PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S5

PROLERT® 100, tablets

PROLERT® 200, tablets

Modafinil

Contains sugar (lactose)

Each 100 mg tablet contains 104 mg lactose.

Each 200 mg tablet contains 208 mg lactose.

Read all of this leaflet carefully before you start taking PROLERT

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, nurse or other healthcare provider.
- PROLERT 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 PROLERT is and what it is used for
2. What you need to know before you take PROLERT
3. How to take PROLERT
4. Possible side effects
5. How to store PROLERT
6. Contents of the pack and other information

1. What PROLERT is and what it is used for

Modafinil is a medicine that promotes wakefulness.

PROLERT is used to treat excessive daytime sleepiness that may for example be caused by narcolepsy (a chronic sleep disorder, characterised by overwhelming daytime drowsiness and sudden attacks of sleep).

2. What you need to know before you take PROLERT

Do not take PROLERT:

- if you are hypersensitive (allergic) to modafinil or any of the other ingredients of PROLERT (listed in section 6)
- if you have an irregular heartbeat
- if you have uncontrolled, moderate to severe high blood pressure (hypertension)
- if you have been diagnosed with major anxiety and are not in hospital
- if you have problems with your kidneys (kidney failure).

PROLERT is not intended for children under 16 years of age.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist or healthcare provider.

Warnings and precautions

Your medical practitioner may refer you for initial specialist assessment and regular monitoring during your treatment.

Take special care with PROLERT if you:

- have any heart problems or high blood pressure. Your doctor will need to check these regularly while you are taking PROLERT

- have ever had depression, low mood, anxiety, psychosis (loss of contact with reality) or mania (over-excitement or feeling of extreme happiness) or bipolar disorder because PROLERT may make your condition worse
- have previously developed a serious skin reaction to a medicine or any other substance. Serious skin rashes have been reported with PROLERT. If you develop a rash, hives, or allergic reaction (see section 4), stop taking PROLERT and tell your doctor immediately
- have kidney or liver problems (because you may need to take a lower dose)
- are elderly and have weaker kidney and/or liver function (because you may need to take a lower dose)
- have had alcohol or drug problems in the past
- take or use hormonal contraceptives. PROLERT can make certain types of birth control pills less effective, which could result in an unplanned pregnancy. Talk with your doctor about the best methods of birth control to use while taking PROLERT.
- suffer from lactose intolerance (see below).

Other things to talk to your doctor or pharmacist about

- Some people have reported having suicidal or aggressive thoughts or behaviour while taking PROLERT.

  Tell your doctor straight away if you notice that you are becoming depressed, feel aggressive or hostile towards other people or have suicidal thoughts or other changes in your behaviour (see section 4). You may want to consider asking a family member or close friend to help you look out for signs of depression or other changes in your behaviour.

- PROLERT has the potential for you to become reliant (dependent) on it after long-term use. If you need to take it for a long time your doctor will check regularly that it is still the best medicine for you.
- Some people may suffer from sleeplessness while taking PROLERT. If this happens, tell your doctor. PROLERT is not a replacement for sleep. Good sleep hygiene should be maintained; ask your healthcare provider for advice.

Children and adolescents

Children aged less than 16 years should not take PROLERT. See “Do not take PROLERT” above.

Other medicines and PROLERT

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

It is especially important to tell your doctor if you are taking any of the following medicines with PROLERT:

- Medicines for epilepsy (e.g. carbamazepine, phenobarbital or phenytoin).
- Hormonal contraceptives (including the contraceptive pill, implants, intrauterine devices (IUDs) and patches). You will need to consider other birth control methods while taking PROLERT, and for two months after stopping treatment, because PROLERT reduces their effectiveness.
- Medicines for thinning the blood (e.g. warfarin). Your doctor will monitor your blood clotting times during treatment.
- Medicines for depression (e.g. clomipramine, desipramine, amitriptyline, citalopram or fluoxetine) or anxiety (e.g. diazepam, buspirone).
- Omeprazole (for acid reflux, indigestion or ulcers).
- Medicines for sleeping (triazolam, midazolam).

