1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S5

PROPRIETARY NAME AND DOSAGE FORM

TRAMASPEN 50 mg

Capsule

Read all of this leaflet carefully before you start taking/using/are given TRAMASPEN 50 mg

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- TRAMASPEN 50 mg 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 TRAMASPEN 50 mg CONTAINS

The active substance is tramadol hydrochloride.

The other ingredients are colloidal silicon dioxide, dibasic calcium phosphate dihydrate, gelatine, magnesium stearate, titanium dioxide (C. I. 77891).

Sugar free

WHAT TRAMASPEN 50 mg IS USED FOR

TRAMASPEN 50 mg belongs to a group of medicines called analgesics, commonly known as pain killers or pain relievers and is used in the management of moderate to moderately severe pain.

BEFORE YOU TAKE TRAMASPEN 50 mg

Do not take TRAMASPEN 50 mg

- If you have a history of being allergic (hypersensitive) to tramadol hydrochloride, or opioids.
- If you have recently taken alcohol, sleeping tablets, other strong pain killers or medicines to treat mental illness.
- If you are taking a monoamine oxidase inhibitor (MAOI) antidepressant or have used a MAOI antidepressant within the last two weeks.
- If you are being treated for substance abuse addictions.
- If you have a reduction in the level of respiratory function especially in the presence of cyanosis (a dark bluish or purplish discolouration of the skin and mucous membranes) and excessive bronchial secretions.
- If you have increased intracranial pressure (pressure within the skull) or central nervous depression due to head injury or brain disease.
- If you are pregnant, planning to become pregnant or are breastfeeding.

Take special care with TRAMASPEN 50 mg

- If you have a history of addiction, a morphine-type physical dependence may develop. A physical dependence may restart again with TRAMASPEN 50 mg, if you have had a previous dependency.

- If you have a history of epilepsy (fits) or are susceptible to seizures (e.g. if you are taking medicines for these seizures or other medicines that may increase the risk of seizures).
- If you have reduced kidney or liver function. Avoid if these conditions are severe.
- If you are taking TRAMASPEN 50 mg together with other central nervous system medicines it is likely to increase and prolong CNS effects.
- If you exceed the recommended dose or if other centrally depressant medicines are given at the same time, there is a possibility of decreased breathing ability.
- TRAMASPEN 50 mg should not be used for the treatment of minor pain.

Pregnancy and breastfeeding

You should not take TRAMASPEN 50 mg if you are pregnant or breastfeeding your baby.

The safety of TRAMASPEN 50 mg during pregnancy and whilst breastfeeding has not been established.

Always tell your healthcare provider if you are taking any other medicine. If you are pregnant or breastfeeding, please consult your healthcare provider for advice before taking/receiving TRAMASPEN 50 mg.

Driving and using machinery

Do not drive a car or operate any tools or machines while using TRAMASPEN 50 mg.

Taking other medicines with TRAMASPEN 50 mg

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

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

- Monoamine oxidase inhibitors (MAOIs): TRAMASPEN 50 mg should not be used at the same time as with MAOIs or within 14 days after stopping such treatment, because of its inhibitory effect on serotonin uptake.
- Central nervous system (CNS) depression-producing medications, including alcohol and anaesthetics: Caution is recommended because concurrent use may potentiate the CNS depressant effects. The duration of anaesthesia may be prolonged when TRAMASPEN 50 mg is combined with barbiturates.
- Carbamazepine: Serum concentrations of TRAMASPEN 50 mg are reduced by carbamazepine, resulting in decreased pain-relieving activity of TRAMASPEN 50 mg. Inhibitors of CYP3A4 such as ketoconazole (antifungal) and erythromycin (antibiotic) may reduce the metabolism of TRAMASPEN 50 mg.

HOW TO TAKE/USE/RECEIVE TRAMASPEN 50 mg

Always take TRAMASPEN 50 mg exactly as your doctor has instructed you.

You should check with your doctor or pharmacist if you are unsure.

