REQUIP XL

Patient Information Leaflet

SCHEDULING STATUS:

S4

REQUIP XL 2 mg Prolonged Release tablets

Contains sugar (lactose 46,32 mg\tablet, mannitol 73,16 mg\tablet and maltodextrin 7,50 mg\tablet)

REQUIP XL 4 mg Prolonged Release tablets

Contains sugar (lactose 44,04 mg\tablet, mannitol 73,16 mg\tablet and maltodextrin 7,50 mg\tablet)

REQUIP XL 8 mg Prolonged Release tablets

Contains sugar (lactose 39,48 mg\tablet, mannitol 73,16 mg\tablet and maltodextrin 7,50 mg\tablet)

Ropinirole as the hydrochloride

Read all of this leaflet carefully before you start taking REQUIP XL.

- 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.
- REQUIP 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 REQUIP XL is and what it is used for

2. What you need to know before you take REQUIP XL

3. How to take REQUIP XL

4. Possible side effects

5. How to store REQUIP XL

6. Contents of the pack and other information.

1. What REQUIP XL is and what it is used for:

REQUIP XL is used to treat Parkinson's disease.

REQUIP XL belongs to a group of medicines called dopamine agonists. Dopamine agonists act in a similar way to the natural dopamine, so helping to reduce the symptoms of Parkinson’s disease.

You may receive REQUIP XL on its own, but it may also be given with another medicine used to treat Parkinson's disease (L-dopa) to make that medicine work better.

2. What you need to know before you take REQUIP XL:

Do not take REQUIP XL:

- if you are allergic (hypersensitive) to ropinirole or any REQUIP XL ingredients listed above
- if you have previously taken REQUIP XL and became unwell, tell your doctor before taking these tablets
- if you become unwell while you are taking your tablets, tell a doctor at once
- if you have severe kidney disease.

Warnings and precautions:

Take special care with REQUIP XL:

Tell your doctor before you start taking REQUIP XL

- if you are under 18

- if you have heart disease
- if you have liver disease
- if you have kidney disease
- if you are intolerant to some sugars (e.g. lactose)
- if you have a serious mental health problem such as schizophrenia, hallucinations (seeing or hearing things that aren't really there) or irrational ideas (delusions), or have had one in the past
- if you have experienced any unusual urges and/or behaviours (such as excessive gambling or excessive sexual behaviour or compulsive shopping or binge eating or agression), tell your doctor before you start taking your tablets.

Check with your doctor if you think any of these apply to you. Your doctor will decide whether REQUIP XL is suitable for you.

Don't stop taking REQUIP XL suddenly. Tell your doctor if you experience symptoms such as difficulty in sleeping, depression, apathy, anxiety, lack of energy, sweating or pain after reducing REQUIP XL. If the problems persist more than a few weeks, your doctor may need to adjust your dose.

Unusual urges or behaviours: Tell your doctor if you or your family/caregivers notices that you are behaving in a way that is unusual for you. Examples of this are an unusual urge to gamble or increased sexual urges or behaviours or an uncontrollable urge to shop or eat, episodes of overactivity, elation or irritability while you are taking REQUIP XL. REQUIP XL may also make you more aggressive.

Other medicines and REQUIP XL:

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

Tell your doctor if:

- you have allergies to any other medicines or substances, such as dyes, foods or preservatives (see REQUIP XL contains lactose and sunset yellow (E110) dye below)
- you are taking any prescription or OTC (over-the-counter) medicines or any medicine you have bought from a supermarket or health food shop
- you are taking any of the following medicines:
  - medicines to treat psychiatric conditions
  - medicines for the lowering of blood pressure or for heart problems
  - antibiotics
  - medicines for asthma, bronchitis or emphysema
  - hormone replacement therapy
  - a medicine called metoclopramide usually taken for digestive disorders
- other medicines for Parkinson's disease.

Because REQUIP XL can make you feel sleepy, tell your doctor or pharmacist if you are taking any other medicines that also make you feel sleepy e.g. tranquilisers, sleeping tablets and antidepressants.

REQUIP XL and L-dopa: When treating Parkinson's disease, REQUIP XL can be taken on its own, or with another medicine called L-dopa (also called levodopa). If you are taking L-dopa you may experience some uncontrolled jerky movements when you start taking REQUIP XL. Tell your doctor if this happens, as your dose of L-dopa may need to be reduced.

REQUIP XL with food and drink and alcohol:

You can take REQUIP XL with or without food.

You should not drink alcohol while you are taking REQUIP XL.

Pregnancy, breastfeeding and fertility:

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

Pregnancy: Tell your doctor if you are pregnant or think you may be pregnant. You should not take REQUIP XL when pregnant unless your doctor tells you to.