- Calcium channel blockers or beta-blockers for high blood pressure or heart problems (e.g. amlodipine, propranolol).
- Antiviral medicines to treat HIV infection (protease inhibitors e.g. indinavir or ritonavir).
- Ciclosporin (used to prevent organ transplant rejection, or for arthritis or psoriasis).
- Statin medicines for lowering cholesterol (e.g. atorvastatin or simvastatin).
- Rifampicin (used to treat tuberculosis).
- Antifungal medicines used to treat infections caused by fungus (e.g. ketoconazole, itraconazole).
- Theophylline (used to treat lung diseases).

PROLERT with food, drink and alcohol

You may take PROLERT without concern about mealtimes.

Absorption may be delayed by approximately one hour if taken with food.

Take PROLERT with water or other soft drink (see section 3).

The use of PROLERT in combination with alcohol has not been studied. You should therefore avoid alcohol while taking PROLERT tablets.

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 healthcare provider for advice.

You should not take PROLERT if you are pregnant. PROLERT is suspected to cause birth defects if taken during pregnancy.

PROLERT may reduce the efficacy of some contraceptive preparations; tell your doctor which contraceptive you are taking or using.

Talk to your doctor about the birth control methods that will be right for you while you are taking PROLERT (and for two months after stopping), or if you have any other concerns.

PROLERT should not be used during breastfeeding.

Driving and using machines

It is not always possible to predict to what extent PROLERT may interfere with the daily activities of a patient.

PROLERT may cause you to become dizzy or to have blurred vision; if this happens you should not drive or handle dangerous tools.

PROLERT contains lactose

PROLERT contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking PROLERT.

3. How to take PROLERT

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

Always take PROLERT exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Adults

The usual dose is 200 mg a day. This is taken once daily, in the morning.

Your doctor may, in some cases, decide to increase your daily dose up to 400 mg.

Elderly patients (over 65 years of age)

The recommended dose is 100 mg a day; your doctor will only increase your dose if you do not have any liver or kidney problems.

Adults with kidney and liver problems

The recommended dose is 100 mg a day.

Your doctor will review your treatment regularly to check that it is right for you.

The tablets should be swallowed whole with water.

Your doctor will tell you how long your treatment with PROLERT will last. If you have the impression that the effect of PROLERT is too strong or too weak, tell your doctor or pharmacist.

If you take more PROLERT than you should

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

Take this leaflet and any remaining tablets with you.

If you take too many tablets you may feel sick, restless, disorientated, confused, agitated, anxious or excited. You may also have difficulty sleeping, diarrhoea, hallucinations (sensing things that are not real), chest pain, a change in the speed of your heartbeat or an increase in blood pressure.

If you forget to take PROLERT

If you forget to take your medicine, take the next dose at the usual time.

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

If you stop taking PROLERT

Talk to your doctor before you stop taking PROLERT**,** as your symptoms may recur.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

PROLERT can have side effects.

Not all side effects reported for PROLERT are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking PROLERT, please consult your healthcare provider for advice.

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

- You have sudden difficulty breathing or wheeziness or your face, mouth or throat begins to swell.
- You notice a skin rash or itching (especially if it affects your whole body). Severe rashes may cause blistering or peeling of the skin, ulcers in your mouth, eyes, nose or genitals. You may also have a high temperature (fever) and abnormal blood test results.
- You feel any change in your mental health and wellbeing. The signs may include:
    - depression, suicidal thoughts or behaviour,
    - agitation or psychosis (a loss of contact with reality which may include delusions or sensing things that are not real), feeling detached or numb,
    - personality disorder, aggression or hostility mood swings or abnormal thinking.

These are all very serious side effects. If you have them, you may have a serious, potentially life-threatening reaction to PROLERT. You may need urgent medical attention or hospitalisation.

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

- Chest pain
- Angina
- Changes in the way your heart beats, for example, if you notice it beating faster
- Difficulty breathing
- Fever
- Less urine than is normal for you
- Yellowing of the skin and eyes, dark urine and tiredness which may be symptoms of liver problems.

