

**Proposed patient information leaflet for FORRESTER PREGABALIN 25 /
75 / 150**

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S5

PROPRIETARY NAME AND DOSAGE FORM

FORRESTER PREGABALIN 25 hard gelatine capsule

FORRESTER PREGABALIN 75 hard gelatine capsule

FORRESTER PREGABALIN 150 hard gelatine capsule

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

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **FORRESTER PREGABALIN** 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.

1. WHAT FORRESTER PREGABALIN CONTAINS

Active ingredient:

Each capsule contains 25 mg, 75 mg or 150 mg pregabalin respectively.

Inactive ingredients:

Pregelatinised starch and talc.

The capsule shell contains gelatine and titanium dioxide, and is imprinted with black printing ink (consisting of black iron oxide and shellac).

The capsule shell of **FORRESTER PREGABALIN 75** also contains iron oxide red (colourant).

Sugar free.

2. WHAT FORRESTER PREGABALIN IS USED FOR

FORRESTER PREGABALIN is used to treat adults with long lasting pain (also called neuropathic pain) caused by damage to the nerves. Diseases like diabetes (high blood glucose levels) and shingles (a painful acute inflammation of the nerves, with a skin eruption often forming a girdle around the middle of the body) can cause neuropathic pain.

3. BEFORE YOU TAKE FORRESTER PREGABALIN

Do not take **FORRESTER PREGABALIN**:

- If you are hypersensitive (allergic) to pregabalin or any of the other ingredients of **FORRESTER PREGABALIN** (see **WHAT FORRESTER PREGABALIN CONTAINS**).

Take special care with **FORRESTER PREGABALIN**:

- If you experience symptoms such as swelling of the face, lips, tongue and throat, as well as diffuse skin rash, you may have had a serious allergic reaction to **FORRESTER PREGABALIN**.
Stop taking **FORRESTER PREGABALIN** immediately. These are all very serious side effects and you may need urgent medical attention or hospitalisation (see **POSSIBLE SIDE EFFECTS**).
- If you are a diabetic and are taking medicine to control your blood glucose levels. You might gain weight while taking **FORRESTER PREGABALIN** and may need an alteration in your diabetic medicines.
- If you have a history of heart disease.

- If while taking **FORRESTER PREGABALIN** you notice a decrease in urination (passing less urine than is normal for you), you should tell your doctor.
- If you have a spinal cord injury, as you may be taking other medicines that have similar side effects to **FORRESTER PREGABALIN** and the severity of these effects may be increased when taken together.
- If you take **FORRESTER PREGABALIN** with medicines that are used to treat depression, as you may experience respiratory failure (symptoms include difficulty breathing or shortness of breath, especially when active, coughing up mucous, wheezing and rapid breathing).
- **FORRESTER PREGABALIN** has been associated with dizziness and drowsiness, which could increase the occurrence of accidental injury (fall) in elderly patients. Therefore, you should be careful until you are used to any effect **FORRESTER PREGABALIN** might have (see **Driving and using machinery**).
- You may experience convulsions (fits) when taking **FORRESTER PREGABALIN** or shortly after stopping **FORRESTER PREGABALIN**. If you experience a convulsion (fit), contact your doctor immediately.
- **FORRESTER 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.
- When **FORRESTER PREGABALIN** 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 have a history of alcoholism or any substance abuse or dependence. Do not take more **FORRESTER PREGABALIN** than prescribed.
- Tell your doctor if you have a history of any serious medical conditions, including

liver or kidney problems. There have been reports of reduction in brain function (encephalopathy) in some patients taking **FORRESTER PREGABALIN** when they have other conditions.

- If you are under 18 years of age you should not take **FORRESTER PREGABALIN**. The safety and effectiveness in children and adolescents (under 18 years of age) have not been established.

Taking FORRESTER PREGABALIN with food and drink:

FORRESTER PREGABALIN may be taken with or without food.

Do not take **FORRESTER PREGABALIN** with alcohol.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your healthcare provider for advice before taking **FORRESTER PREGABALIN**.

Do not take **FORRESTER PREGABALIN** if you are pregnant or breastfeeding.

Driving and using machinery:

FORRESTER PREGABALIN frequently causes dizziness and drowsiness and can affect your ability to drive a vehicle and use machines. Do not drive a vehicle, operate machinery, or do anything else that requires your attention until you know how **FORRESTER PREGABALIN**

affects you.

Taking other medicines with FORRESTER PREGABALIN:

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

Tell your doctor or pharmacist if you are currently using:

- Oxycodone (used to treat pain)
- Lorazepam (used to treat anxiety).

4. HOW TO TAKE FORRESTER PREGABALIN

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

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

The usual starting dose of **FORRESTER PREGABALIN** is 75 mg twice daily (150 mg/day), with or without food.

Based on your individual response and tolerability, your dose may be increased to 150 mg twice daily after an interval of 3 to 7 days.

Your doctor will tell you how long your treatment with **FORRESTER PREGABALIN** will last.

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

If you take more FORRESTER PREGABALIN than you should:

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

Take this leaflet and the rest of the remaining capsules with you so the doctor will know what you have taken.

If you forget to take a dose of FORRESTER PREGABALIN:

If you have missed your dose by only a few hours, take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take **FORRESTER PREGABALIN** at the next regularly scheduled time.

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

Effects when treatment with FORRESTER PREGABALIN is stopped:

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

After stopping long-term or short-term **FORRESTER PREGABALIN** treatment, you may experience side effects such as trouble sleeping, headache, nausea (feeling sick), feeling anxious, diarrhoea, flu-like symptoms, convulsions (fits), nervousness, depression, pain, sweating and dizziness. These symptoms may occur more commonly or severely if you have been taking

FORRESTER PREGABALIN for a longer period of time.