Breastfeeding: Tell your doctor if you are breastfeeding your baby. You should not take REQUIP XL when breastfeeding.

Driving and using machines:

Falling Asleep During Activities of Daily Living:

Patients treated with REQUIP XL have reported falling asleep while engaged in activities of daily living, including the operation of motor vehicles which sometimes resulted in accidents. Although many of these patients reported somnolence (extreme sleepiness) while on REQUIP XL, some said that they had no warning signs of excessive drowsiness and believed that they were alert immediately prior to falling asleep. Some of these events have been reported as late as one year after starting treatment with REQUIP XL.

Somnolence (extreme sleepiness) is a common occurrence in patients receiving REQUIP XL. Many clinical experts believe that falling asleep while engaged in activities of daily living always occurs in patients with a history of somnolence, although many patients may not give such a history. For this reason, your doctor will continually assess you for any signs of drowsiness or sleepiness, especially since these events may occur some time after starting treatment.

Before starting treatment with REQUIP XL, your doctor will advise you on the possibility that you may develop drowsiness and your doctor will ask you questions about the risk factors that may increase this risk e.g. if you are taking other medicines which make you drowsy, any medication that help you sleep, if you have a sleeping disorder, and if you are taking other medicines that increase the levels of ropinirole (active ingredient of REQUIP XL) in your blood (e.g. antibiotics containing ciprofloxacin).

After starting REQUIP XL, if you start to suffer from extreme sleepiness or suddenly begin falling asleep while doing activities that require your active participation (e.g. conversations, eating), do not drive or use machinery and avoid all dangerous activities. Tell your doctor immediately who will reassess your situation and advise you on what to do next.

REQUIP XL contains lactose and sunset yellow (E110) dye:

Patients who are intolerant to lactose should note that REQUIP XL contains a small amount of lactose. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before you start taking this medicine.

REQUIP XL 4 mg tablets contain a colouring called sunset yellow (E110), this may cause allergic reactions in some people.

3. How to take REQUIP XL:

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

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

Your doctor will decide how many tablets you need to take each day.

When you first start taking REQUIP XL, the amount you take will be increased gradually.

Your doctor may increase or decrease the amount that you are taking to give you the maximum benefit from the medicine.

You will be told to take REQUIP XL once daily and at a similar time each day.

You must swallow the tablet whole with water. The tablets must not be chewed, crushed or broken.

REQUIP XL tablet(s) are designed to release the active ingredient over a 24-hour period. If you have a condition where your medicine passes through your body too quickly, e.g., diarrhoea, the tablet(s) may not dissolve completely and may not work properly. You may see tablet(s) in your stool. If this happens, let your doctor know as soon as possible.

If you are taking other medicines for Parkinson's disease, the doctor may decrease the dose of these medicines whilst you are taking REQUIP XL.

If you are taking L-dopa, you may experience some uncontrollable movements (dyskinesias) when you start taking REQUIP XL. Tell your doctor if this happens, as your doctor may need to adjust the doses of the medicines you are taking.

Tell your doctor if you or your family notices that you are developing any unusual behaviours (such as an unusual urge to gamble or increased sexual urges and/or behaviours or an uncontrollable urge to shop or eat, or agression) while you are taking REQUIP XL. Your doctor may need to adjust or stop your dose.

If you take more REQUIP XL than you should:

Someone who has taken an overdose may experience feeling or being sick, dizziness (or a spinning sensation), feeling drowsy, fatigue (mental or physical tiredness), stomach pain, fainting or nervousness.

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 REQUIP XL:

If you do forget to take a dose, leave out that dose completely. Take your next dose at the normal time.

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

If you have forgotten to take REQUIP XL for more than a few days, consult your doctor for advice on restarting REQUIP XL.

If you stop taking REQUIP XL:

You should continue to take your medicine even if you do not feel better, as it may take a number of weeks for your medicine to start to work. If you have the impression that the effect of your medicine is too strong or too weak, talk to your doctor or pharmacist.

If you wish to stop the treatment, this has to be done gradually. You must not stop taking REQUIP XL without your doctor's advice. If your symptoms worsen after you stop treatment with REQUIP XL, you should contact your doctor.

4. Possible side effects:

REQUIP XL can have side effects.

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

Frequent side effects:

- feeling drowsy
- feeling sick (nausea)
- fainting
- experiencing hallucinations
- dizziness (or spinning sensation)
- swelling of the hands, ankles or feet
- constipation
- **a drop in blood pressure that may make you feel dizzy or faint especially when standing up from a sitting or lying position**
- low blood pressure
- being sick (vomiting)
- dyspepsia (e.g. feeling full up and bloated, experiencing heartburn)
- stomach pain.

