

1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S5

TRAMASPEN CO 37,5 mg/325 mg film-coated tablets

Tramadol hydrochloride 37,5 mg and paracetamol 325 mg

Sugar free

Contains 0,122 mmol to 0,182 mmol of sodium

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

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

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

TRAMASPEN CO contains tramadol and paracetamol.

Tramadol is a painkiller belonging to the class of the opioids that acts on the central nervous system. It is used for the management of moderate to moderately severe pain.

Paracetamol, the other active substance, has centrally acting analgesic effects.

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

Do not take TRAMASPEN CO:

- If you are allergic to tramadol, paracetamol, any of the other ingredients mentioned in section 6, or other opioids such as codeine.
- If you are suffering from acute alcohol poisoning.
- If you are taking sleeping pills, pain relievers or medicines that affect mood and emotions.
- If you are also taking medicines such as tranylcypromine and moclobemide or have taken them in the last 14 days before treatment with TRAMASPEN CO. These medicines are used to treat depression and belong to a group called monoamine oxidase inhibitors (MAOIs).
- If you have a severe liver disorder.
- TRAMASPEN CO must not be used for narcotic (an addictive substance) withdrawal treatment.
- You should not take TRAMASPEN CO if you suffer from severe breathing problems.
- You should not take TRAMASPEN CO if you are suffering from increased intracranial pressure or central nervous system depression, which are characterised by decreased rate of breathing, decreased heart rate, and loss of consciousness.

- You should not take TRAMASPEN CO if you have fits that are not controlled.

Warnings and precautions

Take special care with TRAMASPEN CO:

- If you take other medicines containing paracetamol or tramadol.
- If you have liver problems or disease as your eyes and skin may turn yellow, which may suggest jaundice.
- If you have kidney problems.
- If you have recently suffered from a head injury, shock or severe headaches associated with vomiting (being sick).
- If you are dependent on any other medicines (for example morphine).
- If you have epilepsy or have experienced fits or seizures.
- Tramadol, as contained in TRAMASPEN CO, exerts its effect by converting (metabolising) into its active component. If you convert (metabolise) tramadol, as contained in TRAMASPEN CO, to this active component more rapidly and completely than other patients, you are known as an ultra-rapid metaboliser. This means you are more likely to have serious side effects, such as breathing difficulties, with slow or shallow breathing. If you experience these types of side effects, stop taking TRAMASPEN CO and consult with your doctor immediately.
- If you abruptly stop treatment with TRAMASPEN CO you may suffer from panic attacks, severe anxiety (feeling nervous or worried), hallucinations (hearing or seeing things that are not there), paraesthesia (burning or prickling sensation that is usually felt in the hands, arms, legs, or feet) and tinnitus (ringing or buzzing in the ears).

Your doctor will gradually decrease your dose of TRAMASPEN CO to prevent these side effects from occurring.

- TRAMASPEN CO contains paracetamol. If you are allergic to paracetamol, you may break out in a severe skin rash after you take TRAMASPEN CO. You should stop using TRAMASPEN CO at the first appearance of a skin rash or any other sign of allergy.
- TRAMASPEN CO should not be taken with alcohol containing beverages.
- While taking TRAMASPEN CO 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 CO, consult your doctor immediately.
- If you suffer from sleep-related breathing disorders, take special care when taking TRAMASPEN CO.

Talk to your doctor if you develop a craving for TRAMASPEN CO.

Other medicines and TRAMASPEN CO

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

TRAMASPEN CO should not be administered with the following:

- A group of antidepressants called Monoamine Oxidase (MAO) Inhibitors (such as moclobemide and tranylcypromine). When taken together with TRAMASPEN CO it can cause diarrhoea, tachycardia (irregular heartbeat), hyperhidrosis (excessive sweating), trembling, confusional state, even coma.
- Carbamazepine (used to treat seizures). When taken together with TRAMASPEN CO it can cause reduced efficacy and shorter duration due to decreased concentration of tramadol.
- Buprenorphine, nalbuphine or pentazocine (opioid-type pain relievers). The effects of these medicines may be decreased.

Caution is advised when the following medicines are given with TRAMASPEN CO:

- Tramadol, as contained in TRAMASPEN CO, can induce convulsions and increase the potential for certain antidepressants such as citalopram, escitalopram, paroxetine, duloxetine, venlafaxine and amitriptyline, antipsychotics and seizure threshold- lowering medicinal products (such as bupropion, mirtazapine, tetrahydrocannabinol) to cause convulsions.
- Concomitant therapeutic use of tramadol, as contained in TRAMASPEN CO, and citalopram, escitalopram, paroxetine, duloxetine, venlafaxine and amitriptyline, moclobemide and tranylcypromine and mirtazapine may cause serotonin toxicity. Symptoms include involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38 °C.
- If you are taking other pain relievers such as morphine and codeine (also as cough medicine), baclofen (a muscle relaxant), medicines used

to lower blood pressure, or medicines to treat allergies as well as sedative medicines such as benzodiazepines (alprazolam, diazepam, lorazepam) or related medicines with TRAMASPEN CO as there is an increased risk of drowsiness, difficulties in breathing (respiratory depression), coma which may be life-threatening.

- If you are taking warfarin (for blood thinning). The effectiveness of this medicine may be altered, and bleeding may occur.
- If you are taking digoxin used to treat heart problems.
- If you are taking diflunisal used for pain.
- If you are taking ondansetron used to treat vomiting.

