

REWISCA HARD CAPSULES

Pregabalin (50 mg, 75 mg, 150 mg)

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What *Rewisca* is used for

Rewisca belongs to a group of medicines used to treat epilepsy, neuropathic pain and Generalised Anxiety Disorder (GAD) in adults.

Peripheral and central neuropathic pain:

Rewisca is used to treat long lasting pain caused by damage to the nerves. A variety of diseases can cause peripheral neuropathic pain, such as diabetes or shingles. Pain sensations may be described as hot, burning, throbbing, shooting, stabbing, sharp, cramping, aching, tingling, numbness, pins and needles. Peripheral and central neuropathic pain may also be associated with mood changes, sleep disturbance, fatigue (tiredness), and can have an impact on physical and social functioning and overall quality of life.

Epilepsy: *Rewisca* is used to treat a certain form of epilepsy (partial seizures with or without secondary generalisation) in adults. Your doctor will prescribe *Rewisca* for you to help treat your epilepsy when your current treatment is not controlling your condition. You should take *Rewisca* in addition to your current treatment. *Rewisca* is not intended to be used alone, but should always be used in combination with other anti-epileptic treatment.

Generalised Anxiety Disorder:

Rewisca is used to treat Generalised Anxiety Disorder (GAD). The symptoms of GAD are prolonged excessive anxiety and worry that are difficult to control. GAD can also cause restlessness or feeling keyed up or on edge, being easily fatigued (tired), having difficulty concentrating or mind going blank, feeling irritable, and having muscle tension or sleep

disturbance. This is different to the stresses and strains of everyday life.

Fibromyalgia: *Rewisca* is used to treat fibromyalgia. Fibromyalgia is a disorder characterized by widespread musculoskeletal pain accompanied by fatigue, sleep, memory and mood issues.

How *Rewisca* works

Pregabalin, the active substance in *Rewisca*, belongs to antiepileptic drugs. It works by slowing impulses across the brain that are involved in development of epilepsy, neuropathic pain and generalized anxiety disorder.

Before you use *Rewisca*

- *When you must not use it*

Do not take *Rewisca* if you are allergic to pregabalin or any of the other ingredients of this medicine.

Pregnancy and lactation

Do not take *Rewisca* if you are pregnant, trying to get pregnant or think you may be pregnant. If you get pregnant while taking *Rewisca*, stop taking it immediately and contact your doctor.

Do not take *Rewisca* if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- *Before you start use it*

Talk to your doctor or pharmacist before taking *Rewisca*.

- Some patients taking pregabalin have reported symptoms suggesting an allergic reaction. These symptoms include swelling of the face, lips, tongue, and throat, as well as diffuse skin rash. Should you experience any of these reactions, you should contact your physician immediately.
- Pregabalin has been associated with dizziness and somnolence, which could increase the occurrence of accidental injury (fall) in older patients. Therefore, you should be careful until you are used to any effects the medicine might have.
- Pregabalin may cause blurring or loss of vision, or other changes in eyesight, many of which are temporary. You should immediately

tell your doctor if you experience any changes in your vision.

- Pregabalin may cause weight gain and peripheral edema. Some patients with diabetes who gain weight while taking *Rewisca* may need an alteration in their diabetic medicines.
- Certain side effects may be more common, such as sleepiness, because patients with spinal cord injury may be taking other medicines to treat, for example, pain or spasticity, that have similar side effects to *Rewisca* and the severity of these effects may be increased when taken together.
- Before taking this medicine you should tell your doctor if you have a history of heart disease.
- If while taking *Rewisca* you notice decreased urination, you should tell your doctor as stopping the medicine may improve this.
- If, while taking *Rewisca*, you experience unexplained muscle pain, tenderness or weakness particularly if these muscle symptoms are accompanied by malaise or fever, you should immediately tell your doctor.
- A small number of people being treated with anti-epileptics such as pregabalin have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.
- When *Rewisca* is taken with other medicines that may cause constipation (such as some types of pain medicines) it is possible that gastrointestinal problems may occur (e.g., constipation, blocked or paralysed bowel). Tell your doctor if you experience constipation, especially if you are prone to this problem.
- Before taking this medicine you should tell your doctor if you have a history of alcoholism or any drug abuse or dependence. Do not take more medicine than prescribed.
- There have been reports of convulsions when taking pregabalin or shortly after stopping *Rewisca*. If you experience a convulsion, contact your doctor immediately.
- There have been reports of reduction in brain function (encephalopathy) in some patients taking pregabalin when they have

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other conditions. Tell your doctor if you have a history of any serious medical conditions, including liver or kidney disease.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy from a pharmacy, supermarket or health food shop without a prescription.

