PATIENT INFORMATION LEAFLET FOR

PARACETAMOL/TRAMADOL CIPLA

SCHEDULING STATUS: **S5**

PARACETAMOL/TRAMADOL 325 mg/37,5 mg CIPLA, tablets

PARACETAMOL/TRAMADOL 650 mg/75 mg CIPLA, tablets

Paracetamol / Tramadol hydrochloride

Sugar free

Read all of this leaflet carefully before you start taking PARACETAMOL/TRAMADOL

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- PARACETAMOL/TRAMADOL CIPLA 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 is PARACETAMOL/TRAMADOL CIPLA and what is it used for
2. What you need to know before you take PARACETAMOL/TRAMADOL CIPLA

3. How to use PARACETAMOL/TRAMADOL CIPLA

4. Possible side effects

5. How to store PARACETAMOL/TRAMADOL CIPLA

6. Contents of the pack and other information

1. What is PARACETAMOL/TRAMADOL CIPLA and what is it used for

PARACETAMOL/TRAMADOL CIPLA belongs to a class of medicines known as analgesics or painkillers. It is used to treat moderate to moderately severe pain in adults.

PARACETAMOL/TRAMADOL CIPLA is not recommended for minor pain that may be treated adequately through lesser means. Your doctor will decide whether you qualify for treatment with PARACETAMOL/TRAMADOL CIPLA.

PARACETAMOL/TRAMADOL CIPLA contains a combination of two active ingredients, namely tramadol and paracetamol.

2. What you need to know before you take PARACETAMOL/TRAMADOL CIPLA

Do not take PARACETAMOL/TRAMADOL CIPLA

- if you are allergic (hypersensitive) to tramadol, paracetamol, or other opioid painkillers, such as codeine, or to any of the inactive ingredients of PARACETAMOL/TRAMADOL CIPLA (listed in **section 6**).
- if you have moderate to severe reduced liver function (see **Take special care with PARACETAMOL/TRAMADOL CIPLA**). Please ask your doctor if you are not sure.
- if you have also taken alcohol, sleeping tablets, tranquilizers, sedatives, painkillers, opioids or psychiatric medicines. Please speak to your doctor or pharmacist if you are

unsure.

- if you are taking monoamine oxidase inhibitors (MAOIs), e.g. moclobemide or selegiline, for the treatment of depression, anxiety, Parkinson's disease, or dementia; or if it is less than two weeks since you have stopped taking any of these medicines (see **Taking other medicines with PARACETAMOL/TRAMADOL CIPLA).**
- if you have trouble breathing, especially in the presence of bluish discolouration of the skin and excessive mucus secretions in the lungs.
- if you have been diagnosed with increased brain pressure or have a brain disease.
- if you have epilepsy or suffer from seizures.
- Do not give PARACETAMOL/TRAMADOL CIPLA to a child under 12 years of age.
- Do not give PARACETAMOL/TRAMADOL CIPLA to a child under 18 years of age that has just had an operation to remove their tonsils or adenoids.

Warnings and precautions

This product contains paracetamol, which may be fatal in overdose. In the event of overdosage or suspected overdose and notwithstanding the fact that the person may be asymptomatic, the nearest doctor, hospital or poison centre must be contacted immediately.

Do not take more than your recommended dose.

Tell your doctor or health care provider before taking PARACETAMOL/TRAMADOL CIPLA:

- if you have ever had an allergic reaction (characterised by significant skin rash, itching, hives, difficulty breathing, and/or swollen face) while taking codeine or other opioids.

- if you take other medicines containing paracetamol or tramadol.
- if you have liver problems or disease as PARACETAMOL/TRAMADOL CIPLA may not be recommended for you.
- if you have kidney problems.
- if you have severe difficulties in breathing, for example asthma or severe lung problems.
- if you have epilepsy or have already experienced fits or seizures.
- if you are taking any other medicine, because taking some medicines together with PARACETAMOL/TRAMADOL CIPLA may increase your risk of fits (seizures).
- if you use sedatives, tranquilisers, sleeping pills, medicines for pain relief, anaesthetics or if you drink alcohol.
- if you are dependent on alcohol or have a history of alcohol abuse.
- if you suffer from increased pressure in the brain (possibly after a head injury or brain disease).
- if you are taking flucloxacillin.
- if you have recently suffered from a head injury, shock or severe headaches associated with vomiting (being sick).
- if you are dependent on any opioid painkillers (for example morphine).
- if you take other medicines to treat pain that contain buprenorphine, nalbuphine or pentazocine.
- if you are going to have an anaesthetic (tell your doctor or dentist that you are taking PARACETAMOL/TRAMADOL CIPLA).
- if you have a personal or family history of mental health disorders or substance abuse as PARACETAMOL/TRAMADOL CIPLA contains tramadol which may predispose you to an increased risk of drug misuse and abuse.