Do not share your medication with any other person.

If you have the impression that the effect of TRAMASPEN 50 mg is too strong or too weak, talk to your doctor or pharmacist.

The dosage should be adjusted to the severity of your pain and your response to the pain relieving action of TRAMASPEN 50 mg. TRAMASPEN 50 mg should not be used for the treatment of minor pain.

Adults and children over the age of 14 years

Initial dose of 50 mg (one capsule), followed by 100 mg (two capsules) twice daily.

The dose may be increased to 150 mg or 200 mg (3 capsules or 4 capsules) twice daily.

Elderly

The usual doses may be used except in patients 75 years of age and over. A reduced dose and an increase in the interval between doses are recommended.

Kidney impairment

The elimination of TRAMASPEN 50 mg may be slowed. The usual initial dose should be used, but for patients with creatinine clearance < 30 ml/min, the time between doses should be increased to 12 hours.

Liver impairment

The elimination of TRAMASPEN 50 mg may be slowed. The usual initial dose should be used but in severe liver impairment, the time between doses should be increased to 12 hours.

Duration of treatment

Under no circumstances should TRAMASPEN 50 mg be given for longer than absolutely necessary. Your doctor will decide how long your treatment should be. He will examine you at regular intervals to decide if your treatment is to be prolonged.

If you take more TRAMASPEN 50 mg 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 pinpoint pupils, slow heartbeat, slow troubled breathing, weakness, seizures, cold clammy skin.

If you forget to take TRAMASPEN 50 mg

If you forget to take TRAMASPEN 50 mg do not take a double dose to make up for forgotten individual doses.

POSSIBLE SIDE EFFECTS

TRAMASPEN 50 mg can have side effects.

Not all side effects reported for TRAMASPEN 50 mg are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking TRAMASPEN 50 mg, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, stop taking TRAMASPEN 50 mg and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Feeling hot, itching, nausea, vomiting, swelling of the mouth, tongue and throat, causing an obstruction, wheezing and sudden drop in blood pressure. These reactions may occur after the first dose.
- Rapid swelling of the skin and subcutaneous tissue and constriction of the air passages. These reactions may occur after the first dose.
- Toxic Epidermal Necrolysis and Stevens-Johnson Syndrome (life-threatening allergic skin reaction) have been reported.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to TRAMASPEN 50 mg. 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:

- heart and blood vessels collapse
- confusion
- false perceptions
- seizures
- loss of memory
- slow heartbeat
- fast heartbeat
- difficult urination.

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

Tell your doctor if you notice any of the following:

The following side effects have been frequently reported:

- drowsiness
- dizziness
- headache
- nausea
- vomiting
- dry mouth
- heartburn
- constipation
- diarrhoea
- loss of appetite
- stomach pain

- skin rashes
- itching of the skin
- sweating (especially when IV administration is too rapid).

The following side effects have been reported less frequently:

- flushing
- fainting
- dizziness when getting up from a lying or sitting position
- numbness
- tingling pain, or weakness in hands or feet
- frequent urge to urinate
- blurred vision
- blisters under the skin
- redness, swelling, and itching of the skin.

The following side effects have been reported but the frequency is unknown:

- tiredness or sleepiness
- increase in liver enzymes.

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

STORING AND DISPOSING OF TRAMASPEN 50 mg

Store at or below 25 °C.

Protect from light, heat and moisture.

Keep in original packaging 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).

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

PRESENTATION OF TRAMASPEN 50 mg

20, 30, 50 or 100 capsules are packed in a white, opaque polyvinylchloride film sealed with an aluminium foil backing. There are 10 capsules per blister strip and one or more blister strips are packed in an outer cardboard carton together with a leaflet.

Not all pack sizes are necessarily marketed.

IDENTIFICATION OF TRAMASPEN 50 mg

White opaque hard gelatin capsules, containing a white odourless powder.

REGISTRATION NUMBER

42/2.9/0967

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

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912 (South Africa)

Tel: +27 11 239 6200 (Other)

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