Myalica 25 mg, Myalica 75 mg, Myalica 150 mg
Pharma Dynamics (Pty) Ltd
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PATIENT INFORMATION LEAFLET (APPROVED)

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SCHEDULING STATUS:

S5

MYALICA 25 mg capsules

MYALICA 75 mg capsules

MYALICA 150 mg capsules

Pregabalin

MYALICA is sugar free.

Read all of this leaflet carefully before you start taking MYALICA

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist, nurse or other healthcare provider.
- MYALICA 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

PATIENT INFORMATION LEAFLET (APPROVED)

1. What MYALICA is and what it is used for

MYALICA is used to treat peripheral neuropathic pain (long-lasting pain caused by damage to the nerves), due to diabetes or shingles in adults.

2. What you need to know before you take MYALICA

Do not take MYALICA:

- if you are hypersensitive (allergic) to pregabalin or any of the other ingredients of MYALICA (see section 6).

Warnings and precautions

Take special care with MYALICA:

- if you have diabetes and gain weight while you are taking MYALICA, your doctor may need to make a change in your diabetic medicines
- if you experience an allergic reaction while you are taking MYALICA, you must contact your doctor immediately. The symptoms of an allergic reaction include swelling of the face, lips, tongue, and throat, as well as a skin rash

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- serious skin rashes including Stevens-Johnson syndrome and toxic epidermal necrolysis have been reported in association with MYALICA. Stop taking MYALICA and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions (reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes). These serious skin rashes can be preceded by fever and flu-like symptoms
- if you take MYALICA you may experience dizziness, sleepiness, loss of consciousness, confusion, and mental impairment. This could increase the possibility of an accidental injury (fall) if you are an elderly patient. Therefore, you should be careful until you are used to any effect caused by MYALICA
- if you take MYALICA you may experience 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
- if you notice a decrease in passing urine while taking MYALICA, you should tell your doctor. It may improve if you stop taking MYALICA
- if you are taking MYALICA, or shortly after stopping it, you may experience convulsions (including epilepsy). If this happens, contact your doctor immediately. You may also experience withdrawal symptoms after short-term or long-term treatment with MYALICA, which include difficulty in sleeping, headache, nausea, anxiety, diarrhoea, flu syndrome, nervousness, depression, pain, hyperhidrosis and dizziness

- if you have a history of a heart disease you should tell your doctor. Heart failure has been reported in some patients when they were taking MYALICA
- if you are taking medicines for spinal cord injury, you may experience an increase in certain side effects such as sleepiness, when you are also taking MYALICA
- some people have had thoughts to harm or kill themselves while taking medicines belonging to the same group as MYALICA for the treatment of different conditions. If you have thoughts of harming or killing yourself, at any time when you are taking MYALICA, immediately contact your doctor
- when MYALICA 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
- if you experience side effects such as depression or breathing difficulties (shortness of breath) whilst taking MYALICA, inform your doctor immediately, especially if you suffer from respiratory disease (such as chronic obstructive pulmonary disease, a lung disease affecting airflow and breathing), neurological disease, kidney disease or are taking pain medicines (opioids), benzodiazepines (to relieve anxiety and insomnia), antidepressants, antipsychotics (to treat schizophrenia, bipolar disorder and depression), antihistamines or you are older than 65
- if you have a history of alcoholism or substance abuse or dependence, you should tell your doctor. If you think you need more MYALICA than prescribed, tell your doctor

- if you have a history of any serious medical conditions, you should tell your doctor. There have been reports of reduction in brain function (encephalopathy) in some patients when they were taking MYALICA.
- if you are in the first trimester of pregnancy (see Pregnancy and breastfeeding below)

If you are not sure whether any of the above applies to you, ask your pharmacist or your doctor.

Other medicines and MYALICA

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

MYALICA and certain other medicines may influence each other (interaction). When taken with certain other medicines, MYALICA 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 MYALICA is taken together with medicines containing:

- oxycodone (for treatment of pain)
- lorazepam (for treatment of anxiety)
- alcohol.

MYALICA may be taken with oral contraceptives.

MYALICA with food, drink and alcohol

MYALICA may be taken with or without food.

It is advised not to drink alcohol while you are taking MYALICA.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using MYALICA.