If you use PARACETAMOL/TRAMADOL CIPLA over the long-term, you may become dependent on (addicted to) the tramadol it contains. You may crave PARACETAMOL/TRAMADOL CIPLA even in the absence of pain, while you may have to use higher doses to get the same effect. If you have been diagnosed with addiction to opioid medicines or drugs (e.g. heroin, morphine, codeine), you should not use PARACETAMOL/TRAMADOL CIPLA. Please inform your doctor.

If you have used PARACETAMOL/TRAMADOL CIPLA for an extended period, you may experience withdrawal symptoms if you abruptly stop taking it. You may develop panic attacks, severe anxiety, hear or see things that are not real, experience pins and needles, or ringing in the ears. Ask your doctor or pharmacist for advice about slowly reducing the dose of PARACETAMOL/TRAMADOL CIPLA to prevent withdrawal symptoms.

If you combine PARACETAMOL/TRAMADOL CIPLA with other medicines that influence serotonin levels in the body, you may develop serotonin syndrome. Please see **Taking other medicines with PARACETAMOL/TRAMADOL CIPLA** for a list of medicines that you should not combine with PARACETAMOL/TRAMADOL CIPLA. If you develop loose stools, fever, agitation, sweating, confusion, shivering, a rapid heart rate, excitation, or alteration in consciousness, stop taking PARACETAMOL/TRAMADOL CIPLA and immediately report to your doctor.

If any of these applies to you, tell your doctor or nurse before you are given PARACETAMOL/TRAMADOL CIPLA.

Serious skin reactions have been reported with PARACETAMOL/TRAMADOL CIPLA. You should stop taking PARACETAMOL/TRAMADOL CIPLA and seek medical attention

immediately, if you develop any skin rash, lesions of the mucous membranes, blisters or other signs of allergy since this can be the first signs of a very serious skin reaction.

Some patients taking PARACETAMOL/TRAMADOL CIPLA may experience low levels of sodium in the blood (hyponatraemia). Symptoms of low blood sodium 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 get any of these symptoms while taking PARACETAMOL/TRAMADOL CIPLA, consult with your doctor immediately.

PARACETAMOL/TRAMADOL CIPLA 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 anyone notices you stop breathing from time to time whilst sleeping.

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. These patients 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 PARACETAMOL/TRAMADOL CIPLA and consult with your doctor immediately.

Opioid painkillers can sometimes cause a temporary problem with your adrenal glands, which are responsible for producing important hormones (adrenal insufficiency). This may require

monitoring or possibly taking medicines (glucocorticoids) to replace the missing hormones. Symptoms of adrenal insufficiency may include severe abdominal pain, feeling sick (nausea and vomiting), low blood pressure, extreme tiredness, decreased appetite and weight loss.

Children and adolescents

PARACETAMOL/TRAMADOL CIPLA can only be used in children 16 years of age and older.

Other medicines and PARACETAMOL/TRAMADOL CIPLA

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

It is particularly important that you mention the following:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of PARACETAMOL/TRAMADOL CIPLA with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines as PARACETAMOL/TRAMADOL CIPLA may affect how well they work:

- Monoamine Oxidase Inhibitors (MAOIs) or Selective Serotonin Reuptake Inhibitors (SSRI's), used to treat depression or Parkinson's Disease,
- medicines used to treat depression, e.g. mirtazapine, tricyclic antidepressants, trazadone,
- triptans, used to treat migraines,

