

PATIENT INFORMATION LEAFLET

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SCHEDULING STATUS: **S5**

PREGABALIN PCH 25 (capsule)

PREGABALIN PCH 50 (capsule)

PREGABALIN PCH 75 (capsule)

PREGABALIN PCH 150 (capsule)

Pregabalin

Contains sugar (mannitol).

Read all of this leaflet carefully before you start taking PREGABALIN PCH.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- PREGABALIN PCH 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 PREGABALIN PCH IS AND WHAT IT IS USED FOR

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PREGABALIN PCH

3. HOW TO TAKE PREGABALIN PCH

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Teva Pharmaceuticals (Pty) Ltd

Product name: PREGABALIN PCH 25/50/75/150 (Pregabalin 25/50/75/150 mg capsules)

Registration no: 46/2.5/0768.764; 46/2.5/0769.765; 46/2.5/0770.766; 46/2.5/0771.767

1. WHAT PREGABALIN PCH IS AND WHAT IT IS USED FOR:

PREGABALIN PCH belongs to a group of medicines used to treat neuropathic pain, which is a long lasting pain caused by damage to the nerves, in adults which can be caused by diabetes or shingles (a viral infection which causes a painful skin rash).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PREGABALIN PCH:

Do not take PREGABALIN PCH:

- If you are hypersensitive (allergic) to pregabalin or any of the other ingredients of PREGABALIN PCH (see **section 6**).

Warnings and precautions:

Take special care with PREGABALIN PCH:

- PREGABALIN PCH may cause an allergic reaction. Please inform your doctor immediately if you experience any of the following symptoms: swelling of the face, lips, tongue and throat, as well as a skin rash.
- Serious skin rashes including Stevens-Johnson syndrome, toxic epidermal necrolysis have been reported in association with pregabalin. Stop using PREGABALIN PCH and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions as described in **section 4**.
- PREGABALIN PCH may cause dizziness and drowsiness which can cause accidental falls particularly in the elderly. PREGABALIN PCH can also cause loss of consciousness, confusion and mental impairment. Therefore care should be taken until you know how PREGABALIN PCH affects you.
- Please inform your doctor if you are taking any anti-depressant medicines, since they may cause breathing problems if taken with PREGABALIN PCH.
- When treatment with PREGABALIN PCH is stopped withdrawal symptoms may occur with symptoms such as inability to sleep, headache, nausea (feeling sick), anxiety, flu symptoms, nervousness, depression, pain, fits (seizures), increased sweating and dizziness. Please inform your doctor if you experience any of these symptoms.
- If you suffer from any kidney disease or kidney failure or if while taking PREGABALIN PCH you notice decreased urination, you should notify your doctor.
- Please inform your doctor if you have any heart problems such as congestive heart failure, especially if you are elderly.
- Please inform your doctor if you have diabetes and you gain weight while taking PREGABALIN PCH, since the dose of your diabetic medicines may need to be adjusted.
- PREGABALIN PCH may cause blurring or loss of vision, or temporary changes in your eyesight. You should tell your doctor immediately if you experience any changes in your vision.
- If you are taking PREGABALIN PCH due to a spinal cord injury, side effects such as drowsiness may be increased (see **section 4 - POSSIBLE SIDE EFFECTS**). This may be caused by other medicines needed to

treat this condition which may have similar side effects as PREGABALIN PCH. If any of these apply to you, your doctor may need to monitor you more closely while you are taking PREGABALIN PCH.

- If you develop thoughts of harming or killing yourself while taking PREGABALIN PCH contact your doctor immediately.
- Please inform your doctor if you are taking other medicines which can cause constipation such as pain-relieving medicines containing codeine or morphine, since constipation can occur with PREGABALIN PCH, especially in females and the elderly.
- Before you take PREGABALIN PCH you should tell your doctor if you have a history of alcoholism or any drug abuse or dependence problems.
- Before you take PREGABALIN PCH please tell your doctor if you have a history of any serious medical conditions, including liver or kidney disease which can cause a brain condition known as encephalopathy.
- There have been reports of breathing difficulties with PREGABALIN PCH. If you have nervous system disorders, respiratory (breathing) disorders, renal (kidney) impairment, or you are older than 65, your doctor may prescribe a different dosing regimen for you. Contact your doctor if you experience trouble breathing or shallow breaths.

