PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S5

CEPATRESIC 37,5 / 325, Film-coated tablets

Tramadol hydrochloride / paracetamol

Sugar free

Read all of this leaflet carefully before you start taking CEPATRESIC 37,5 / 325

- 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.
- CEPATRESIC 37,5 / 325 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 CEPATRESIC 37,5 / 325 is and what it is used for

CEPATRESIC 37,5 / 325 is used to treat moderate to moderately-severe pain when your doctor recommends that a combination of tramadol hydrochloride and paracetamol is needed.

2. What you need to know before you take CEPATRESIC 37,5 / 325

Do not take CEPATRESIC 37,5 / 325:

- if you are hypersensitive (allergic) to tramadol hydrochloride, any other opioids such as codeine, paracetamol or any of the other ingredients (listed in section 6)
- in cases of acute alcohol poisoning
- if you are taking sleeping pills, pain relievers or medicines that affect mood and emotions
- to treat withdrawal symptoms caused by the stopping of narcotic medication such as morphine, codeine.
- if you struggle to breathe
- if you had a severe head injury or suffer from any brain disease
- if you have a liver disorder.
- if you are also taking medicines called monoamine oxidase inhibitors (MAOIs) or have taken MAOIs in the last 14 days before treatment with CEPATRESIC 37,5 / 325. MAOIs are used in the treatment of depression or Parkinson's disease.
- if you have epilepsy or suffer from seizures.
- Do not give CEPATRESIC 37,5 / 325 to children younger than 12 years old.
- Do not give CEPATRESIC 37,5 / 325 to children younger than 18 years old that have just had surgery to remove their tonsils or adenoids.

Warnings and precautions

Take special care with CEPATRESIC 37,5 / 325:

Talk to your doctor before taking CEPATRESIC 37,5 / 325

- if you take other prescription or over the counter medicines containing paracetamol or tramadol
- if you have kidney problems

- if you have liver problems. If you notice your eyes and skin turning yellow, this may suggest jaundice. Tell your doctor immediately.
- if you are dependent on alcohol or have previously suffered from alcohol abuse
- if you have severe difficulties in breathing, for example asthma or severe lung problems
- if you are dependent on any medicine (for example morphine)
- if you have epilepsy or have already experienced fits or seizures
- if you take other medicines to treat pain that contain buprenorphine, nalbuphine or pentazocine
- if you have previously had an allergic reaction to codeine or other opioid medicines
- if you are going to have an anaesthetic (tell your doctor or dentist that you are taking CEPATRESIC 37,5 / 325)
- if you experience symptoms of low sodium levels such as nausea, vomiting, headache, muscle cramps or weakness while taking CEPATRESIC 37,5 / 325
- CEPATRESIC 37,5 / 325 can cause low levels of oxygen in the blood and a problem called sleep apnoea (stopping breathing from time to time whilst sleeping). Tell your doctor if you have a history of sleep apnoea or if someone notices that you stop breathing while sleeping or you find yourself gasping for breath during sleep.

CYP2D6 ultra-rapid metabolisers

- Tramadol works by being converted (metabolised) into its active component. Some patients convert (metabolise) tramadol to this active component more rapidly and completely than other patients. If you are such a patient be aware and tell your doctor immediately if you experience difficulty breathing, sleepiness, confusion, nausea, vomiting, constipation or lack of appetite.

Drug abuse and Dependence

- Tramadol has the potential to be addictive, as a result addiction may develop with the long-term use of CEPATRESIC 37,5 / 325. Tell your doctor if you have an opioid addiction or a history of drug abuse.

Concomitant use of sedative medicines such as benzodiazepines

- Tell your doctor if you are taking any sleeping tablets used for anxiety as they may result in sleepiness, breathing problems, coma and death.

Withdrawal

- CEPATRESIC 37,5 / 325 should not be abruptly stopped, the dose should be gradually reduced. Symptoms such as panic attacks, severe anxiety, hallucinations, abnormal sensation for example 'pins and needles' and ringing in the ears may be experienced when CEPATRESIC 37,5 / 325 is suddenly stopped.

Serious skin reaction

A severe skin reaction may develop while taking CEPATRESIC 37,5 / 325.

Stop taking CEPATRESIC 37,5 / 325 and tell your doctor immediately if you experience skin rash, especially:

- A red rash covered with small pus-filled bumps that can spread over the body, sometimes with a fever (acute generalised exanthematous pustulosis);
- A life-threatening rash with blisters and peeling skin over much of the body (toxic epidermal necrolysis);
- A severe rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome);

If any of the above-mentioned points applied to you in the past or applies to you while you are taking CEPATRESIC 37,5 / 325, please make sure your medical practitioner knows. He/she can then decide whether you should continue to use this medicine.

Children and adolescents

CEPATRESIC 37,5 / 325 is not for use in children and adolescents under 16 years (see section 2).

