1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S5

TRAMASPEN SR 100 mg sustained release tablets

Tramadol hydrochloride

Contains sugar: Lactose monohydrate 2,52 mg

TRAMASPEN SR 150 mg sustained release tablets

Tramadol hydrochloride

Contains sugar: Lactose monohydrate 2,52 mg

TRAMASPEN SR 200 mg sustained release tablets

Tramadol hydrochloride

Contains sugar: Lactose monohydrate 2,52 mg

Read all of this leaflet carefully before you start taking TRAMASPEN SR

- 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.
- TRAMASPEN 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.

What is in this leaflet

1. What TRAMASPEN SR is and what it is used for
2. What you need to know before you take TRAMASPEN SR
3. How to take TRAMASPEN SR
4. Possible side effects
5. How to store TRAMASPEN SR
6. Contents of the pack and other information

1. What TRAMASPEN SR is and what it is used for

TRAMASPEN SR belongs to a group of medicines called opioid analgesics or painkillers. Its pain-relieving action is due to its effect on specific nerve cells in the spinal cord and brain.

TRAMASPEN SR is used in the treatment of moderate to severe pain.

2. What you need to know before you take TRAMASPEN SR

Do not take TRAMASPEN SR:

- If you are hypersensitive (allergic) to tramadol hydrochloride or any of the other ingredients of TRAMASPEN SR (listed in section 6).
- If you are intoxicated with alcohol or with sedative medicines including sleeping pills, other painkillers or medicines that affect mood and emotions (psychotropic medicines).
- If you are taking, or have taken in the last two weeks, certain medicines called "monoamine oxidase inhibitors" or MAOIs (used to treat depression). The combination could result in a serious, potentially life-threatening interaction (see section Other medicines and TRAMASPEN SR).
- If you have epilepsy that is not controlled with your current medicine.

- If you have illnesses of the lungs, affecting your breathing, especially if you have low levels of oxygen in your blood causing a blueish colour on your body, or if you have excessive mucus (bronchial secretions).
- If you have high pressure within your head, or have a head injury, or have any conditions affecting your brain.
- After a tonsillectomy (removal of tonsils) or adenoidectomy (removal of adenoids) if you are younger than 18 years of age.
- If you are pregnant or breastfeeding your baby (see Pregnancy, breastfeeding and fertility).

TRAMASPEN SR is contraindicated in children younger than 12 years of age

TRAMASPEN SR is not suitable in the treatment of drug addiction.

Warnings and precautions

Take special care with TRAMASPEN SR:

- TRAMASPEN SR may cause serious breathing problems. Tell your doctor immediately if you experience difficulty breathing, slow shallow breathing or daytime sleepiness (see section **Do not take TRAMASPEN SR**).
- You may experience epileptic fits when taking TRAMASPEN SR even when taking it at the recommended dose level. The risk may be increased when doses of TRAMASPEN SR exceed the recommended upper daily dose limit (see section **Do not take TRAMASPEN SR**).
- If you suffer from epilepsy or fits (seizures) or have had them in the past, because tramadol could increase the risk of you having further fits (see section **Do not take TRAMASPEN SR**).
- As with all strong painkillers, TRAMASPEN SR may lead to psychological and physical dependence or addiction in some people, especially with long term use. The dose needed to achieve the desired effect may increase with time.

TRAMASPEN SR should be used with caution, and only for short periods, in patients who are addicted to other opioid painkillers.

- If you have liver or kidney problems.
- If you are in a state of shock (cold sweat may be a sign of this) or not fully conscious.
- You may stop feeling the pain-killing effects of TRAMASPEN SR if you take TRAMSPEN SR for a very long time. This called tolerance.
- When your doctor stops your treatment with TRAMASPEN SR, he will gradually lower your dose until you finally stop taking TRAMASPEN SR (see section below). You may feel severe pain if TRAMASPEN SR is stopped suddenly.
- If you take high dose of TRAMASPEN SR you may experience increased levels of pain (opioid-induced hyperalgesia (OIH)). May manifest as a broader or more widespread area of discomfort or heightened sensitivity such that normally non-painful stimuli, such as light touch, may be perceived as painful (a condition known as allodynia). Your doctor may lower your dose or change your treatment.
- TRAMASPEN SR is transformed in the liver by an enzyme. Some people have a variation of this enzyme and this can affect people in different ways. In some people, they may not get enough pain relief but other people are more likely to get serious side effects. If you notice any of the following side effects, you must stop taking TRAMASPEN SR and seek immediate medical advice: slow or shallow breathing, confusion, sleepiness, small pupils, feeling or being sick, constipation, lack of appetite.
- Long term use of TRAMASPEN SR may cause decreased hormones, which may result in a low sex drive (libido), loss of ability to attain an erection (impotence) and inability to conceive a baby (infertility). Tell your doctor if you notice these symptoms.