5. POSSIBLE SIDE EFFECTS

FORRESTER PREGABALIN can have side effects.

Not all side effects reported for **FORRESTER PREGABALIN** are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking **FORRESTER PREGABALIN**, please consult your healthcare provider for advice.

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

- Swelling of your hands, feet, ankles, face, skin, 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 **FORRESTER PREGABALIN**. 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:

Less frequent:

- Changes in the way your heart beats, if you notice it beating faster or slower or skipping a beat.
- Heart rhythm disturbances.
- Chest pain or tightness.
- Congestive heart failure (a heart disease with shortness of breath and swelling of the feet or legs due to fluid build-up).
- Difficulty in breathing.
- Pulmonary oedema (a condition caused by excess fluid in the lungs).
- Signs of recurrent infections such as fever, sore and swollen throat, cough, blocked or runny nose.
- Inflammation of the pancreas (symptoms include nausea (feeling sick), vomiting (being sick), fever, swollen and tender stomach, fast heart rate).
- Loss of consciousness, mental impairment, reversible paralysis (loss of the ability to move), convulsions (fits).

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:

- Increased appetite, increased weight.
- Feeling extremely happy, confused, irritable or disorientated.
- Dizziness, drowsiness, headache, tiredness.
- Unsteadiness when walking, abnormal coordination, problems with your balance, abnormal way of walking.
- Memory impairment, abnormal thinking, disturbance in attention, loss of memory.
- Difficulty in speaking, tingling or numbness of the hands and feet, shaking (tremors).

- Uncontrollable twitching, jerking movements, spasmodic contraction of groups of muscles.
- Blurred vision or double vision.
- Vertigo (spinning sensation), feeling drunk.
- Over-sensitivity to certain frequency and volume ranges of sound.
- Dry mouth, constipation, nausea (feeling sick), diarrhoea, vomiting (being sick), flatulence (gas/wind).
- Decreased sexual drive, the inability to get or keep an erection.
- Accidental injury due to a fall.
- A sudden feeling of cold with shivering accompanied by a rise in temperature, pain, thirst.

Less frequent side effects:

- Loss of appetite, low sugar levels in the blood (symptoms may include sweating, weakness, hunger, dizziness, trembling, headache, flushing or paleness, numbness, having a fast, pounding heartbeat).
- Feeling nervous, depressed, restless, agitated.
- Persistent inability to achieve orgasm despite responding to sexual stimulation, increased sexual drive.
- Mood swings, inability to sleep, seeing, feeling or hearing things that are not there, abnormal dreams.
- Having thoughts and feelings that seem unreal and not to belong to yourself.
- Acute anxiety (symptoms include difficulty breathing, chest pain, fast heart rate), elevated or depressed mood.
- Lack of interest, enthusiasm or concern.
- Difficulty in finding words, difficulty with writing properly.
- Decreased or increased feeling or sensitivity, especially in the skin.

- Slow body movement, abnormal weakness of certain muscles, numbness or weakness of the arms and legs, fainting.
- Loss of taste function, loss of smell.
- Dry, swollen, painful, irritated eyes.
- Dilated pupils, tears flowing from the eyes.
- Presence of perceived flashes of light.
- Altered visual depth perception.
- Abnormal alignment of the eyes (the condition of having a squint).
- Rapid, uncontrolled movements of the eyes.
- High or low blood pressure, flushing, hot flushes, cold hands and feet.
- Bloating stomach, an excessive secretion of saliva.
- Gastro-oesophageal reflux disease, a digestive disorder that affects the ring of muscle between the oesophagus and stomach.
- The accumulation of fluid causing abdominal swelling.
- Difficulty in swallowing.
- Bleeding nose, snoring.
- Excessive sweating, itchy rash, skin rash with flat, red areas.
- Muscle twitching, muscle cramp, muscle stiffness, painful muscles.
- Back pain, pain in the arms or legs, neck pain or spasm.
- Swollen and painful joints.
- Breast enlargement in men and women, breast pain.
- Painful menstruation or no menstruation.
- Weight loss.
- Changes in blood and liver test results

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF FORRESTER PREGABALIN

- Store at or below 30 °C.
- Keep blister strips in the carton until required for use.
- Protect from light and moisture.
- **STORE ALL MEDICINES OUT OF REACH OF CHILDREN.**
- Do not use after the expiry date printed on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

7. PRESENTATION OF FORRESTER PREGABALIN

FORRESTER PREGABALIN 25, 75 and 150 are packed in blister strips of clear PVC/aluminium and packed into an outer carton containing 10, 14, 56 or 100 capsules each.

8. IDENTIFICATION OF FORRESTER PREGABALIN

FORRESTER PREGABALIN 25: Opaque white, size “4” hard gelatin capsules, radially imprinted with ‘A’ on cap and ‘140’ on body with black ink, filled with white to off-white powder.

FORRESTER PREGABALIN 75: Opaque white and opaque orange, size “4” hard gelatine capsules, radially imprinted with ‘A’ on cap and ‘142’ on body with black ink, filled with white to off-white powder.

FORRESTER PREGABALIN 150: Opaque white, size “2” hard gelatin capsules, radially imprinted with ‘A’ on cap and ‘144’ on body with black ink, filled with white to off-white powder.

9. REGISTRATION NUMBERS

FORRESTER PREGABALIN 25: Will be allocated by Council upon registration.

FORRESTER PREGABALIN 75: Will be allocated by Council upon registration.

FORRESTER PREGABALIN 150: Will be allocated by Council upon registration.

10. NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Forrester Pharma (Pty) Ltd

13 Pasita Street

Rosen Heights

Rosen Park

Bellville

7530

Tel: (021) 943 0600

11. DATE OF PUBLICATION

Registration date: Will be allocated by Council upon registration.