CEPATRESIC 37,5 / 325 is not for use in children younger than 18 years old that have just had surgery to remove their tonsils or adenoids (see section 2).

Other medicines and CEPATRESIC 37,5 / 325

Always tell your healthcare provider if you are taking any other medicine.

(This includes all complementary or traditional medicines.)

You should not take CEPATRESIC 37,5 / 325 with:

- monoamine oxidase inhibitors (MAOIs) – medicines used to treat depression and Parkinson's disease
- carbamazepine (a medicine used to treat epilepsy or some types of pain)
- phenytoin, used to treat seizures
- buprenorphine, nalbuphine or pentazocine (opioid-type pain relievers)

The risk of side effects increases:

- If you are taking medicines that slow or reduce the conversion (metabolism) of this medicine to its active form (CYP2D6 inhibitors) such as fluoxetine, paroxetine, quinidine and amitriptyline, bupropion.

- if you are taking medicines to treat depression called selective serotonin re-uptake inhibitors (SSRIs) or serotonin-noradrenaline reuptake inhibitors (SNRIs) together with CEPATRESIC 37,5 / 325. Inform

your medical practitioner if you experience confusion, restlessness, fever, sweating, uncoordinated movement of limbs or eyes, uncontrollable jerking of muscles or diarrhoea.

- if you are taking medicines that slow down your central nervous system (CNS depressants) such as other pain relief medication (opioids) e.g., morphine and codeine (also as cough medicine), medication for anxiety, medication to sleep (e.g., benzodiazepines), antipsychotics, thalidomide (medication to treat certain types of cancer), baclofen (a muscle relaxant), medication that lower blood pressure, or medicines to treat allergies or alcohol. These medications reduce alertness and increase drowsiness.

- if you are taking medicines which may cause convulsions (fits), such as certain antidepressants (SSRIs, SNRIs, mirtazapine or bupropion) or antipsychotics. The risk of having a fit may increase if you take CEPATRESIC 37,5 / 325 at the same time. Your medical practitioner will tell you whether CEPATRESIC 37,5 / 325 is safe to take with these medicines.

- if you are taking warfarin (to prevent blood clots). The effectiveness of such medicines may be altered, and bleeding may occur.

The effectiveness of CEPATRESIC 37,5 / 325 may be altered if you also take:

- metoclopramide, domperidone or ondansetron (medicines used to treat nausea and vomiting/being sick).
- Diflunisal, may elevate paracetamol plasma levels.
- Antibiotics to treat infections, e.g., erythromycin, flucloxacillin, rifampin, linezolid.
- Antifungals used to treat fungal infections, e.g., ketoconazole.
- Anti-retrovirals used to treat HIV/AIDs, e.g., ritonavir.
- Cimetidine, used to treat heart burn and peptic ulcers.

CEPATRESIC 37,5 / 325 with food and alcohol

Do not drink alcohol while you are taking CEPATRESIC 37,5 / 325, as you may feel drowsier.

Pregnancy, breastfeeding and fertility

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 CEPATRESIC 37,5 / 325.

You should not take CEPATRESIC 37,5 / 325 if you are pregnant or breastfeeding your baby.

Driving and using machines

CEPATRESIC 37,5 / 325 may make you sleepy or dizzy. It may also affect your concentration and ability to drive safely.

It is not always possible to predict to what extent CEPATRESIC 37,5 / 325 may interfere with your daily activities. You should ensure that you do not engage in driving a vehicle or use machines until you are aware of the measure to which CEPATRESIC 37,5 / 325 affects you.

CEPATRESIC 37,5 / 325 contains sodium.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

3. How to take CEPATRESIC 37,5 / 325

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

Always take CEPATRESIC 37,5 / 325 exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Do not exceed the maximum daily doses of paracetamol or tramadol from this or other medicines.

In general the lowest pain-relieving dose should be taken.

Take CEPATRESIC 37,5 / 325 for as short a time as possible and no longer than your doctor has told you.

Do not take more than the dose prescribed by your doctor.

Adults and adolescents over 12 years

The usual dose is 1 to 2 tablets every 4 to 6 hours as required for pain relief.

The shortest time between doses must be at least 4 hours.

Do not take more than 8 tablets per day.

Not for use in children under 16 years of age

Severe kidney disease (insufficiency)/dialysis patients

Patients with severe kidney insufficiency should not take CEPATRESIC 37,5 / 325. If in your case the insufficiency is mild or moderate, your doctor may recommend prolonging the dosage interval. Do not exceed 2 tablets every 12 hours.

Method of administration

The tablets are for oral use.

Swallow the tablets whole with sufficient liquid.

Do not break or chew the tablets.

The tablets may be taken with or without food.

Your medical practitioner will tell you how long your treatment with CEPATRESIC 37,5 / 325 will last. If you have the impression that the effect of CEPATRESIC 37,5 / 325 is too strong or too weak, tell your healthcare provider.