- 5-HT3 receptor antagonists, used to treat nausea and vomiting such as ondansetron,
- medicines that slow down your central nervous system (CNS depressants) such as sedatives, sleeping pills, medicines for surgery (anaesthetics), tranquilisers (benzodiazepines), medicines used to treat certain mental conditions (psychotropic medicines), some strong painkillers (opioids), or alcohol,
- carbamazepine, used to treat epilepsy and some types of pain,
- phenytoin, used to treat seizures,
- quinidine, used to treat heart conditions (antiarrhythmics),
- warfarin like compounds, used to stop blood clotting (blood thinners),
- medicines that slow or reduce the conversion (metabolism) of this medicine to its active form (CYP2D6 inhibitors) such as fluoxetine, paroxetine, amitriptyline and bupropion,
- cimetidine, used to treat heart burn and peptic ulcers,
- antibiotics to treat infections, e.g. erythromycin, rifampin, linezolid, flucloxacillin,
- antifungals used to treat fungal infections, e.g. ketoconazole,
- anti-retrovirals used to treat HIV/AIDs, e.g. ritonavir,
- medicines which decrease the analgesic effect such as buprenorphine, nalbuphine, pentazocine.

PARACETAMOL/TRAMADOL CIPLA with food, drink and alcohol

Do not drink alcohol during treatment with PARACETAMOL/TRAMADOL CIPLA as the effects of PARACETAMOL/TRAMADOL CIPLA and alcohol may intensify each other.

You may take PARACETAMOL/TRAMADOL CIPLA at any time of the day with or without food.

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 health care provider for advice before taking PARACETAMOL/TRAMADOL CIPLA.

The safe use of PARACETAMOL/TRAMADOL CIPLA has not been demonstrated in pregnant and breastfeeding women. PARACETAMOL/TRAMADOL CIPLA is thus not recommended for pregnant and breastfeeding mothers, as small amounts of tramadol may pass into breast milk.

Opioid medicines can slow the breathing of a newborn child

Prolonged use of PARACETAMOL/TRAMADOL CIPLA during pregnancy can cause withdrawal symptoms in your newborn baby that could be life-threatening if not recognised and treated. The risk is increased in the last trimester of pregnancy.

Driving and using machines

PARACETAMOL/TRAMADOL CIPLA may cause drowsiness or dizziness and may affect your reactions to the extent that your ability to drive and operate machinery may be impaired. This is enhanced if you are taking PARACETAMOL/TRAMADOL CIPLA with other psychiatric medicines and/or alcohol (see **Taking other medicines with PARACETAMOL/TRAMADOL CIPLA**). Do not drive a car or operate machinery until you know how PARACETAMOL/TRAMADOL CIPLA affects you.

It is not always possible to predict to what extent PARACETAMOL/TRAMADOL CIPLA 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 PARACETAMOL/TRAMADOL CIPLA affects them.

3. How to take PARACETAMOL/TRAMADOL CIPLA

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

Always take PARACETAMOL/TRAMADOL CIPLA exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

PARACETAMOL/TRAMADOL CIPLA should only be used by adults and children over 16 years of age.

DO NOT EXCEED THE RECOMMENDED DOSE.

The usual dose is:

For the management of pain, the recommended dose for adults and adolescents (16 years and older) is:

- PARACETAMOL/TRAMADOL 325 mg/37,5 mg CIPLA: 1 or 2 tablets every 4 to 6 hours, as needed for pain relief, up to a maximum of 8 tablets per day.
- PARACETAMOL/TRAMADOL 650 mg/75 mg CIPLA: ½ or 1 tablet every 4 to 6 hours, as needed for pain relief, up to a maximum of 4 tablets per day.

Your doctor may decide to start you on a lower dose of PARACETAMOL/TRAMADOL CIPLA and to increase the dose over several days.

Impaired kidney function

Please inform your doctor if you have been diagnosed with kidney disease or reduced kidney function, since you may need to wait 12 hours between PARACETAMOL/TRAMADOL CIPLA doses. If you have severely reduced kidney function (creatinine clearance < 10 mL/min), your doctor will not prescribe PARACETAMOL/TRAMADOL CIPLA for you (see **Take special care with PARACETAMOL/TRAMADOL CIPLA**).

Impaired liver function

Please speak to your doctor if you have liver disease as you may require less frequent dosing of PARACETAMOL/TRAMADOL CIPLA. If you have moderate to severe impaired liver function, you should not take PARACETAMOL/TRAMADOL CIPLA (see **Do NOT take PARACETAMOL/TRAMADOL CIPLA**).

