PROPOSED PATIENT INFORMATION LEAFLET - CLEAN

SCHEDULING STATUS

S5

TIMIRIL 25, TIMIRIL 50, TIMIRIL 75, TIMIRIL 100, TIMIRIL 150

(Capsules)

Pregabalin

Read all of this leaflet carefully before you start taking TIMIRIL

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

TIMIRIL belongs to a group of medicines used to treat damaged nerves (neuropathic pain). A variety of diseases can cause 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.

2. What you need to know before you take TIMIRIL

Do not take TIMIRIL:

If you are allergic (hypersensitive) to pregabalin or any of the other ingredients of TIMIRIL (listed in section 6).

Warnings and precautions

Take special care with TIMIRIL:

- If you have symptoms suggesting an allergic reaction. These symptoms include swelling of the face, lips, tongue, and throat, as well as skin rash. Should you experience any of these reactions, you should contact your doctor immediately.
- If you suffer from kidney problems or get kidney dialysis, your doctor may prescribe a different dosing schedule.
- If you have a history of heart problems or heart disease.
- TIMIRIL has been associated with dizziness and somnolence, which could increase the occurrence of accidental injury (fall) in elderly patients. Therefore, you should be careful until you are used to any effect the medicine might have.
- If you have diabetes, as you may gain weight while taking TIMIRIL and may need an alteration in your diabetic medicines
- As a small number of people being treated with TIMIRIL have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.
- When TIMIRIL 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 drug abuse or dependence, you should tell your doctor before taking TIMIRIL. Do not take more medicine than prescribed
- As there have been reports of reduction in brain function (encephalopathy) in some patients taking TIMIRIL when they have other conditions.

Children and adolescents

The safety and efficacy in children and adolescents (under 18 years of age) has not been established and therefore, pregabalin should not be used in this age group.

Other medicines and TIMIRIL

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

TIMIRIL could interact with other medicines and the dosages of the medicines might have to be changed by your doctor as the amounts of TIMIRIL or other medicines in your blood may be affected.

Tell your doctor or pharmacist:

- If you are taking any medicines that have sedative effects (such as opioids) as TIMIRIL may make these side effects worse and could lead to respiratory failure and coma. The amount of dizziness, sleepiness and decreased concentration may be increased if TIMIRIL is taken together with medicines containing oxycodone (used as a painkiller), lorazepam (used for treating anxiety) or alcohol
- TIMIRIL is also not expected to interact with the contraceptive pill.

TIMIRIL with food, drink and alcohol

TIMIRIL may be taken with or without food.

It is advised not to drink alcohol while taking TIMIRIL.

Pregnancy, breastfeeding and fertility

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

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

Driving and using machines

TIMIRIL may cause dizziness, blurred vision and tiredness. You should not drive, operate heavy machinery, or do other dangerous activities until you know how TIMIRIL affects you.

3. How to take TIMIRIL

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

Always take TIMIRIL exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Adults:

- Take the number of capsules as instructed by your doctor.
- The dose is adjusted for you and for your condition and will be between 150 – 300 mg per day. Your doctor will tell you to take TIMIRIL either once or two times a day.
- For twice a day dosing take TIMIRIL once in the morning and once in the evening, at about the same time each day.
- TIMIRIL can be taken with or without food.

Your doctor will tell you how long your treatment with TIMIRIL will last. If you have the impression that the effect of TIMIRIL is too strong or too weak, tell your doctor or pharmacist.

If you take more TIMIRIL than you should

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

Take along any capsules that you have not taken, together with the container and the leaflet so that the hospital can easily tell what medicine you have taken. You may feel sleepy, confused, agitated, or restless.

If you forget to take TIMIRIL

If you forget to take a capsule, take the missed dose right away, unless it is almost time for your next dose. Do not take a double dose to make up for forgotten individual doses.

If you stop taking TIMIRIL

Do not stop taking TIMIRIL or decrease the dose without checking with your doctor. If your treatment is stopped it should be done gradually over a minimum of 1 week. After stopping treatment with TIMIRIL, you may experience certain side effects such as insomnia, headache, nausea and diarrhoea.

4. Possible side effects

TIMIRIL can have side effects.