Other medicines and PREGABALIN PCH:

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

PREGABALIN PCH may increase the side effects (such as impaired concentration and loss of co-ordination) of the following medicines:

- oxycodone (strong pain medicine)
- lorazepam (medicine used to treat anxiety).

The use of PREGABALIN PCH with alcohol may further impair your co-ordination, therefore the consumption of alcohol while you are taking PREGABALIN PCH is not advised.

Taking PREGABALIN PCH with food and drink:

PREGABALIN PCH may be taken with or without food.

You should avoid alcohol while taking PREGABALIN PCH (see **Other medicines with PREGABALIN PCH**).

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking PREGABALIN PCH.

Pregnancy:

PREGABALIN PCH should not be used during pregnancy since safety and efficacy has not been established, therefore effective contraception must be used in women of childbearing potential.

Breastfeeding:

PREGABALIN PCH is excreted in breast milk therefore, breastfeeding is not recommended, since the effects on newborns/infants are unknown.

Driving and using machines:

PREGABALIN PCH may cause dizziness, drowsiness, impaired concentration or blurred vision. Therefore, you should not engage in activities such as driving or operating machinery until you know how PREGABALIN PCH affects you.

PREGABALIN PCH contains mannitol:

PREGABALIN PCH contains mannitol and may have a laxative effect.

3. HOW TO TAKE PREGABALIN PCH:

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

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

- Your doctor will determine the appropriate dose according to your specific needs.
- PREGABALIN PCH is for oral use and can be taken with or without food.
- Take the capsules as instructed by your doctor. Swallow the capsule whole with water.
- Your doctor may adjust your dose after 3 to 7 days depending on your condition.

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

If you take more PREGABALIN PCH than you should:

You may feel sleepy, confused, depressed, agitated, restless or get fits or collapse as a result of taking more PREGABALIN PCH 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.

If you forget to take a dose of PREGABALIN PCH:

If you forget to take a dose of PREGABALIN PCH, take it as soon as you remember, unless it is time for your next dose. In that case, continue to take the next capsule at the usual time. Do not take a double dose to make up for a forgotten dose.

Effects when treatment with PREGABALIN PCH is stopped:

Do not stop taking PREGABALIN PCH unless your doctor tells you to. If your treatment with PREGABALIN PCH is stopped, it should be done gradually over a minimum of 1 week.

After stopping PREGABALIN PCH treatment, you may experience symptoms such as difficulty in sleeping, headache, nausea, feeling anxious, diarrhoea, flu-like symptoms, nervousness, depression, pain, increased sweating and dizziness.

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

4. POSSIBLE SIDE EFFECTS:

PREGABALIN PCH can have side effects.

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

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

- serious skin reactions characterised 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, toxic epidermal necrolysis)
- swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.

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

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

- irregular heart beat or shortness of breath, excessive tiredness and swelling of the legs (indicative of heart failure)
- decreased urination
- seizures (fits)
- yellowing of the eyes or skin.

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

The following side effects may occur frequently:

- increased appetite
- confusion, decreased sexual drive, irritability, disorientation
- dizziness, drowsiness, impaired muscle co-ordination, decreased attention, impaired memory, tremor, difficulty speaking, pins and needles, lack of energy
- blurred or double vision
- dry mouth, constipation, vomiting, flatulence, nausea (feeling ill), loose stools, bloating
- erectile dysfunction

- fatigue, feeling drunk, swelling of the body, abnormal style of walking, falls, feeling abnormal
- increased weight
- difficulty sleeping
- headache, memory loss, numbness, balance disorder
- muscle cramps, joint pain, back pain, pain in limbs, neck spasm.