If you take more CEPATRESIC 37,5 / 325 than you should

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

If you forget to take CEPATRESIC 37,5 / 325

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

If you stop taking CEPATRESIC 37,5 / 325

Generally, there will be no after-effects when treatment with CEPATRESIC 37,5 / 325 is stopped. People who have been using a medicine containing tramadol may become dependent on it, making it hard to stop taking it. If you have been taking CEPATRESIC 37,5 / 325 for some time and want to stop, contact your medical practitioner because your body may have become used to CEPATRESIC 37,5 / 325.

If you experience

- feel agitated, anxious, nervous or shaky, panic attacks
- restlessness
- difficulty sleeping
- hallucinations, unusual perceptions such as itching, tingling and numbness
- ringing in the ears.

After stopping this medicine, please contact your medical practitioner. Other side effect information is listed in section 4.

4. Possible side effects

CEPATRESIC 37,5 / 325 can have side effects.

Not all side effects reported for CEPATRESIC 37,5 / 325 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CEPATRESIC 37,5 / 325, please consult your healthcare provider for advice.

If any of the following happens, stop taking CEPATRESIC 37,5 / 325 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
- convulsions and fainting

These are all very serious side effects. If you have them, you may have had a serious reaction to CEPATRESIC 37,5 / 325. 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:

- Diarrhoea, vomiting, muscle spasms, high body temperature, sweating, shivering, clumsiness, tremors, confusion and other mental changes
- difficulty breathing
- flu-like symptoms appear first and a painful rash that spreads and blisters follows (Stevens-Johnson syndrome)

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

- nausea
- vomiting, constipation, flatulence, diarrhoea, stomach pain, dry mouth, indigestion
- dizziness, headache, tiredness, shaking
- confusion, sleep disorders, mood changes (anxiety, nervousness, feeling of intense excitement), loss of appetite
- excessive sweating
- physical weakness, lack of energy, hot flushes.

Less frequent side effects

- weakness and fatigue due to anaemia (a decrease in number of red blood cells (RBCs) or less than the normal quantity of haemoglobin in the blood)
- increase in pulse or blood pressure, heart rate or heart rhythm disorders, decrease in blood pressure
- vision blurred, constriction of the pupil (miosis)
- excessive dilation of the pupils (mydriasis)
- abnormal vision
- ringing in the ears, feeling of spinning
- difficulty swallowing, blood in the stools, swollen tongue
- chills, chest pain
- changes in appetite
- muscle weakness
- changes that show up in blood tests of the liver

- respiratory depression
- serious skin reactions
- weight loss
- tingling, numbness or feeling of pins and needles in the limbs, involuntary muscle contractions, memory loss, difficulty with balance
- speech disorders
- stiff muscles, aggravated migraine, unresponsiveness, feeling of spinning
- depression, nightmares, hallucinations (hearing, seeing or sensing things that are not really there)
- confused thinking and reduced awareness of the environment
- drug dependence
- impotence
- difficulty, or pain in passing urine
- chest pain, sudden feeling of cold with shivering accompanied by a rise in temperature, withdrawal syndrome.

Side effects with unknown frequency

- decrease in blood sugar level (hypoglycaemia) with symptoms such as feeling shaky, sweating, fast heartbeat, dizziness, hunger, irritability, confusion, blurry vision, weakness and headache.
- feeling faint when getting up from a lying or sitting position, slow heart rate
- thoughts of hurting yourself
- 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. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of CEPATRESIC 37,5 / 325.

5. How to store CEPATRESIC 37,5 / 325

Store all medicine out of reach of children.

Store at or below 25 °C.

Do not use the tablets after the expiry date shown on the container.

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 CEPATRESIC 37,5 / 325 contains

The active ingredients are tramadol hydrochloride and paracetamol.

The other ingredients are:

Tablet core:

Pregelatinised starch, powdered cellulose, sodium starch glycolate (Primogel), maize starch, sodium starch glycolate and magnesium stearate.

Tablet coating: Opadry yellow 15B32209 consisting of:

Hydropropyl methylcellulose 2910 3cp, Hydropropyl methylcellulose 2910 6cp, titanium dioxide, polyethylene glycol 400, iron oxide yellow and polysorbate 80.

What CEPATRESIC 37,5 / 325 looks like and contents of the pack

Tramadol hydrochloride and paracetamol 37,5 mg/325 mg film-coated tablets are light yellow, capsule shaped, biconvex film coated tablets embossed with ‘C8’ on one side and plain on other side.

CEPATRESIC 37,5 / 325 is packaged as follows:

Opaque PVC/Alu blister in an outer carton.

The blister pack of 10 tablets is packed into an outer carton.

Pack sizes: 2, 10, 20, 30, 40, 50, 60, 70, 80, 90 and 100 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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