

## PATIENT INFORMATION LEAFLET FOR ZANERVA 25 / 75 / 150

### SCHEDULING STATUS

S5

### PROPRIETARY NAME AND DOSAGE FORM

**ZANERVA 25** hard gelatine capsule

**ZANERVA 75** hard gelatine capsule

**ZANERVA 150** hard gelatine capsule

**Read all of this leaflet carefully before you start taking ZANERVA.**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **ZANERVA** 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 ZANERVA 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 **ZANERVA 75** also contains iron oxide red (colourant).

Sugar free.

### 2. WHAT ZANERVA IS USED FOR

**ZANERVA** 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 ZANERVA

#### Do not take ZANERVA:

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

#### Take special care with ZANERVA:

- 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 **ZANERVA**. Stop taking **ZANERVA** 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 **ZANERVA** and may need an alteration in your diabetic medicines.
- If you have a history of heart disease.
- If while taking **ZANERVA** 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 **ZANERVA** and the severity of these effects may be increased when taken together.
- If you take **ZANERVA** 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).

- **ZANERVA** 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 **ZANERVA** might have (see **Driving and using machinery**).
- You may experience convulsions (fits) when taking **ZANERVA** or shortly after stopping **ZANERVA**. If you experience a convulsion (fit), contact your doctor immediately.
- **ZANERVA** 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 **ZANERVA** 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 **ZANERVA** 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 **ZANERVA** when they have other conditions.
- If you are under 18 years of age you should not take **ZANERVA**. The safety and effectiveness in children and adolescents (under 18 years of age) have not been established.

**Taking ZANERVA with food and drink:**

**ZANERVA** may be taken with or without food.

Do not take **ZANERVA** with alcohol.

**Pregnancy and breastfeeding:**

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

Do not take **ZANERVA** if you are pregnant or breastfeeding.

**Driving and using machinery:**

**ZANERVA** 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 **ZANERVA** affects you.

**Taking other medicines with ZANERVA:**

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 ZANERVA**

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

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

The usual starting dose of **ZANERVA** 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 **ZANERVA** will last.

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

**If you take more ZANERVA than you should:**

In the event of an overdose, 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 ZANERVA:**

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 **ZANERVA** at the next regularly scheduled time.

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

**Effects when treatment with ZANERVA is stopped:**

Do not stop taking **ZANERVA** 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 **ZANERVA** 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 **ZANERVA** for a longer period of time.

**5. POSSIBLE SIDE EFFECTS**

**ZANERVA** can have side effects.

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

If any of the following happens, stop taking **ZANERVA** 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 **ZANERVA**. 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 ZANERVA

- 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 ZANERVA

**ZANERVA 25, 75 and 150** are packed in blister strips of clear PVC/aluminium and packed into an outer carton containing 10, 14, 56, 60 or 100 capsules each.

## 8. IDENTIFICATION OF ZANERVA

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

**ZANERVA 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.

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

## 9. REGISTRATION NUMBERS

**ZANERVA 25:** 48/2.5/1336

**ZANERVA 75:** 48/2.5/1337

**ZANERVA 150:** 48/2.5/1338

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

Forrester Pharma (Pty) Ltd  
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## 11. DATE OF PUBLICATION

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