAKE COGNIMET 10

Do not take COGNIMET 10 if:

- You are allergic (hypersensitive) to memantine hydrochloride or any of the other ingredients of **COGNIMET 10.** (See **WHAT COGNIMET 10 CONTAINS.)**
- You are younger than 18 years of age.

Take special care with COGNIMET 10.

Before treatment with COGNIMET 10, tell your doctor if any of the following applies to you as your dose may need to be adjusted:

- you have kidney problems and/or suffer from excess acid forming substances in the blood due to kidney problems (renal tubular acidosis – RTA);
- you recently had a urinary tract infection (inflammation);
- you recently drastically changed your diet, for example from eating meat to eating only vegetables, or if you intend to change your diet;
- you have a history of epileptic seizures (fits);
- you recently experienced a heart attack, or if you suffer from heart disease;
- If you are taking medicines containing the substances amantadine (antiviral: medicines used to treat against viruses), ketamine (used for anaesthesia during operations) or dextromethorphan (used to stop coughs).
- Tell your doctor if you are pregnant or if you are breastfeeding your baby. (See **Pregnancy and breastfeeding**).

Taking COGNIMET 10 with food and drink

COGNIMET 10 can be taken with or without food.

Pregnancy and breastfeeding

You should not take **COGNIMET 10** if you are pregnant.

You should not take **COGNIMET 10** if you are breastfeeding your baby.

If you are pregnant or plan to become pregnant or are breastfeeding your baby consult your doctor, pharmacist or other health care professional for advice before taking **COGNIMET 10.**

Driving and using machinery

COGNIMET 10 may make you feel sleepy, dizzy, tired or less alert.

Do not drive or use any tools or machines when taking **COGNIMET 10.**

Important information about some of the ingredients of COGNIMET 10

COGNIMET 10 tablets contain milk sugar (lactose monohydrate). If you are aware that lactose is harmful to you, do not take **COGNIMET 10** tablets. If you are unsure, speak to your doctor.

Taking other medicines with COGNIMET 10

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

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

COGNIMET 10 and other medicines can affect each other causing side-effects.

Tell your doctor if you are taking:

- L-dopa and bromocriptine (usually for Parkinson's disease);
- anticholinergic medicines (usually used to treat movement disorders, stomach cramps, asthma, incontinence (uncontrollable flow of urine), or depression and sleep disorders);
- barbiturates (used for calming or sleep);
- neuroleptics (used to treat mental disorders);
- dantrolene and baclofen (muscle relaxants);

- amantadine (used against viruses);
- ketamine (for anaesthesia during operations);
- dextromethorphan (to stop coughing);
- cimetidine and ranitidine (for stomach ulcers);
- procainamide and quinidine (to correct heart rhythm);
- quinine (for malaria);
- phenytoin (usually to treat epilepsy (fits);
- hydrochlorothiazide ('water pills'), alone or in combination with other substances;
- warfarin (causes thinning of the blood);
- nicotine.

4. HOW TO TAKE COGNIMET 10

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

Always take **COGNIMET 10** exactly as your doctor told you. Check with your doctor or pharmacist if you are not sure.

Do not change the dose or stop taking **COGNIMET 10** without talking with your doctor or pharmacist.

Your doctor will prescribe an appropriate dose for your condition.

If you have the impression that the effect of **COGNIMET 10** is too strong or too weak, tell your doctor or pharmacist.

COGNIMET 10 is for oral use.

You should swallow your tablet whole with a glass of water.

It may take a few weeks before you see the full benefit of **COGNIMET 10.**

To help to remember to take **COGNIMET 10**, it easier to take it at the same time every day.

If you take more COGNIMET 10 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.

Symptoms of overdose include restlessness, seeing strange things that seem real but are not real and are actually created by the mind (psychosis and hallucinations), fits, shaking, confusion, and sleepiness, feeling dazed and confused, and loss of consciousness (black-out).