The following side effects may occur less frequently:

- loss of appetite/weight loss, decreased blood glucose levels
- inability to reach sexual climax, restlessness, feeling depressed, agitation, mood swings, difficulty finding words, hallucinations, abnormal dreams, increased sexual drive, panic attack, elevated mood, aggression, parkinsonism that is symptoms resembling Parkinson's disease such as tremor, bradykinesia (decreased ability to move) and rigidity (muscle stiffness)
- decreased concentration, involuntary eye movement, speech disorder, muscle twitching, reduced reflexes, hyperactivity, sensitive skin, loss of taste, burning sensation, decreased or loss of consciousness, fainting, reduced muscle movement, loss of smell, difficulty writing, mental impairment, feeling unwell
- dry eye, eye swelling, eye pain, watery eyes, light sensitivity, eye irritation, visual disturbances
- increased hearing sensitivity
- hot flushes, high or low blood pressure, coldness in the hands and feet
- short breath, nasal dryness, cough, nasal congestion, nose bleeds, runny nose, snoring, throat tightness
- increased saliva, heartburn, numbness around the mouth, difficulty swallowing, swollen tongue, fluid accumulation in the abdomen, inflamed pancreas (which can cause severe upper abdominal pain, nausea and vomiting)
- joint swelling, muscle pain, muscle stiffness, neck pain
- difficulty urinating
- delayed ejaculation, sexual dysfunction, abnormal or no menstruation, breast pain, breast discharge, enlarged breasts
- weakness, thirst, chest tightness, swelling of the skin, fever, chills
- decreased weight.

The following side effects may also occur:

- reversible loss of ability to move your body
- trouble breathing, shallow breaths.

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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 PREGABALIN PCH.

5. HOW TO STORE PREGABALIN PCH:

Store at or below 25 °C in the original container.

Keep blisters in the outer carton until required for use. Keep bottles well closed.

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.

Do not use after the expiry date stated on the box, label or blister.

6. CONTENTS OF THE PACK AND OTHER INFORMATION:

What PREGABALIN PCH contains:

The active substance is pregabalin.

PREGABALIN PCH 25: Each hard capsule contains 25 mg pregabalin

PREGABALIN PCH 50: Each hard capsule contains 50 mg pregabalin

PREGABALIN PCH 75: Each hard capsule contains 75 mg pregabalin

PREGABALIN PCH 150: Each hard capsule contains 150 mg pregabalin

The other ingredients are: maize starch, mannitol, talc.

The capsule shell contains: colourants (titanium dioxide, yellow iron oxide and red iron oxide) and gelatin.

Contains sugar (mannitol).

What PREGABALIN PCH looks like and contents of the pack:

PREGABALIN PCH hard gelatin capsules contain a white to off-white, granulated powder.

PREGABALIN PCH 25: Ivory opaque hard gelatin capsule imprinted in black with '25' on the capsule body.

PREGABALIN PCH 50: Ivory opaque hard gelatin capsule with the capsule cap imprinted with a radial black band and the capsule body imprinted in black with '50' and a radial black band.

PREGABALIN PCH 75: Opaque hard gelatin capsule with a pink cap and ivory body imprinted in black with '75'.

PREGABALIN PCH 150: Ivory opaque hard gelatin capsule imprinted in black with '150' on the capsule body.

Packaging material and pack size:

- PREGABALIN PCH 25, 50, 75 & 150 are packed in PVC/aluminium blisters. The blister consists of a silver/grey aluminum foil with a transparent, colourless PVC foil. Blisters are contained in an outer carton.
Pack size 14: Each carton contains 1 blister strip with 14 capsules per blister.
Pack size 56: Each carton contains 4 blister strips with 14 capsules per blister.
Pack size 60: Each carton contains 6 blister strips with 10 capsules per blister.
Pack size 100: Each carton contains 10 blister strips with 10 capsules per blister.
- PREGABALIN PCH 75 is packed in a white, high density polyethylene (HDPE) 150 ml bottle, with a white polypropylene closure with an inner seal. Pack size: 200 capsules.
- PREGABALIN PCH 150 is packed in a white, high density polyethylene (HDPE) 300 ml bottle, with a white polypropylene closure with an inner seal. Pack size: 200 capsules.

Not all pack sizes are marketed.

Holder of Certificate of Registration:

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