1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S5

Paracetamol/Tramadol 325 mg/37,5 mg Cipla TABLETS

Paracetamol/Tramadol 75 mg/650 mg Cipla TABLETS

Paracetamol / Tramadol

Sugar free

Read all of this leaflet carefully because it contains important information for you

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- 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 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 severely 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, 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 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, which is not adequately controlled by your current medicine.

Warnings and precautions

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

- 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 severe difficulties in breathing, for example asthma or severe lung problems
- if you have epilepsy or have already experienced fits or seizures
- if you have recently suffered from a head injury, shock or severe headaches associated with vomiting (being sick)
- if you are dependent on any medicine (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 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.

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.

PARACETAMOL/TRAMADOL CIPLA is not recommended to be taken with the following:

• carbamazepine (a medicine used to treat epilepsy or some types of pain).

• buprenorphine, nalbuphine or pentazocine (opioid-type pain relievers).

The risk of side effects increases:

• if you are taking triptans (used for migraine) or selective serotonin re-uptake inhibitors (SSRIs, used for depression). Check with your doctor if you experience confusion, restlessness, fever, sweating, uncoordinated movement of limbs or eyes, uncontrollable jerking of muscles or diarrhoea.

• 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. Check with your doctor if you feel drowsy or feel faint.

Concomitant use of PARACETAMOL/TRAMADOL CIPLA and sedative medicines such as benzodiazepines or related drugs increases the risk of drowsiness, difficulties in breathing

(respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible. However, if your doctor prescribes PARACETAMOL/TRAMADOL CIPLA together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor.

Please tell your doctor about all sedative medicines you are taking, and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

• if you are taking medicines which may cause convulsions (fits), such as certain antidepressants or antipsychotics. The risk of having a fit may increase if you take PARACETAMOL/TRAMADOL CIPLA at the same time. Your doctor will tell you whether PARACETAMOL/TRAMADOL CIPLA is suitable for you.

• if you are taking certain antidepressants. PARACETAMOL/TRAMADOL CIPLA may interact with these medicines and you may experience symptoms such as 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 blood thinning medicines as the effectiveness may be altered and bleeding may occur (see section 4).

The effectiveness of PARACETAMOL/TRAMADOL CIPLA may be altered if you also take:

• metoclopramide, domperidone or ondansetron (medicines used to treat nausea and vomiting/being sick)

• cholestyramine (medicine used to reduce cholesterol in the blood)

PARACETAMOL/TRAMADOL CIPLA with food and alcohol

Do not drink alcohol while you are taking PARACETAMOL/TRAMADOL CIPLA, as you may feel drowsier.

Pregnancy and breastfeeding

Do not take PARACETAMOL/TRAMADOL CIPLA if you are pregnant or breastfeeding your baby, since the tramadol in PARACETAMOL/TRAMADOL CIPLA may cross the placenta and is excreted in breast milk.

If you are pregnant or breastfeeding your baby while taking PARACETAMOL/TRAMADOL CIPLA, please consult your doctor, pharmacist or other healthcare professional for advice.

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 applies particularly 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.

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 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 severely 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 you should

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. 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.

If you forget to use PARACETAMOL/TRAMADOL CIPLA

Always take PARACETAMOL/TRAMADOL CIPLA as prescribed. If you miss a dose, take it as soon as you remember. If you do not remember the missed dose until the next dose is due, skip the missed dose and go back to your regular dosing schedule. 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.

Very few people may also get:
• 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 / using 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:

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
- dizziness, drowsiness
- vomiting (being sick), digestion problems
- (constipation, flatulence, diarrhoea), stomach pain, dry mouth
- itching, sweating (hyperhidrosis)
- headache, shaking
- confusional state, sleep disorders, mood changes (anxiety, nervousness, feeling of high spirits).

Less Frequent side effects:

- increase in pulse or 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
- depression, nightmares, hallucinations (hearing, seeing or sensing things that are not really there), memory lapses
- difficulty breathing
- allergic (hypersensitive) reactions
- difficulty swallowing, blood in the stools
- severe skin reactions (for example rashes, hives)
- increase in liver enzyme values
- presence of albumin in urine, difficulties or pain on passing urine

- shivering, hot flushes, pain in the chest
- fits (seizures), uncoordinated movements, transient loss of consciousness (syncope)
- drug dependence
- delirium
- vision blurred, constriction of the pupil (miosis)
- speech disorders
- excessive dilation of the pupils (mydriasis)

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
- worsening of existing asthma
- nose bleeds or bleeding gums, which may result from a low blood platelet count.
- very rare cases of serious skin reactions have been reported with paracetamol.
- rare cases of respiratory depression have been reported with tramadol.
- decrease in blood sugar level (hypoglycaemia)

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

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 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 or to Cipla at drugsafetysa@cipla.com.

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 all medicines out of reach and sight of children.

Store in a cool, dry place, at or below 25 ºC.

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 tramadol and paracetamol.

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 15 aluminium/polyethylene strips of 4 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

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Access to the corresponding Professional Information

To access corresponding Professional Information, scan the QR Code below.

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