If you forget to take COGNIMET 10

If you miss a dose, take it as soon as you remember. However, if it is time for your next dose, skip the missed dose and take only a single dose at the usual time. Do not take two doses at the same time. Do not take more than the daily amount of **COGNIMET 10** that has been prescribed for you in one day.

If you stop taking COGNIMET 10

Do not stop taking your tablets without the advice of your doctor, even if you feel better.

5. POSSIBLE SIDE EFFECTS

COGNIMET 10 can have side effects.

Not all side effects reported for COGNIMET 10 are included in this leaflet. Should your general health worsen while taking

COGNIMET 10, please consult your doctor, pharmacist or other health care professional for advice.

If any of the following happens, stop taking **COGNIMET 10** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- 'swelling of the hands, feet, ankles, face, lips, tongue, mouth or throat, which may cause difficulty in swallowing or breathing', throat tightness.
- allergic reactions, including death, can happen in patients taking **COGNIMET 10**, even after only one dose.

- If you feel very depressed or have thoughts of suicide or of harming yourself.
- have a seizure (a fit/convulsion).
- develop shortness of breath, swelling of feet, ankles, legs and/or abdomen, racing heart. These may be some of the symptoms of a serious heart problem.
- develop pain, swelling or redness in, for example, a leg (may be due to a blood clot).
- flu-like symptoms, nausea, diarrhoea, yellow skin, yellow whites of eyes and or tongue (some of the symptoms of hepatitis).
- Hallucinations (hearing voices, seeing things that are not there, being out of touch with reality).
- These are all very serious side effects. If you have them,

  you may have had a serious allergic reaction to

  COGNIMET 10.

  - You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

- inflammatory conditions caused by a fungus (fungal infections).
- vomiting.
- runny tummy (diarrhoea).
- constipation.
- inflammation of the pancreas, usually accompanied by tummy pain.
- injuries.
- hypertonia (increased muscle tone).
- headache.
- dizziness.
- fatigue (tiredness).
- losing balance i.e. nearly falling or falling.
- walking in an abnormal way.
- high blood pressure.

- trouble sleeping.
- agitation.
- restlessness.
- sleeplessness or feeling very sleepy, feeling very excited, disturbed or worried, hearing, seeing or experiencing sensations that appear real but are actually not and are created by the mind.
- feeling anxious.
- confusion.
- weak bladder.
- inflammation of the urinary bladder, usually accompanied by frequent painful urination.
- increase in sex drive.
- increase in coughing, shortness of breath.
- changes in liver function (detected by blood tests).
- inflammation of the liver.

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

6. STORING AND DISPOSING OF COGNIMET 10

Store at or below 25 °C in a dry place.

Keep the tablets in the blisters, and the blisters in the outer carton

until required for use.

If in a HDPE plastic container, keep in original container and keep well-closed.

Keep all medicines out of the reach and sight of children

Do not store in bathrooms.

Do not use after the expiry date stated on the carton/blister.

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

Ask your pharmacist how to dispose of medicines no longer required. These measures will help to

protect the environment.

7. PRESENTATION

HDPE containers: The tablets are packed in white HDPE containers with white child resistant or white ribbed caps, with 30, 60, 90 or 500 tablets per container. Each container is packed in an outer printed cardboard carton.

Blister packs: The tablets are packed in silver coloured PVC-PVdC/Alu or PVC/Alu blister strips, 10 tablets per strip and 3 strips (30 tablets): packed in an outer cardboard carton.

8. IDENTIFICATION

COGNIMET 10 is a grey-coloured, dumbbell-shaped, biconvex, film coated tablet with a break line on both sides.

9. REGISTRATION NUMBER / REFERENCE NUMBER

44/34/0438

10. NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Dr. Reddy's Laboratories (Pty) Ltd.

The Place North Wing

1 Sandton Drive

Sandton

2196

11. DATE OF PUBLICATION OF THIS PATIENT INFORMATION LEAFLET

23 March 2015

Date of revision of the text: To be allocated