- While taking TRAMASPEN SR you may experience low levels of sodium in your blood (hyponatraemia). Symptoms may include nausea and vomiting, headaches, feeling confused, feeling very tired, feeling restless, feeling irritable, muscle weakness, spasms or cramps and seizures. Elderly patients and patients taking other medicines that lower sodium in the blood are most at risk for this side effect. If you experience any of these symptoms while taking TRAMASPEN SR, consult your doctor immediately.
- TRAMASPEN SR can occasionally cause adrenal insufficiency which could present with symptoms like severe stomach pain, nausea, vomiting, extreme fatigue, decreased appetite and weight loss.
- If you have a family history of substance abuse or mental illness. You may have an increased risk of becoming addicted to TRAMASPEN SR.
- If you are taking a serotonergic medicine like a Selective Serotonin Reuptake Inhibitor (SSRI) which is used for depression, inform your doctor, as you are at risk of certain side effects.

Children

TRAMASPEN SR should not be given to children below 12 years of age.

Caution is advised against use of TRAMASPEN SR in adolescents between 12 and 18 years of age who are extremely overweight (obese), have airflow blockage while sleeping (obstructive sleep apnoea syndrome), or have serious lung disease.

TRAMASPEN SR is not recommended for use in children with breathing problems, including neuromuscular disorders (conditions that impair the functioning of the

muscles, either directly or indirectly, through the nervous system), severe heart or lung conditions, lung infections, several serious injuries or major surgery.

If a child accidently swallows TRAMASPEN SR, rush the child to the casualty department at your nearest hospital. Ensure that TRAMASPEN SR is disposed of correctly and kept out of reach of children at all times.
TRAMASPEN SR is not recommended in children with breathing problems, since the symptoms of toxicity may be worse in these children.

Other medicines and TRAMASPEN SR

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

Tell your doctor if you are taking any of the following:

- Monoamine oxidase inhibitors (e.g. selegiline): medicines used to treat depression (see section Do not take TRAMASPEN SR).
- Centrally depressant medicines (e.g. tranquillisers, sleeping pills, other pain relievers, cough medicines): medicines which make you feel sleepy.
- Carbamazepine: medicine used to treat fits (seizures).
- Buprenorphine, nalbuphine, pentazocine: medicines used to treat pain.
- Medicines which may cause fits (convulsions), such as certain antidepressants or antipsychotics.
- Tricyclic antidepressants (e.g. amitriptyline) and mirtazapine may cause serotonin syndrome, a potentially life-threatening condition.
- Selective serotonin re-uptake inhibitors (such as fluoxetine, paroxetine): medicines used to treat depression. TRAMASPEN SR may interact with these medicines and you may experience symptoms such as confusion, involuntary

muscle contractions, high body temperature (fever), excessive sweating, exaggeration of reflexes, increased muscle tension, loose stools.

- Migraine medicines: medicines used to treat severe headaches.
- Coumarin derivatives (e.g. warfarin): medicines used to prevent blood clots.
- Ketoconazole: medicine used to treat fungal infections.
- Erythromycin: medicine used to treat bacterial infections.
- Ondansetron: medicine used to treat nausea and vomiting may cause TRAMASPEN SR to be less effective.
- Sedative medicines such as benzodiazepines: medicines which make you feel sleepy. If taken with TRAMASPEN SR, you may experience difficulties in breathing (respiratory depression), coma and it may be life-threatening.
- Medicines which may increase the CYP3A4 enzyme in your body, such as rifampicin (used to prevent and treat tuberculosis) and St John's wort (an herbal supplement that may assist with symptoms of depression).

TRAMASPEN SR with food, drink and alcohol

TRAMASPEN SR should be swallowed whole with sufficient liquid, with or without meals.

Do not drink alcohol during treatment with TRAMASPEN SR as its effect may be intensified.

Pregnancy, breastfeeding and fertility

You should not take TRAMASPEN SR if you are pregnant or breastfeeding your baby (see section **Do not take TRAMASPEN SR**).

Tell your doctor if you experience low sex drive (libido), males unable to attain an erection (impotence, erectile dysfunction), lack of menstruation, or inability to conceive a baby (infertility).