Less frequent side effects:

- other psychotic reactions in addition to hallucinations, such as severe confusion (delirium), irrational ideas (delusions) and irrational suspiciousness (paranoia)
- increased sexual desire
- **some patients taking REQUIP XL have shown urges to behave in a way unusual for them. Examples of this are an unusual urge to gamble, increased sexual urges and/or behaviours, or an uncontrollable urge to shop or eat, or acting aggressively. Tell your doctor as soon as possible if you notice any of these changes in your behaviour. Your doctor may need to adjust or stop your dose.**

Other side effects include:

- fall asleep suddenly without apparently feeling sleepy. If you feel extremely tired during the day or fall asleep suddenly without apparently feeling sleepy you should see your doctor
- allergic reactions such as red, itchy swellings on the skin (hives), swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing, rash or intense itching
- difficulty in sleeping, depression, apathy, anxiety, lack of energy, sweating or pain may occur (called dopamine agonist withdrawal syndrome or DAWS) after stopping or reducing your REQUIP XL treatment
- episodes of overactivity, elation or irritability.

When REQUIP XL is taken with levodopa/L-dopa you may also experience the following side effects: uncontrollable movements (dyskinesias) are a frequent side effect. If you are taking L-dopa you may experience some uncontrollable movements (dyskinesias) when you start taking REQUIP XL. Tell your doctor if this happens, as your doctor may need to adjust the doses of the medicines you are taking.

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 or pharmacist. 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 REQUIP XL.

5. How to store REQUIP XL:

Store at or below 25 °C. Store in original package.

The expiry date of this medicine is printed on the label. Do not use the medicine after this date.

Store all medicines out of reach of children. 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 REQUIP XL contains:

The active substance is ropinirole.

REQUIP XL 2 mg: Each tablet contains 2,0 mg ropinirole as the hydrochloride.

REQUIP XL 2 mg contains sugar (lactose 46,32 mg\tablet, mannitol 73,16 mg\tablet and maltodextrin 7,50 mg\tablet).

REQUIP XL 4 mg: Each tablet contains 4,0 mg ropinirole as the hydrochloride.

REQUIP XL 4 mg contains sugar (lactose 44,04 mg\tablet, mannitol 73,16 mg\tablet and maltodextrin 7,50 mg\tablet)

REQUIP XL 4 mg tablets contain the azo colouring called sunset yellow (see 'REQUIP XL contains lactose and sunset yellow (E110) dye')**.**

REQUIP XL 8 mg: Each tablet contains 8,0 mg ropinirole as the hydrochloride.

REQUIP XL 8 mg contains sugar (lactose 39,48 mg\tablet, mannitol 73,16 mg\tablet and maltodextrin 7,50 mg\tablet)

The other ingredients are:

Tablet core: Hypromellose 2208, hydrogenated castor oil, carboxymethylcellulose sodium, povidone, maltodextrin, magnesium stearate, lactose monohydrate, colloidal silicon dioxide, mannitol (E421), ferric oxide yellow (E172), glyceryl behenate.

REQUIP XL tablets contain lactose (see 'INSTRUCTIONS BEFORE TAKING REQUIP XL: Important information about some of the inactive ingredients').

Film coat: The tablet strengths of REQUIP XL are distinguished by colour therefore, the composition of the film coat varies. All film coats contain hydroxypropyl methylcellulose, titanium dioxide and polyethylene glycol, other variations are shown below:

2 mg: ferric oxide yellow (E172) and ferric oxide red (E172).

4 mg: sunset yellow (E110) and indigo carmine (E132).

8 mg: ferric oxide yellow (E172), ferric oxide black (E172), and ferric oxide red (E172).

What REQUIP XL looks like and contents of the pack:

REQUIP XL 2 mg: Pink, film-coated, biconvex capsule-shaped tablet, debossed with 'GS' on one face and '3V2' on the other face.

REQUIP XL 4 mg: Light brown (tan), film-coated, biconvex capsule-shaped tablet, debossed with 'GS' on one face and 'WXG' on the other face.

REQUIP XL 8 mg: Red, film-coated, biconvex capsule-shaped tablet, debossed with 'GS' on one face and '5CC' on the other face.

REQUIP XL 2 mg: Cartons containing 28 or 84 tablets packed in opaque PVC/PCTFE/PVC blisters.

REQUIP XL 4 mg: Cartons containing 28 or 84 tablets packed in opaque PVC/PCTFE/PVC blisters.

REQUIP XL 8 mg: Cartons containing 28 or 84 tablets packed in opaque PVC/PCTFE/PVC blisters.

Holder of certificate of registration:

GlaxoSmithKline South Africa (Pty) Ltd

39 Hawkins Avenue

Epping Industria 1, 7460

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