TRAMASPEN CO with food and drink

Do not drink alcohol during treatment with TRAMASPEN CO as the effects of TRAMASPEN CO and alcohol may intensify each other.

Pregnancy, breastfeeding and fertility

TRAMASPEN CO must not be taken during pregnancy.

TRAMASPEN CO must not be taken during breastfeeding since there is no information available regarding safety during breastfeeding.

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

Do not drive while taking this medicine until you know how it affects you.

TRAMASPEN CO can affect your ability to drive as it may make you sleepy or dizzy.

If you feel drowsy while taking TRAMASPEN CO, do not drive, use tools or use machinery.

This medicine contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially 'sodium free'.

3. How to take TRAMASPEN CO

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

Always take TRAMASPEN CO exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. Your doctor will tell you how long your treatment with TRAMASPEN CO will last. If you have the impression that the effect of TRAMASPEN CO is too strong or too weak, talk to your doctor or pharmacist.

- Swallow the tablets whole with sufficient liquid.
- Do not break or chew the tablets

Adults:

The recommended dosage is 1 or 2 tablets every 4 to 6 hours, unless otherwise prescribed by your doctor. If required, further doses may be taken, as instructed by your doctor.

Do not take more than 8 tablets per day.

If you take more TRAMASPEN CO 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.

Immediate medical advice should be sought in the event of an overdose even if you feel well, because of the risk of delayed, serious liver damage from too much paracetamol, as contained in TRAMASPEN CO. Your kidneys can also become damaged in the absence of liver damage.

If you forget to take TRAMASPEN CO

If you forgot to take a dose, take it as soon as you remember unless it is nearly time for your next dose. Do not take a double dose to make up for forgotten individual doses.

If you stop taking TRAMASPEN CO

Withdrawal symptoms may occur if TRAMASPEN CO is discontinued abruptly. You may experience anxiety, nervous excitement, difficulty sleeping, excessive abnormal movements, tremor and gastrointestinal symptoms.

Other symptoms that have very rarely been seen if tramadol hydrochloride, as contained in TRAMASPEN CO, is discontinued abruptly include: panic attacks, severe anxiety, hallucinations, tingling or prickling sensation and ringing in the ears.

4. Possible side effects

TRAMASPEN CO can have side effects.

Not all side effects reported for TRAMASPEN CO are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking TRAMASPEN CO, please consult your healthcare provider for advice.

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

- Rash or itching all over the body.

- Allergic reactions along with breathing problems or closing of the throat.
- Increased bleeding time.

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

The following side effects occur frequently:

- Irregular heartbeat that is rapid and more pronounced than usual.
- Elevated liver enzymes, resulting in abdominal pain, dark urine, pale stools, weakness and fatigue.
- Severe stomach pain, which may reach to your back. This could be a sign of inflammation of your pancreas (pancreatitis).

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:

- Confusional state, sleep disorders, mood changes (anxiety, nervousness, feeling of high spirits);
- dizziness, excessive sleepiness;
- headache, trembling;
- nausea, vomiting, constipation, dry mouth, diarrhoea, stomach pain, indigestion, stomach gas.

Less frequent side effects:

- Depression, seeing, hearing, smelling, tasting or imagining things, nightmares;
- involuntary muscular contractions, tingling or prickling sensation, loss of memory;

- ringing in the ears;
- rapid, strong, or irregular heartbeat, very fast heartbeat, dysrhythmia;
- difficulty swallowing, blood in faeces;
- confused thinking and reduced awareness of the environment (delirium);
- chills;
- chest pain;
- problems with urination;
- difficulty breathing;
- increase in blood pressure, hot flushes;
- low blood sugar;
- drug dependence;
- mental confusion and emotional disruption;
- convulsions, fainting;
- slurred speech, stumbling, convulsions, syncope, speech disorders;
- vision blurred, constriction of the pupil (miosis);
- excessive dilation of the pupils (mydriasis).

In addition, the following side effects have been reported by people using medicines that contain only tramadol or only paracetamol:

- Feeling faint when getting up from a lying or sitting position, slow heart rate, fainting;
- changes in appetite;
- muscle weakness, slower or weaker breathing;
- mood changes, changes in activity, changes in perception;
- worsening of existing asthma.

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. This includes any possible side effects not listed in this leaflet. You can also report side effects to:

SAHPRA: via the “6.04 Adverse Drug Reactions Reporting Form”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>

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 this medicine.

5. How to store TRAMASPEN CO

Store all medicines out of reach of children.

Store at or below 25 °C.

Keep the blisters in the carton until required for use.

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 CO contains

The active substance is 37,5 mg of tramadol hydrochloride and 325 mg of paracetamol per tablet.

The other ingredients are hypromellose, iron oxide yellow, macrogol, magnesium stearate, microcrystalline cellulose, polysorbate, pregelatinised starch, sodium starch glycolate, titanium dioxide.

Sugar free.

What TRAMASPEN CO looks like and contents of the pack

TRAMASPEN CO is a yellow coloured, elongated, film-coated tablet with “325” debossed on the one side and “37,5” debossed on the other side.

TRAMASPEN CO is packed in blister strips of white opaque PVC/PVDC film with aluminium foil lidding containing 10 tablets. 60 tablets are packed in an outer cardboard carton.

Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912

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Registration number



44/2.9/0880

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

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