MYALICA should not be taken during pregnancy or when breastfeeding. Effective contraception must be used by women of child-bearing potential.

MYALICA use during the first 3 months of pregnancy may cause birth defects in the unborn child that require medical treatment. Abnormalities of the face (clefts), the eyes, the nervous system (including the brain), kidneys and genitals have been reported.

Driving and using machines

MYALICA may cause dizziness, sleepiness and decreased concentration. Head and body injuries and road traffic incidents have also been reported with MYALICA. You should not drive, operate machinery or engage in other potentially hazardous activities until you know whether MYALICA affects your ability to perform these activities.

It is not always possible to predict to what extent MYALICA may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which MYALICA affects them.

3. How to take MYALICA

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

Always take MYALICA exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Your doctor will determine what dose is appropriate for you.

Adults:

The usual dose is: 75 mg twice daily, (150 mg/day), with or without food. Based on individual patient response and tolerability, the dose may be increased to 150 mg twice daily after an interval of 3 - 7 days.

MYALICA is a long-term treatment and you may need to take it for some time. Your doctor will tell you how long your treatment with MYALICA will last.

MYALICA is for oral use only. MYALICA is taken orally with or without food. Swallow the capsule whole with water.

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

Children and adolescents

The safety and efficacy in children and adolescents (under 18 years of age) has not been established and therefore MYALICA should not be given to patients in this age group.

Kidney disorders

Your doctor may prescribe a different dosing schedule and/or dose.

Elderly patients

If you are an elderly patient (over 65 years of age), you should take MYALICA normally except if you have problems with your kidneys. Discuss with your doctor.

If you take more MYALICA 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.

Symptoms of overdose may include:

- feeling sleepy, confused, agitated, or restless
- fits have also been reported.

If you forget to take MYALICA

It is important to take your MYALICA capsules regularly at the same time each day. If you forget to take a dose, take it as soon as you remember, unless it is time for your next dose. In that case, just carry on with the next dose as normal. Do not take a double dose to make up for forgotten individual doses.

If you stop taking MYALICA

Do not stop taking MYALICA unless your doctor tells you to. If your treatment is stopped it should be done gradually over a minimum of one week.

4. Possible side effects

MYALICA can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching

- fainting

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

Patients and caregivers should seek medical attention immediately if someone experiences symptoms of respiratory problems, because these can be life-threatening. Symptoms to watch for include:

- confusion or disorientation
- unusual dizziness or lightheadedness
- extreme sleepiness or lethargy
- slowed, shallow or difficult breathing
- unresponsiveness, which means a person does not answer or react normally or you cannot wake them up
- bluish-coloured or tinted skin, especially on the lips, fingers and toes.

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

- heart disorders including heart failure, heart rhythm disturbances, such as increased heart rate, irregular heartbeat

- extremely severe skin reactions characterized by reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome and/or toxic epidermal necrolysis)
- inflammation of the eyes (keratitis)
- urinary incontinence, difficulty in passing urine, kidney failure, passing small amounts of urine, urinary retention
- inflammation of the liver (hepatitis)
- yellowing of the skin and eyes (jaundice).

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:

- inflammation of nasal passages (common cold)
- increased appetite
- feeling of elation, confusion, irritability, disorientation, sleeplessness, and changes in sexual interest
- dizziness, sleepiness, headache
- clumsiness, tremor, difficulty with speaking, forgetfulness, loss of memory, disturbance in attention, numbness or ‘pins and needles’, abnormally decreased sensitivity to stimulation

- sedation, abnormal style of walking (balance disorder), lack of energy
- blurred vision, double vision
- sensation of movement
- vomiting, nausea, constipation, diarrhoea, feeling bloated, abdominal distension, dry mouth
- muscle cramp, pain in a joint, back pain, pain in a limb, cervical spasm
- difficulties with erection
- swelling of feet and lower legs caused by fluid retention, abnormal manner of walking, falling, feeling drunk, abnormal feeling, tiredness
- weight gain.