If you have the impression that the effect of PARACETAMOL/TRAMADOL CIPLA is too strong or too weak, please discuss this with your doctor or pharmacist.

If you take more PARACETAMOL/TRAMADOL CIPLA than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, immediately seek help at the nearest hospital or poison control centre.

Prompt treatment is essential if you have taken more PARACETAMOL/TRAMADOL CIPLA than you should have. A delay in starting treatment may mean that the antidote is given too late to be effective. Even if you feel well after having taken more PARACETAMOL/TRAMADOL CIPLA than you should have, you should still seek medical assistance as there is a risk of delayed, serious liver damage.

Breathing difficulties with slow or shallow breathing and/or fits (seizures), irritation and discomfort in the stomach and gut, loss of appetite, nausea, vomiting, feeling unwell, unusually pale colour and sweating. Cases of abnormal electrical conduction in the heart (QT prolongation) have been reported.

Your doctor will take the necessary measures.

If you forget to use PARACETAMOL/TRAMADOL CIPLA

Always take PARACETAMOL/TRAMADOL CIPLA as prescribed. Do not take a double dose to compensate for the forgotten individual dose.

Effects when treatment with PARACETAMOL/TRAMADOL CIPLA is stopped

After using PARACETAMOL/TRAMADOL CIPLA for a long period, abruptly stopping treatment may cause withdrawal symptoms (see **Take special care with PARACETAMOL/TRAMADOL CIPLA**).

Your doctor will therefore reduce your dosage gradually.

People may:

• feel agitated, anxious, nervous or shaky

• be overactive

• have difficulty sleeping

• have stomach or bowel disorders

• panic attacks

• hallucinations, unusual perceptions such as itching, tingling and numbness

• ringing in the ears.

If you experience any of these complaints after stopping this medicine, please contact your

doctor.

4. Possible side effects

PARACETAMOL/TRAMADOL CIPLA can have side effects.

Not all side effects reported for PARACETAMOL/TRAMADOL CIPLA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking PARACETAMOL/TRAMADOL CIPLA please consult your health care provider for advice.

If any of the following happens, stop taking PARACETAMOL/TRAMADOL CIPLA 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,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to PARACETAMOL/TRAMADOL CIPLA. 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:

- difficulty breathing,

- skin rash or itching, which may include redness, hives (red, itchy bumps), blisters, pustules or peeling of the skin (toxic epidermal necrolysis) and bleeding in the lips, eyes, mouth, nose and genitals (toxic epidermal necrolysis or Stevens-Johnson Syndrome),
- a severe skin reaction known as DRESS syndrome can occur. Symptoms of DRESS include skin rash, swelling of lymph nodes and an increase of eosinophils (a type of white blood cells),
- a red, scaly widespread rash with bumps under the skin and blisters mainly localized on the skin folds, trunk and upper extremities accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis),
- a skin reaction that causes a rash to appear in the same location on the body each time the medicine is taken (fixed drug eruption [FDE]),
- drug-induced hypersensitivity syndrome (DIHS) (a severe reaction usually characterized by fever, rash and multiorgan failure).
- potentially life-threatening symptoms (mental status change, hyperreflexia, fever, shivering, tremor, seizures, coma) that can occur when antidepressants are taken with tramadol (serotonin 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 (being sick),
- digestion problems,

- constipation,
- flatulence,
- diarrhoea,
- stomach pain,
- dry mouth,
- dizziness,
- drowsiness,
- itching,
- sweating (hyperhidrosis),
- headache,
- shaking,
- confusional state, sleep disorders, mood changes (anxiety, nervousness, feeling of high spirits),
- trouble falling asleep or staying asleep (insomnia),
- anorexia (an eating disorder causing people to obsess about weight and what they eat),
- decreased muscle strength,
- tiredness,
- hot flushes.

