**SCHEDULING STATUS:**

**S4**

**REMCEPT XL XL 8 mg** (Prolonged release hard capsules)

**REMCEPT XL XL 16 mg** (Prolonged release hard capsules)

**REMCEPT XL XL 24 mg** (Prolonged release hard capsules)

Sugar free.

**Read this leaflet carefully before you start taking REMCEPT XL:**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- **REMCEPT XL** 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 REMCEPT XL IS AND WHAT IT IS USED FOR**
2. **WHAT YOU NEED TO KNOW BEFORE YOU TAKE REMCEPT XL**
3. **HOW TO TAKE REMCEPT XL**
4. **POSSIBLE SIDE EFFECTS**
5. **HOW TO STORE REMCEPT XL**
6. **CONTENTS OF THE PACK AND OTHER INFORMATION**

## 1. What REMCEPT XL is and what it is used for:

**REMCEPT XL** is used for:

- the treatment of symptoms of dementia related to Alzheimer's disease.

## 2. What you need to know before you take REMCEPT XL:

**Do not take REMCEPT XL:**

- If you are hypersensitive (allergic) to galantamine or to any of the other ingredients of **REMCEPT XL** (see **WHAT REMCEPT XL CONTAINS**).
- If you have serious liver or kidney disease
- If you have problems with urinary flow or recovering from bladder surgery.

**Warnings and precautions:**

**Take special care with REMCEPT XL:**

- **REMCEPT XL** must only be taken under the supervision of your doctor, who will regularly monitor you, after he has diagnosed your condition
- Inform your doctor immediately if you notice a skin rash as **REMCEPT XL** may cause serious skin reactions including a potential life threatening reaction called Stevens Johnson syndrome (purplish rash) or blisters containing pus (see **POSSIBLE SIDE EFFECTS**).
- You may experience weight loss, which will be monitored by your doctor during your treatment.
- If you suffer from any heart condition, had a recent heart attack, or suffer from any disorder that can cause irregular, often rapid heart rate .
- If you suffer from electrolyte disturbances (naturally occurring chemicals in the blood).
- If you are taking any medication such as digoxin or beta-blockers, inform your doctor before taking **REMCEPT XL**, as your heart rate will need to be monitored.
- If you have an ulcer, history of ulcers or are taking anti-inflammatory medicine .
- If you have any obstruction in your stomach or recovering from surgery.

- If you suffer from seizures or Parkinson's disease.
- If you have a history of severe asthma or lung infection.
- If you suffer from urinary flow problems or are recovering from bladder surgery.
-

**Other medicines with REMCEPT XL:**

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

Please tell your doctor if you are taking any of the following medicines:

- Ambenomium (used to improve muscle strength), donepezil (used to treat Alzheimer's), neostigmine, pyridostigmine, rivastigmine (to treat muscle weakness), pilocarpine (to treat glaucoma).
- Heart medication such as digoxin, beta-blockers and amiodarone (see **Take special care with REMCEPT XL**).
- Food slows the absorption of **REMCEPT XL,** but to reduce side effects, it should be taken with food.
- Paroxetine or fluoxetine (to treat depression) ketoconazole (to treat fungal infections), erythromycin (antibiotic) as this may increase the levels of **REMCEPT XL** in your blood and increase side effects such as nausea and vomiting.
- Before surgery, tell your doctor if you are taking **REMCEPT XL**.
-

**Taking REMCEPT XL with food and drink:**

It is recommended that **REMCEPT XL** be taken with food, to reduce any side effects that may occur without food.

**Pregnancy, breastfeeding and fertility:**

If you are pregnant or breastfeeding your baby, please contact your doctor, pharmacist or other healthcare professional for advice before taking **REMCEPT XL.**

You should not take **REMCEPT XL**:

- if you are pregnant, planning to become pregnant or if you suspect you are pregnant;
- if you are breastfeeding your baby

If you become pregnant whilst taking **REMCEPT XL**, please consult your doctor immediately.

**Driving and using machines:**

You may experience dizziness or blurred vision while taking **REMCEPT XL**. Do not drive, operate machinery, or do anything else that could be dangerous until you know how you react on **REMCEPT XL,** especially during the first weeks of your treatment.

## 3. How to take REMCEPT XL:

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

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

**REMCEPT XL** capsules should be taken once daily in the morning, preferably with food.

The recommended starting dose is 8 mg/day.

Your doctor may adjust your dose depending on your condition and your reaction to the medicine.

**Children:**

Use of **REMCEPT XL** in children is not recommended.

**If you take more REMCEPT XL than you should:**

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

In the event of overdose, you may experience nausea, vomiting, stomach cramps, muscle weakness or dizziness.

**If you forget to take REMCEPT XL:**

It is important to take your medicine every day. However, if you forget to take one or more doses, take another as soon as you remember and then go on as prescribed on a normal daily dose.

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

**Effects when treatment with REMCEPT XL is stopped:**

It is important that you continue the course of treatment. Do not stop taking **REMCEPT XL** unless your doctor instructs you to.

