APPROVED PATIENT INFORMATION LEAFLET: TRAMADOL 50 mg AUSTELL CAPSULES

SCHEDULING STATUS:

S5

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

TRAMADOL 50 mg AUSTELL CAPSULES

Read all of this leaflet carefully before you start using TRAMADOL AUSTELL

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

Each capsule contains 50 mg of the active ingredient: Tramadol hydrochloride.

The inactive ingredients are: colloidal silicon dioxide, magnesium stearate, microcrystalline cellulose and sodium starch glycolate. The capsule shell is composed of ferric oxide yellow, gelatin, indigo carmine, methyl paraben, propyl paraben, sodium lauryl sulphate and titanium dioxide.

Sugar free.

2. WHAT TRAMADOL AUSTELL IS USED FOR

TRAMADOL AUSTELL capsules are used in the management of moderate to moderately severe pain, so in other words it is a pain reliever or pain killer.

3. BEFORE YOU TAKE TRAMADOL AUSTELL

Do not take TRAMADOL AUSTELL capsules:

- If you are allergic to tramadol, opioids or any ingredients in **TRAMADOL AUSTELL**
- If you suffer from asthma.
- If you suffer from respiratory depression (difficulty in breathing).
- If you have increased intracranial pressure or central nervous depression due to head injury or cerebral disease (any form of increased pressure in the brain).
- If you suffer from severe kidney or liver problems.
- If you have epilepsy and your seizures ("fits") are not adequately controlled by your treatment.
- Do not use **TRAMADOL AUSTELL** for withdrawal from narcotic (addictive) substances.

Take special care with TRAMADOL AUSTELL capsules:

- If you suffer from liver or kidney problems.
- If you have a history of epilepsy or are susceptible to seizures ("fits").
- If you suffer from hypothyroidism (problems with your thyroid gland), enlarged prostrate or low blood pressure.
- **TRAMADOL AUSTELL** is not suitable for children under the age of 12 years.

Taking TRAMADOL AUSTELL with food and drink

Take **TRAMADOL AUSTELL** capsules with a drink of water.

Take with or without food.

You are advised not to drink alcohol while taking **TRAMADOL AUSTELL**

Pregnancy and Breastfeeding

If you are pregnant or breastfeeding your baby while taking this medicine please consult your doctor, pharmacist or other health care professional for advice before taking **TRAMADOL AUSTELL**

Driving and using machinery

TRAMADOL AUSTELL may make you feel drowsy or sleepy. Do not drive or operate machinery until you know how **TRAMADOL AUSTELL** affects you.

Using other medicines with TRAMADOL AUSTELL

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

If you are taking other medicines on a regular basis, concomitant use of TRAMADOL AUSTELL capsules may cause undesirable interactions. Please consult your doctor or a pharmacist if you are taking any of the following:

- Carbamazepine (used to treat epilepsy and some types of pain).
- Tricyclic antidepressants (medicines used mainly for the treatment of depression).
- Monoamine-oxidase inhibitors (these are medicines used to treat depression or Parkinson's disease).
- Cytochrome P450 inhibitors such as quinidine (medicine used for treating heart problems), ketoconazole (anti-fungal) or erythromycin (antibiotic).
- Anticoagulants (medicine used to 'thin' the blood) such as warfarin.
- Cimetidine (medicine used for heartburn or ulcers).
- Barbiturates (medicine used to treat epilepsy or for sleeping problems).
- Ondansetron (medicine used to treat nausea and vomiting).

HOW TO TAKE TRAMADOL AUSTELL

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

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

Adults and Children over 14 years:

Oral administration:

Moderate pain:

Initial dose of 50 mg, followed by 50 mg or 100 mg (1 to 2 capsules) 4-6 hourly.

Severe pain:

Initial dose of 100 mg followed by 50 mg or 100 mg (1 to 2 capsules) 4-6 hourly.

Do not take more than 8 capsules (400 mg) in a 24-hour period.

If you are older than 75 years, or have a kidney or a liver problem, your doctor may prolong the dosage interval.

If you have the impression that **TRAMADOL AUSTELL** is too strong or too weak, tell your doctor or pharmacist.

If you take more TRAMADOL AUSTELL than you should:

If you have taken too much **TRAMADOL AUSTELL** you may experience pinprick pupils, heart problems, difficulty breathing, seizures “fits” and cold, clammy skin.

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 TRAMADOL AUSTELL:

If you forget to take a dose, take it as soon as you remember and then take the next dose at the right time. Do not take a double dose to make up for a missed dose.

If you stop taking TRAMADOL AUSTELL:

If you stop taking **TRAMADOL AUSTELL,** your pain may come back. Some people may become dependent on medicines containing tramadol. If you want to stop taking **TRAMADOL AUSTELL,** contact your doctor who will gradually decrease the dose you are taking.

4. POSSIBLE SIDE EFFECTS

Not all side-effects reported for TRAMADOL AUSTELL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking TRAMADOL AUSTELL, **please consult your doctor, pharmacist or other health care professional for advice.**

TRAMADOL AUSTELL capsules can have side effects.

If any of the following happen, stop taking TRAMADOL AUSTELL capsules and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Wheezing, difficulty breathing, chest pain or chest tightness, and/or feeling dizzy/faint, severe itching of the skin or raised lumps on the skin, swelling of the face, lips, tongue and /or throat, which may cause difficulty in swallowing, collapse. These may be signs of a serious allergic reaction.
- fever (high temperature) and sore throat with a rash, that develops quickly, with itching and peeling or flaking of your skin and possibly blistering of the mouth and the genital and anal regions. Your eyes may also be affected and may be red and swollen. These may be signs of a severe skin reaction.
- Slowed breathing- usually when high doses of **TRAMADOL AUSTELL** are taken.

These are very serious side effects. 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:

- Seizures (“fits”),
- Feeling faint or collapsing.

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

Tell your doctor if you notice any of the following:

Frequent:

- nausea (feeling “sick”), vomiting, dry mouth, indigestion, constipation, diarrhoea, lack of appetite, pain in the stomach,
- Sweating, dizziness, headaches.

Less frequent:

- hallucinations (seeing or hearing things that are not there), feeling confused or forgetting (“memory loss”), sleepiness or drowsiness,
- postural hypotension (feeling dizzy or light-headed when standing up after you have been sitting or lying down), flushing,
- tingling of skin “pins and needles”,
- blurred vision, dilation of the pupil,
- changes in heartbeat,
- increase in liver enzymes (seen on a blood test),
- needing to urinate frequently or difficulty urinating,
- itching of the skin, hives, fluid filled rash, skin rash,
- muscle weakness,
- feeling tired.

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

5. STORING AND DISPOSING OF TRAMADOL AUSTELL

Store in a cool dry place at or below 25 °C. Protect from light.

Keep in outer carton until required for use.

Do not transfer the medicine to any other container.

Do not use after the date, which is stamped on the pack. Return all unused medicines to your doctor or pharmacist.

6. PRESENTATION OF TRAMADOL AUSTELL

Blister pack (Opaque PVDC coated PVC film & Aluminium foil) of 1 x 10, 2 x 10 and 10 x 10 capsules.

IDENTIFICATION OF TRAMADOL AUSTELL

Green/Yellow coloured hard gelatin capsules, size 3 filled with a homogeneous white to off white powder.

7. REGISTRATION NUMBER

A40/2.9/0388

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

Austell Pharmaceuticals (Pty) Ltd

1 Sherborne Road

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9. DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET

Date of registration: 05 October 2007

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