Less frequent side effects

- increase in pulse or blood pressure,
- decrease in blood pressure,
- heart rate or heart rhythm disorders,
- tingling, numbness or feeling of pins and needles in the limbs,

- ringing in the ears,
- involuntary muscle twitching,
- muscle overactivity (hypertonia),
- migraine,
- aggravated migraine,
- a sudden internal or external spinning sensation (vertigo),
- a state of reduced consciousness and mental function where a person is unresponsive (stupor),
- depression,
- nightmares,
- hallucinations (hearing, seeing or sensing things that are not really there),
- drug dependence,
- delirium,
- depersonalisation (persistent feeling of observing oneself from outside one's body or having a sense that one's surroundings aren't real),
- rapid, extreme changes in mood or affect (emotional lability),
- impotence (inability to get and maintain and erection),
- abnormal thinking,
- memory lapses,
- difficulty swallowing,
- blood in the stools,
- tongue swelling (oedema),
- increase in liver enzyme values,
- liver test abnormalities,
- inflammation of the liver,

- weight decrease,
- presence of albumin in urine,
- difficulties or pain on passing urine,
- urination less than normal (oliguria),
- chills,
- shivering,
- withdrawal syndrome,
- pain in the chest,
- fits (seizures),
- uncoordinated movements,
- transient loss of consciousness (syncope),
- vision blurred,
- abnormal vision,
- constriction of the pupil (miosis),
- speech disorders,
- excessive dilation of the pupils (mydriasis),
- a condition where your body doesn't produce enough healthy red blood cells, or the red blood cells you have does not function properly (anaemia),

Side effects of which the frequency is unknown

- changes in appetite,
- muscle weakness, slower or weaker breathing,
- mood changes, changes in activity, changes in perception, suicidal tendencies,
- difficulty concentrating,

- worsening of existing asthma,
- bleeding in digestive system resulting in blood in your stool or vomit (gastrointestinal bleeding),
- nose bleeds or bleeding gums, which may result from a low blood platelet count,
- rare cases of respiratory depression have been reported with tramadol,
- decrease in blood sugar level (hypoglycaemia),
- hyponatraemia (low blood sodium),
- blood pressure drops suddenly when standing up (postural hypotension) which results in feeling faint,
- slower than normal heart rate (bradycardia),
- collapse,
- widening of blood vessels which can lower blood pressure (vasodilation),
- a condition that occurs when the heart muscle does not receive enough oxygen and blood (myocardial ischaemia),
- fluid build-up in your lungs (pulmonary oedema),
- alterations of warfarin effect, elevation of prothrombin times (blood taking longer than normal to clot),
- elevated creatinine levels,
- liver inflammation,
- liver failure,
- hiccups,
- condition where you have very few white blood cells (agranulocytosis).

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 (who-umc.org) found on the SAHPRA website, or to Cipla Medpro (Pty) Ltd. by e-mail: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free). By reporting side effects, you can help provide more information on the safety of PARACETAMOL/TRAMADOL CIPLA.

5. How to store PARACETAMOL/TRAMADOL CIPLA

Store at or below 25 ºC.

Store in a cool, dry place.

Store all medicines out of reach of children.

Store in the original container.

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

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 PARACETAMOL/TRAMADOL CIPLA contains

The active substances are a combination of two active ingredients, namely paracetamol and tramadol.

PARACETAMOL/TRAMADOL 325 mg/37,5 mg CIPLA:

Each tablet contains 325 mg paracetamol and 37,5 mg tramadol hydrochloride.

PARACETAMOL/TRAMADOL 650 mg/75 mg CIPLA:

Each tablet contains 650 mg paracetamol and 75 mg tramadol hydrochloride.

The other ingredients are:

colloidal anhydrous silica

magnesium stearate

povidone

pregelatinised maize starch

sodium potato starch glycollate (type A).

What PARACETAMOL/TRAMADOL CIPLA looks like and contents of the pack

PARACETAMOL/TRAMADOL 325 mg/37,5 mg CIPLA:

Carton containing 60 tablets packed either in 4 aluminium/polyethylene strips of 15 tablets each or 6 PVC/PVDC blister strips of 10 tablets each.

PARACETAMOL/TRAMADOL 650 mg/75 mg CIPLA:

Carton containing 30 tablets packed either in 3 aluminium/polyethylene strips or PVC/PVDC blister strips of 10 tablets each.

Holder of Certificate of Registration

CIPLA MEDPRO (PTY) LTD.

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Access to the corresponding Professional Information

To access corresponding Professional Information and translated Patient Information Leaflet, scan the QR Code below.

PLACE HOLDER: The QR Code to be generated and included after approval.