The active ingredient, tramadol, can pass into breastmilk. There is a risk of serious side effects in breastfed babies, such as the baby feeling extremely sleepy (excess sleepiness), difficulty breastfeeding or serious breathing problems that could result in death.

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 medicine.

Driving and using machines

TRAMASPEN SR may cause side effects such as drowsiness and blurred vision. If this happens, do not drive or use any tools/machines and do not perform any hazardous tasks.

It is not always possible to predict to what extent TRAMASPEN SR may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which TRAMASPEN SR affects them (see section 4).

TRAMASPEN SR contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking TRAMASPEN SR.

3. How to take TRAMASPEN SR

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

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

The dosage should be adjusted to the intensity of your pain and your individual pain sensitivity.
In general, the lowest pain-relieving dose should be taken.

TRAMASPEN SR should only be used if other treatment options have been ineffective, not tolerated or otherwise inadequate in managing the pain. Your doctor will make this decision.

The usual dose of TRAMASPEN SR is:
Adults and children over 12 years
The usual initial dose is 100 mg twice daily, to be taken whole, not divided or chewed, with sufficient liquid, with or without meals, preferably mornings and evenings.
You should not normally take more than 400 mg a day.
TRAMASPEN SR is not suitable for children under the age of 12 years.
Your doctor will tell you how long your treatment with TRAMASPEN SR will last. If you have the impression that the effect of TRAMASPEN SR is too strong or too weak, tell your doctor or pharmacist.

If you take more TRAMASPEN SR than you should

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

but are not limited to vomiting, narrowing of the pupil, severe lowering of blood pressure which may result in loss of consciousness (cardiovascular collapse), prolonged unconsciousness (coma), rapid/shallow breathing, racing/irregular heartbeat and profuse sweating (respiratory collapse).

If you forget to take TRAMASPEN SR

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

If you have missed a dose of TRAMASPEN SR, take the dose that you have missed as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. If you have forgotten to take several doses, contact your doctor without delay.

If you stop taking TRAMASPEN SR

You should not suddenly stop taking TRAMASPEN SR unless your doctor tells you to. If you want to stop taking your medicine, discuss this with your doctor first, particularly if you have been taking it for a long time. Your doctor will advise you when and how to stop, which may be by lowering the dose gradually to reduce the chance of developing unnecessary side effects (withdrawal symptoms). If you have been taking this medicine for a very long time, you may get the following side effects if you suddenly stop treatment: restlessness, anxiety, nervousness, shaking or an upset stomach. Very few people may get panic attacks, seeing or hearing things that are not really there (hallucinations), unusual perceptions such as itching, tingling and numbness, and ringing in the ears (tinnitus). Further unusual CNS symptoms, e.g. confusion, delusions, change of perception of the own personality (depersonalisation), and change in perception of reality (derealisation) and delusion of persecution (paranoia) have been seen very rarely. If you get any of these effects after stopping treatment with TRAMASPEN SR, please talk to your doctor.

4. Possible side effects

TRAMASPEN SR can have side effects.

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

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

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching all over the body,
- Stevens-Johnson syndrome, toxic epidermal necrolysis
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to TRAMASPEN SR. 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:

- Mental and physical dependence or addiction to TRAMASPEN SR,
- chest pain, myocardial infarction
- fits (convulsions),
- hallucinations,
- changes in the way your heart beats (palpitations, tachycardia, bradycardia),

- severe stomach pain, which may reach to your back. This could be a sign of inflammation of your pancreas (pancreatitis),
- difficulty breathing (dyspnoea) in adults and children, worsening of asthma,
- difficulty passing urine (micturition disorders).

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:

- Dizziness, headache, sedation, vertigo, feeling very sleepy (somnolence)
- nausea, vomiting, difficulty passing stools, dry mouth, constipation, diarrhoea, abdominal pain,
- sweating, dermal reactions (e.g. pruritis, skin rash)
- feeling very tired (fatigue),
- dyspepsia,
- allergic reactions (e.g. dyspnoea, bronchospasm, wheezing, angioneurotic oedema), anaphylaxis,
- anorexia,
- depression,
- Fatigue, influenza-like illness, asthenia

Less frequent side effects:

- Changes in appetite,
- seeing or hearing things that are not really there (hallucinations), confusion, sleep disorders, anxiety, nightmares, changes in your mood (mostly feeling happy, occasionally irritated/unhappy), decreased/increased activity, restlessness, nervousness, changes in mental and sensory perception (errors in judgement, changes in senses and recognition, mental confusion (delirium),