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

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

- skin rash,
- swelling of your face, lips and tongue.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Increased appetite.
- Feeling of elation, confusion, disorientation, decrease in sexual interest, irritability.
- Disturbance in attention, clumsiness, loss of memory, tremor or shaking, difficulty with speaking, tingling feeling, numbness, sedation, lethargy, feeling tired.
- Blurred vision, double vision.
- Vertigo, problems with balance.
- Dry mouth, constipation, vomiting, flatulence or wind, diarrhoea, nausea (feeling sick), swollen abdomen.
- Difficulties with erection.
- Swelling of the body including extremities.
- Feeling drunk, abnormal style of walking.
- Weight gain.

Less frequent side effects:

- Loss of appetite, weight loss, low blood sugar.
- Change in how you feel about yourself, restlessness, depression, agitation, insomnia, mood swings, difficulty finding words, hallucinations, abnormal dreams, panic attack, lack of interest or emotion, elevated mood, difficulty with thinking.
- Increase in sexual interest, problems with sexual functioning including inability to

achieve a sexual climax, delayed ejaculation, painful menstrual periods**,** breast discharge, abnormal breast growth, interrupted menstrual periods.

- Changes in eyesight, unusual eye movement, changes in vision including tunnel vision, difficulty talking, jerky movements, reduced reflexes, increased activity, dizziness on standing, sensitive skin, loss of taste, burning sensation, tremor on movement, decreased or loss of consciousness, fainting, increased sensitivity to noise.
- Dry eyes, eye swelling, eye pain, weak eyes, watery eyes, eye irritation.
- Heart rhythm disturbances, increased heart rate, low blood pressure, high blood pressure, changes in heartbeat, heart failure, coldness of hands and feet.
- Flushing, hot flushes.
- Difficulty breathing, dry nose, nasal congestion, nose bleeds, snoring, runny nose, coughing.
- Increased saliva production, heartburn, difficulty swallowing, increased fluid in the abdomen.
- Sweating, rash, chills, fever.
- Muscle twitching, joint swelling or pain, muscle stiffness, pain including muscle pain, neck pain.
- Difficulty with or painful urination, loss of bladder control.
- Weakness, thirst, chest tightness, fever.
- Changes in blood and liver test results.
- Headache, loss of consciousness.
- Hypersensitivity or allergic reactions, swollen face, itchiness, hives.
- Reduced urine volume
- Heart failure/problems.

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 TIMIRIL.

5. How to store TIMIRIL

Store all medicines out of reach of children.

Store at or below 25 °C.

Store in the original container.

HDPE Bottles: Keep the bottle tightly closed until use.

Blisters: Do not remove blisters from carton until required for use.

Do not store in a bathroom.

Do not use TIMIRIL after the expiry date.

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 TIMIRIL contains:

The active substance is pregabalin. Each capsule contains either 25 mg, 50 mg, 75 mg, 100 mg, or 150 mg pregabalin.

Other ingredients are: pregelatinized starch, talc, gelatin, titanium dioxide (E171), printing ink (which contains black iron oxide (E172), potassium hydroxide, propylene glycol, shellac, ammonia solution).

TIMIRIL 75 mg, and 100 mg capsules also contain red iron oxide (E172)

What TIMIRIL looks like and contents of the pack

TIMIRIL 25

Hard gelatin capsule with a white coloured cap and white coloured body, printed with "S" on cap and "466" on body with black ink containing a white to off-white crystalline powder.

TIMIRIL 50

Hard gelatin capsule with a white coloured cap and white coloured body, printed with "S" on cap and "467" on body with black ink containing a white to off-white crystalline powder.

TIMIRIL 75

Hard gelatin capsule with an orange coloured cap and white coloured body, printed with "S" on cap and "468" on body with black ink containing a white to off-white crystalline powder.

TIMIRIL 100

Hard gelatin capsule with an orange coloured cap and orange coloured body, printed with "S" on cap and "469" on body with black ink containing a white to off-white crystalline powder.

TIMIRIL 150

Hard gelatin capsule with a white coloured cap and white coloured body, printed with "S" on cap and "470" on body with black ink containing a white to off-white crystalline powder.

TIMIRIL is available in white HDPE bottles sealed with a white child-resistant cap containing 90 capsules. In addition, TIMIRIL is available in clear PVC/Aluminium blisters containing 100 capsules for the 50 mg, 75 mg, 100 mg and 150 mg strengths. Blisters are kept in a cardboard carton.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

To follow