Less frequent side effects:

- reduced numbers of white blood cells which may make you more likely to get infections (neutropenia)
- loss of appetite, low blood sugar
- seeing or hearing things that are not there, panic attacks, restlessness, exceeding restlessness, depression, depressed mood, elevated mood, aggression, mood swings, change in perception of self (depersonalisation), difficulty speaking, abnormal dreams, lack of feeling or emotion, loss of inhibition

- fainting, numbness, contraction of a muscle, loss of consciousness, jerky movements, difficulty of movement, dizziness on standing, tremor on movement, unusual eye movement, decreased consciousness, difficulty with thinking, speech disorder, reduced reflexes, increased sensitiveness of the skin, burning sensation, loss of taste, feeling of bodily discomfort, convulsions, perversion of the sense of smell, partial or complete loss of muscle movement, inability to write coherently, as a symptom of brain disease or damage
- vision loss, peripheral vision loss, visual disturbance, eye swelling, visual field defect, reduced visual sharpness, eye pain, eye condition that manifests itself through nonspecific symptoms such as fatigue, pain in or around the eyes, the presence of flashes of light, dry eyes, watery eyes, eye irritation
- visual field disturbance, altered visual depth perception, abnormal dilation of the pupil, squinting of eye(s), visual brightness
- increased sensitivity to sound
- low blood pressure, high blood pressure, hot flushes, redness of the neck and face, feeling cold
- shortness of breath, nosebleed, cough, blocked nose, runny nose, snoring, nasal dryness, fluid in the lungs, tightness of the throat
- heartburn, increased saliva production, numbness around the mouth, abdominal swelling, inflammation of the pancreas, swollen tongue, difficulty in swallowing
- hives, excessive sweating, itching of the skin, cold sweat

- joint swelling, pain in a muscle or muscles, muscle twitching, neck pain, muscle stiffness, breakdown of muscle tissue
- problems with sexual functioning including inability to achieve a sexual climax, increased libido, difficulties with erection, delayed ejaculation, painful menstrual periods, breast pain, absence of menstrual period, breast discharge, breast enlargement, breast enlargement in men
- generalised swelling caused by fluid retention, swelling of the face, chest tightness, pain, fever, thirst, chills, weakness
- changes in blood and liver test results - increased blood creatinine phosphokinase, increased alanine amino transferase, increased blood glucose, increased aspartate aminotransferase, decreased platelet count, increased blood creatinine, decreased blood potassium, decreased white blood cell count.

The following side effects have been reported but the frequency for them to occur is not known:

- thoughts of harming or killing one-self.

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety of MYALICA. You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

5. How to store MYALICA

Store all medicines out of reach of children.

Store at or below 25 ºC.

Protect from light and moisture.

Keep the container tightly closed.

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

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 MYALICA contains

The active substance is pregabalin.

MYALICA 25 mg: Each capsule contains 25 mg pregabalin.

MYALICA 75 mg: Each capsule contains 75 mg pregabalin.

MYALICA 150 mg: Each capsule contains 150 mg pregabalin.

The other ingredients are

Pregelatinised starch, talc.

Composition of gelatine capsule shell:

Gelatine, iron oxide red (75 mg strength), purified water, sodium lauryl sulphate, titanium dioxide.

***Composition of imprinting ink on gelatine capsule*:**

Black iron oxide, butyl alcohol, dehydrated alcohol, isopropyl alcohol, potassium hydroxide, propylene glycol, purified water, shellac, strong ammonia solution.

What MYALICA looks like and contents of the pack

MYALICA 25 mg: Size ‘4’ capsules with white cap and white body, imprinted with “PG” on cap and “25” on body in black ink, containing white to off-white powder.
MYALICA 75 mg: Size ‘4’ capsules with dark brown cap and white body, imprinted with “PG” on cap and “75” on body in black ink, containing white to off-white powder.
MYALICA 150 mg: Size ‘2’ capsules with white cap and white body, imprinted with “PG” on cap and “150” on body in black ink, containing white to off-white powder.

Contents of the pack

Clear, transparent PVC/aluminium blister strips packed inside an outer carton. Each carton contains 56 capsules.

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Holder of Certificate of Registration

Pharma Dynamics (Pty) Ltd

1st Floor, Grapevine House, Steenberg Office Park

Silverwood Close

Westlake, Cape Town

7945, South Africa

Tel: + 27 21 707 7000

or 0860-PHARMA (742 762)

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