PROPOSED PATIENT INFORMATION LEAFLET FOR TRAMAZAC SR 100, 150 AND 200

SCHEDULING STATUS

Schedule 5

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

TRAMAZAC SR 100 film coated tablet

TRAMAZAC SR 150 film coated tablet

TRAMAZAC SR 200 film coated tablet

Please read this leaflet carefully before using TRAMAZAC SR.

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

Active ingredient:

Each **TRAMAZAC SR 100** contains 100 mg tramadol hydrochloride.

Each **TRAMAZAC SR 150** contains 150 mg tramadol hydrochloride.

Each **TRAMAZAC SR 200** contains 200 mg tramadol hydrochloride.

Other ingredients:

Magnesium stearate, microcrystalline cellulose, polyethylene oxide, povidone K-30, Opadry orange 03F53885 (for **TRAMAZAC SR 150**), Opadry pink 03F84640 (for **TRAMAZAC SR 200**), Opadry white 03F58750 (for **TRAMAZAC SR 100**).

Sugar free.

2. WHAT TRAMAZAC SR IS USED FOR

TRAMAZAC SR is used to relieve moderate to moderately severe pain.

3. BEFORE YOU TAKE TRAMAZAC SR

Do not take TRAMAZAC SR:

- If you are allergic (hypersensitive) to tramadol hydrochloride, opioids or any other ingredients (see **WHAT TRAMAZAC SR CONTAINS**).
- If you are under the influence of alcohol or if you are currently being treated for any form of alcohol abuse or if you are consuming large amounts of alcohol.
- If you have taken an antidepressant of the monoamine oxidase type within the last 2 weeks.
- If you have asthma or breathing problems, especially if you have excessive bronchial secretions.
- If you have a head injury or brain disease or had a stroke.
- If you are pregnant, suspect that you are pregnant or if you are breastfeeding your baby.
- If you have suicidal thoughts or tendencies.
- If you have taken sleeping pills, tranquillisers, antidepressants or other strong medicines for pain as you may develop difficulty breathing.
- **Do not** give **TRAMAZAC SR** to a child under the age of 12 years.

Take special care with TRAMAZAC SR:

- If you have a tendency for medicine abuse, a history of medicine dependence or chronically using opioids (strong pain killers) such as codeine.
- If you have a liver or a kidney disorder.
- If you have epilepsy or previously had a seizure or fit since it may increase the risk of having a seizure or fit.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **TRAMAZAC SR**.

DO NOT take **TRAMAZAC SR** if you are pregnant, suspect that you are pregnant or breastfeeding your baby. Contact your doctor immediately.

Driving and using machinery:

TRAMAZAC SR may impair your ability to drive and use machinery. Do not drive, operate machinery, or do anything else that could be dangerous until you know how **TRAMAZAC SR** affects you.

Taking TRAMAZAC SR with food or drink:

TRAMAZAC SR can be taken with or without food.

Taking other medicines with TRAMAZAC SR:

- Always tell your healthcare professional if you are taking any other medicine.
- If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **TRAMAZAC SR** with these medicines may cause undesirable interactions.
- Not all interactions that may occur with **TRAMAZAC SR** are included in this leaflet.
- Do not take the following medicines in combination with **TRAMAZAC SR:**
  - Monoamine oxidase inhibitors (antidepressants) used in the treatment of depression.
  - Opioids (like morphine) used in the treatment of severe pain.
  - Hypnotics (like benzodiazepine or tranquilizers) used in the treatment of anxiety.
  - Analgesics (pain killers) used in the treatment of pain and fever.
  - Carbamazepine used in the treatment of epilepsy (seizures / fits).
  - Warfarin used in the treatment of blood clotting.

Consult your doctor or pharmacist before taking any of the medicines listed above.

4. HOW TO TAKE TRAMAZAC SR

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

You should not take **TRAMAZAC SR** for minor pain.

Always take **TRAMAZAC SR** exactly as your doctor has instructed you. You should consult your doctor or pharmacist if you are unsure. If you have any questions about the proper dose of **TRAMAZAC SR**, ask your doctor.

If you take more TRAMAZAC SR than you should:

In the event of overdosage consult your doctor or pharmacist as soon as possible. If neither is available, contact the nearest hospital or poison control centre. Take this leaflet and any remaining tablets with you, so that the doctor knows what you have taken.

If you forget to take your TRAMAZAC SR:

Take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take the medicine at the next regularly scheduled time. Do not take a double dose to make up for the missed dose.

5. POSSIBLE SIDE EFFECTS

TRAMAZAC SR may have side effects. Not all side effects reported for **TRAMAZAC SR** are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking TRAMAZAC SR please consult your doctor, pharmacist or other healthcare professional for advice.

Stop taking **TRAMAZAC SR** and seek emergency help if you have any of these signs of an allergic reaction:

Hives; difficulty breathing; swelling of your face, lips, tongue, or throat.

Consult your doctor if any of the following side effects continue or are bothersome which may occur frequently:

- Unusual tiredness, extreme emotional disturbance, anxiety, nervousness, sleepiness, dizziness, flushing, headache.
- Nausea, vomiting, dry mouth, heartburn, constipation, diarrhoea, weight loss, stomach pain.
- Increased sweating.
- Physical weakness, influenza-like illness.

Less frequent side effects that may occur include the following:

- Abnormal slow or fast heartbeat, heart disorders.
- Flushing, light headedness, swelling of the face, mouth, throat or intestines, usually due to an allergic reaction.
- Numbness, tingling, pain or weakness in hands or feet, loss of memory, seizures / fits, fainting, restlessness.
- Severe stomach cramps, fever, bloating.
- Blurred vision, skin rash, itching.
- Difficulty in urination.
- Upper respiratory tract infection, nasal congestion, runny nose.

6. STORING AND DISPOSING OF TRAMAZAC SR

- Store at or below 25 °C. Protect from light and moisture.
- Do not remove from outer carton until required for use.
- **STORE ALL MEDICINES OUT OF REACH OF CHILDREN.**
- Do not use after the expiry date printed on the label or 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 TRAMAZAC SR

White opaque PVC/PVDC/Aluminium blister strips containing 10 tablets per blister strip. 10, 30, 60 or 100 tablets will be packed into a cardboard box.

8. IDENTIFICATION OF TRAMAZAC SR

TRAMAZAC SR 100: White to off-white, round shaped, biconvex, film coated tablets, debossed with “100” on one side and plain on the other side.

TRAMAZAC SR 150: Pale orange, round shaped, biconvex, film coated tablets, debossed with “150” on one side and plain on the other side.

TRAMAZAC SR 200: Slightly brownish orange, round shaped, biconvex, film coated tablets, debossed with “200” on one side and plain on the other side.

9. REGISTRATION NUMBERS

TRAMAZAC SR 100: 44/2.9/0496

TRAMAZAC SR 150: 44/2.9/0497

TRAMAZAC SR 200: 44/2.9/0498

10. NAME AND ADDRESS OF REGISTRATION HOLDER

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22 Karee Street

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0157

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11. DATE OF PUBLICATION

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