- tingling or prickling in the fingers or toes (paraesthesia),
- uncontrollable rhythmic movement of one part or one limb of your body (tremor),
- uncontrollable muscle movements, loss of coordination of muscles, fainting (syncope),
- changes in the way you speak (speech disorders),
- blurred vision, constriction of the pupil in the eye (miosis), dilation of the pupil in the eye (mydriasis),
- high blood pressure,
- drop in blood pressure when standing up (postural hypotension),
- feeling the urge to vomit (retching),
- stomach discomfort, feeling pressure in the stomach, loose stools,
- skin inflammation/irritation (itchy, dry skin or rash),
- vesicles, cellulitis, dermatitis,
- increases in liver enzymes which show up in blood tests,
- Respiratory depression, dyspnoea, worsening of asthma, rhinorrhoea, nasal congestion, bronchospasm, respiratory depression in children,
- Muscle weakness, arthralgia, myalgia, joint stiffness or swelling, back pain,
- Paraesthesia, tremor, epileptiform convulsions, involuntary muscle contractions, abnormal coordination, syncope, speech disorders, hypaesthesia, amnesia, abnormal gait, abnormal sensation, trembling.

Side effects with an unknown frequency

- Low blood sugar levels (hypoglycaemia),
- serotonin syndrome
- hiccups

- upper respiratory tract infection such as bronchitis (cough, production of mucus, shortness of breath, fever).

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (whoumc.org) found on SAHPRA website.

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

By reporting side effects, you can help provide more information on the safety of TRAMASPEN SR.

5. How to store TRAMASPEN SR

Store all medicines out of reach of children.

Store at or below 25 °C.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

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 TRAMASPEN SR contains

The active substance in TRAMASPEN SR 100 mg is 100 mg tramadol hydrochloride.

The other ingredients are colloidal silicon dioxide, hypromellose, magnesium stearate, microcrystalline cellulose, Opadry II White (coating material).

Opadry II White contains hypromellose (E464), lactose monohydrate, macrogol (E1521), propylene glycol (E1520), talc (E553b), titanium dioxide (E171).

Contains sugar: Lactose monohydrate 2,52 mg

The active substance in TRAMASPEN SR 150 mg is 150 mg tramadol hydrochloride.

The other ingredients are colloidal silicon dioxide, hypromellose, magnesium stearate, microcrystalline cellulose, Opadry II Beige (coating material).

Opadry II Beige contains hypromellose (E464), iron oxide red (E172), lactose monohydrate, macrogol (E1521), propylene glycol (E1520), quinoline yellow aluminium lake (E104), talc (E553b), titanium dioxide (E171).

Contains sugar: Lactose monohydrate 2,52 mg

The active substance in TRAMASPEN SR 200 mg is 200 mg tramadol hydrochloride.

The other ingredients are colloidal silicon dioxide, hypromellose, magnesium stearate, microcrystalline cellulose, Opadry II Pink (coating material).

Opadry II Pink contains hypromellose (E464), iron oxide red (E172), iron oxide yellow (E172), lactose monohydrate, macrogol (E1521), propylene glycol (E1520), talc (E553b), titanium dioxide (E171).

Contains sugar: Lactose monohydrate 2,52 mg

What TRAMASPEN SR looks like and contents of the pack

TRAMASPEN SR 100 mg: Round, white coloured film-coated tablet debossed with "E95" on one side and plain on the other side.

TRAMASPEN SR 150 mg: Round, pale orange coloured film-coated tablet debossed with "E96" on one side and plain on the other side.

TRAMASPEN SR 200 mg: Round, brownish orange coloured film-coated tablet debossed with “E97” on one side and plain on the other side.

PVC/PVDC/Aluminium blisters or PVC/PE/PVDC/Aluminium blisters with 10 tablets per blister strip.

TRAMASPEN SR 100 mg and 150 mg:

1, 3, 6 or 10 blister strips and a package insert are packed in a carton. Pack sizes of 10, 30, 60 or 100 tablets.

TRAMASPEN SR 200 mg:

6 blister strips and a package insert are packed in a carton. Pack size of 60 tablets.

Not all packs or pack sizes may be marketed.

Holder of Certificate of Registration

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TRAMASPEN SR 100 mg - 51/2.9/2000

TRAMASPEN SR 150 mg - 51/2.9/2001

TRAMASPEN SR 200 mg - 51/2.9/2002

Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088