## 4. Possible side effects:

**REMCEPT XL** can have side effects.

Not all side effects reported for **REMCEPT XL** are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking **REMCEPT XL**, please consult your healthcare provider for advice.

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

- Swelling of the hands, feet ankles, lips, mouth or throat which may cause difficulty in breathing,

- rash or itching,

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **REMCEPT XL**. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go the casualty department at your nearest hospital if you notice any of the following:

- Very slow heartbeat making you feel dizzy, rapid heartbeat, irregular heartbeat, heart attack (with symptoms such as chest pain, sweating and shortness of breath)
- Abnormally higher heartbeat
- High or low blood pressure, of feeling dizzy when you stand up, swelling of hands and feet, flushing, nose bleed
- Stevens Johnson syndrome (a serious skin disorder, with purple rash) or blisters on the skin containing pus and acute generalised exanthematous pustulosis, characterised by a sudden onset of fever and rash
- Suicidal thoughts and tendencies, depression, seeing or hearing things that aren't there, confusion and anxiety
- Seizures (fits), blurred vision
- Mouth or throat infection
- Liver problems, characterised by increased liver enzymes, upper abdominal pain, nausea, vomiting
- Urinary tract infection, which is characterised by difficulty in urination, blood in the urine, urinating more often than usual, inability to urinate or feeling the need to urinate at night.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Lack of healthy red blood cells, characterised by fatigue, shortness of breath, light-headedness and dizziness
- decreased appetite
- decreased weight
- feeling sleepy
- constipation
- feeling bloated
- stomach pain and discomfort
- diarrhoea
- indigestion
- increased sweating
- headache
- tremor
- dizziness
- fainting or a sudden temporary loss of consciousness
- muscle spasms
- excessive runny nose
- inflammation of tubes in the lungs, causing coughing of thickened mucous and shortness of breath
- feeling very tired, weak or unwell
- chest or back pain
- falls.

Less frequent side effects:

- Low blood platelet count, characterised by more bruises than usual, bleeding gums, black or bloody looking faeces
- dehydration
- high blood sugar
- dry mouth
- hiccups
- increased saliva
- rectal bleeding
- dark faeces
- retching
- difficulty in swallowing
- pins and needles
- involuntary muscle contractions
- loss of movement
- leg cramps
- feeling a sense of spinning or dizziness
- inability to perform actions or formulate certain words
- encountering difficulty with skilled movements
- increased libido
- ringing in the ears
- inflamed liver
- muscle weakness

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, pharmacist or nurse. 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 **REMCEPT XL**.

## 5. How to store REMCEPT XL:

Store at or below 25 °C.

Do not remove capsule from blister until required for use.

Keep the blister in the outer container until required for use.

Keep the HDPE container tightly closed.

Keep the HDPE bottle in the carton container.

Do not take this medicine after the expiry date which is clearly marked on the blister and outside of the box.

Return all unused medicine to your pharmacist.

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

## 6. Contents of the pack and other information:

**What REMCEPT XL contains:**

The active ingredient is:

**REMCEPT XL** prolonged release capsules contain galantamine hydrobromide, equivalent to respectively 8 mg, 16 mg and 24 mg galantamine base.

The other ingredients are:

Ethyl cellulose, erythrocin FD&C Red 3, gelatine, hypromellose, Indigo carmine FD&C Blue 2, magnesium stearate, microcrystalline cellulose, red iron oxide (E172), titanium dioxide, (E172), yellow iron oxide (E172).

**What REMCEPT XL looks like and contents of the pack:**

**REMCEPT XL:**

**REMCEPT XL 8 mg**: Opaque white-white size 2 hard gelatine capsules containing one round biconvex tablet of 8 mg.

**REMCEPT XL 16 mg**: Opaque, flesh-flesh size 2 hard gelatine capsules containing two round biconvex tablets of 8mg.

**REMCEPT XL 24 mg**: Opaque orange-orange size 2 hard gelatine capsules containing three round biconvex tablets of 8mg.

**CONTENTS OF PACK:**

Packs of 28's or 30's prolonged release hard capsules packed in glossy, transparent , PVC/PE/PVDC film and aluminium foil, shiny on the inside and dull (matte) on the outside blisters in a cardboard carton.

White opaque, round HDPE bottles with a white plastic child-resistant tamper-evident screw cap and an aperture for desiccant in packs of 100's prolonged release hard capsules in a cardboard carton.

**HOLDER OF THE CERTIFICATE OF REGISTRATION:**

Teva Pharmaceuticals (Pty) Ltd

Maxwell Office Park

Magwa Crescent West, Waterfall City

Midrand

South Africa.

**This leaflet was last revised in:**

30 April 2021

**REGISTRATION NUMBER:**

**REMCEPT XL 8 mg:** 46/5.3/0998

**REMCEPT XL 16 mg:** 46/5.3/0999

**REMCEPT XL 32 mg:** 46/5.3/1000