Rewisca and certain other medicines may influence each other (interaction). When taken with certain other medicines, *Rewisca* may potentiate the side effects seen with these medicines, including respiratory failure and coma. The degree of dizziness, sleepiness and decreased concentration may be increased if *Rewisca* is taken together with medicinal products containing:

- Oxycodone (used as a pain-killer)
- Lorazepam (used for treating anxiety)
- Alcohol

Rewisca may be taken with oral contraceptives.

How to use *Rewisca*

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Your doctor will determine what dose is appropriate for you. Take the number of capsules as instructed by your doctor. The dose, which has been adjusted for you and your condition, will generally be between 150 mg and 600 mg each day.

If you are an older patient (over 65 years of age), you should take *Rewisca* normally except if you have problems with your kidneys. Your doctor may prescribe a different dosing schedule and/or dose if you have problems with your kidneys.

- When to use it

Your doctor will tell you to take *Rewisca* either twice or three times a day. For twice a day take *Rewisca* once in the morning and once in the evening, at about the same time each day. For three times a day take *Rewisca* once in

the morning, once in the afternoon and once in the evening, at about the same time each day.

- How long to use it

Continue taking *Rewisca* for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

You may feel sleepy, confused, agitated, or restless as a result of taking more *Rewisca* than you should.

While you are using it

- Things you must do

Rewisca is for oral use only. The capsules may be taken with or without food. Swallow the capsule whole with water. Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists that are treating you that you are taking *Rewisca*.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor. If your treatment is stopped it should be done gradually over a minimum of 1 week.

After stopping long and short-term *Rewisca* treatment, you need to know that you may experience certain side effects. These include trouble sleeping, headache, nausea, feeling anxious,

diarrhea, flu-like symptoms, convulsions, nervousness, depression, pain, sweating, and dizziness. These symptoms may occur more commonly or severely if you have been taking *Rewisca* for a longer period of time.

Do not take any new medicines without consulting your doctor. Do not drink alcohol while taking *Rewisca*.

Do not give *Rewisca* to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

Rewisca may cause dizziness, sleepiness and decreased concentration. You should not drive, operate complex machinery or engage in other potentially hazardous activities until you know whether this medicine affects your ability to perform these activities.

Side effects

Like all medicines, *Rewisca* can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

If you experience swollen face or tongue or if your skin turns red and starts to blister or peel you should seek immediate medical advice.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Very common: Dizziness, drowsiness.

Common: Inflammation of the nose and throat, weight loss increased appetite, feeling of elation, confusion, irritability, depression, disorientation, insomnia, decrease in sexual interest, abnormal style of walking, difficulties with coordination, tremor, difficulty in finding words, loss of memory, memory impairment, disturbance in attention, tingling feeling, decrease of sensitivity of senses, sedation, problem with balance, lethargy, blurred vision, double vision, vertigo, vomiting, constipation, flatulence, swollen abdomen, dry mouth, muscle cramp, joint pain, back pain, pain in limb,

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cervical spasm, swelling of the body including extremities, abnormal gait, fall, feeling drunk, feeling abnormal, fatigue, weight gain,.