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

- loss of appetite
- sleepiness, extreme tiredness or difficulty sleeping (insomnia)
- headache
- dizziness
- nervousness, anxiety, abnormal thinking, confusion, irritability
- weakness, numbness or tingling of the hands or feet (‘pins and needles’)
- loss of balance, speech or muscle tone
- blurred vision or lazy eye
- awareness of your heartbeat, which may be faster than normal
- flushing

- fainting
- problems with your lungs
- stomach pain, feeling sick (nausea), dry mouth, heartburn, diarrhoea or constipation
- gum disease
- dry or infected skin
- joint problems
- chest pain
- abnormal blood test results showing how your liver is working (increased liver enzymes)
- abnormal ejaculation.

Less frequent side effects:

- sore throat (pharyngitis) or inflamed nasal passages (sinusitis)
- abnormal blood test results showing that the numbers of your white blood cells have changed
- hay fever (itchy/runny nose and watery eyes)
- diabetes with increased blood sugar (shown in blood test)
- high blood cholesterol (shown in blood test)
- increased appetite
- disrupted sleep or abnormal dreams
- loss of sex drive
- over-excitement or hyperactivity, feeling of extreme happiness (mania)
- memory problems (amnesia)
- restlessness with increased body movement
- vertigo (spinning sensation)

- migraine
- coordination problems (difficulty moving muscles smoothly or other movement problems)
- speech and taste problems
- abnormal vision or dry eyes
- changes in blood pressure (high or low), abnormal heart trace (ECG), and irregular or unusually slow heartbeat
- increased cough, asthma or shortness of breath
- nosebleed
- difficulty swallowing (dysphagia), swollen tongue (glossitis), mouth ulcers
- excess wind, reflux (bringing back fluid from the stomach), increased appetite, weight changes
- being sick (vomiting)
- sweating
- skin rash, acne or itchy skin
- back pain, neck pain, muscle pain, muscle weakness, leg cramps, joint pain, twitching
- abnormal urine or more frequent urination
- abnormal menstrual periods
- swollen hands and feet
- thirst
- increased or decreased weight.

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 Reactions 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 PROLERT.

5. How to store PROLERT

Store all medicines out of reach of children.

Store at or below 25 °C, in the original packaging.

Keep blisters in the carton until required for use.

Do not store in a bathroom.

Do not take this medicine after the expiry date which is stated on the blister and the carton after 'EXP'. The expiry date refers to the last day of that month. This medicine does not require any special storage conditions.

Return all unused medicine to your pharmacist.

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

These measures will help protect the environment.

6. Contents of the pack and other information

What PROLERT contains

The active substance is modafinil.

Each PROLERT 100 tablet contains 100 mg of modafinil.

Each PROLERT 200 tablet contains 200 mg of modafinil.

The other ingredients are lactose monohydrate, crospovidone, povidone K30, lactose anhydrous, talc, colloidal anhydrous silica, sodium stearyl fumarate.

What PROLERT looks like and contents of the pack

PROLERT 100: The product is presented as a white to off-white capsule shaped tablet embossed with '100', containing 100 mg of modafinil.

PROLERT 200: The product is presented as a white to off-white capsule shaped tablet embossed with '200', containing 200 mg of modafinil.

PROLERT 100 & 200 tablets are packed in blisters of PVC/PE/PCTFE 191/70/51 white opaque laminate with aluminium lidding foil blisters or in PVC/PVDC 250/60 white opaque laminate with aluminium lidding foil blisters. Batch number and Expiry date are overprinted/embossed on the blister.

The blister strips are packed in cartons. Each carton contains 10, 20, 30, 60, 90 or 100 tablets.

Not all strengths or pack sizes may be marketed at one time.

Holder of Registration Certificates

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Access to the corresponding Professional Information

Please refer to the SAHPRA Repository of Professional Information and Patient Information Leaflets: https://www.sahpra.org.za/pi-pil-repository/.