Uncommon: Decrease in blood neutrophil count, anorexia, low blood sugar, hallucinations, restlessness, agitation, depressed mood, elevated mood, mood swings, change in perception of self, abnormal dreams, difficulty finding words, increase in sexual interest, problems with sexual functioning including inability to achieve a sexual climax, fainting, muscle twitching, increased activity, jerky movements, dizziness on standing, tremor on movement, unusual eye movement, difficulty with thinking, difficulty with speaking, reduced reflexes, increase of sensitivity of senses, burning sensation, changes in vision including tunnel vision, changes in eyesight, eye swelling, visual field defect, reduced visual acuity, eye pain, weak eyes, flashes of light, dry eyes, watery eyes, eye irritation, increased sensitivity to noise, heart rhythm disturbances, increased heart rate, low blood pressure, high blood pressure, hot flushes, flushing, coldness of hands and feet, difficulty breathing, nose bleed, cough, runny nose, inflammation of the nose, snoring, heartburn, increased saliva production, numb around mouth, rash, hives, sweating, joint swelling, pain including muscle pain, neck pain, muscle stiffness, difficulty with urination, incontinence, difficulties with erection, sexual dysfunction, delayed ejaculation, interrupted menstrual periods, swelling of the body, chest tightness, pain, fever, thirst, chills, weakness, changes in blood and liver test results (blood creatinine phosphokinase increased, alanine amino transferase increased, aspartate aminotransferase increased, high blood glucose, platelet count decreased, blood potassium decreased), weight loss.

Rare: Panic attack, disinhibition, slow or reduced movement of body, loss of taste, difficulty with writing properly, swinging vision, altered perception of depth, dilated pupils, cross eyes, visual brightness, changes in the recording of electrical changes (ECG) in the heart which correspond to heart rhythm disturbances, dry nose, tightness of the throat, increased fluid in the abdomen,

inflammation of the pancreas, difficulty in swallowing, cold sweat, muscle damage, kidney failure, reduced urine volume, breast pain, loss of menstruation, breast discharge, abnormal breast growth, decreased in white blood cell count, increase in blood creatinine.

The following side effects were also reported: swelling of mouth and throat, allergic reaction, hypersensitivity, headache, loss of consciousness, mental impairment, inflammation of the eye, heart failure, increase fluid in the lungs, swollen tongue, diarrhea, nausea, swelling of the face, itching, urinary retention, breast growth in males, feeling unwell.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835549, or visiting the website npra.moh.gov.my [Public → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of *Rewisca*

- Storage

Keep this medicine out of the sight and reach of children.

Do not store above 30 °C.

Do not use your medicine after the expiry date which is stated on the pack after 'EXP'. The expiry date refers to the last day of that month.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

50 mg hard capsules:

The body of the capsule is white colour, the cap of the capsule is bright yellow colour. Capsule cap is imprinted with black mark P50. The content of the capsule is white to off white powder. Capsule size No. 3.

75 mg hard capsules:

The body of the capsule is brownish yellow colour, the cap of the capsule is brownish yellow colour. Capsule cap is imprinted with black mark P75. The content of the capsule is white to off white powder. Capsule size No. 4.

150 mg hard capsules:

The body of the capsule is white colour, the cap of the capsule is yellowish brown colour. Capsule cap is imprinted with black mark P150. The content of the capsule is white to off white powder. Capsule size No. 2.

Blisters packs: 60 hard capsules in a folding box. Each blister contents 10 capsules.

- Ingredients

Active ingredient:

The active substance is pregabalin. Each hard capsule contains 50 mg, 75 mg or 150 mg pregabalin.

Inactive ingredients:

The other ingredients are pregelatinised starch, talc (E553b) in capsule contents.

The other ingredients of 50 mg and 75 mg hard capsules are titanium dioxide (E171), gelatin, yellow iron oxide (E172), black printing ink (shellac, black iron oxide (E172), propylene glycol) in capsule shell.

The other ingredients of 150 mg hard capsules are titanium dioxide (E171), gelatin, red iron oxide (E172), yellow iron oxide (E172), black printing ink (shellac, black iron oxide (E172), propylene glycol) in capsule shell.

- MAL numbers:

Rewisca 50 mg hard capsules:
MAL*****

Rewisca 75 mg hard capsules:
MAL*****

Rewisca 150 mg hard capsules:
MAL*****

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Manufacturer

KRKA, d.d., Novo mesto,
Šmarješka cesta 6,
8501 Novo mesto,
Slovenia

Product Registration Holder

Pahang Pharmacy Sdn. Bhd.
Lot 5979, Jalan Teratai,
5 ½ Mile Off Jalan Meru,
41050, Klang, Selangor,
MALAYSIA

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11/06/2018

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TBD