PATIENT INFORMATION LEAFLET FOR

TENSOPYN

SCHEDULING STATUS: **S2**

TENSOPYN

Paracetamol 450 mg, codeine phosphate 10 mg, caffeine anhydrous 30 mg, doxylamine succinate 5 mg Tablets

Sugar free

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

- TENSOPYN is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use TENSOPYN carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share TENSOPYN with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 5 days.

What is in this leaflet

1. What TENSOPYN is and what it is used for
2. What you need to know before you take TENSOPYN
3. How to take TENSOPYN
4. Possible side effects
5. How to store TENSOPYN

6. Contents of the pack and other information.

1. What TENSOPYN is and what it is used for

TENSOPYN is used for the relief of mild to moderate pain associated with tension.

2. What you need to know before you take TENSOPYN

Do not take TENSOPYN:

- if you are hypersensitive (allergic) to paracetamol, codeine phosphate, caffeine or doxylamine succinate or any of the other ingredients of TENSOPYN tablets (listed in **Section 6**).
- if you are a child under the age of 12 years.
- if you are a child below 18 years who is receiving surgery for the removal of the tonsils or adenoids to treat obstructive sleep apnoea (breathing problems while you are sleeping), as you may be more susceptible to breathing problems.
- if you have severely impaired liver or kidney function.
- if you have acute intermittent porphyria.
- if you have problems with breathing and impaired lung function.
- if you have heart failure as a result of chronic lung disease.
- if you are having an asthma attack.
- if you had an operation on your bile ducts.
- if you had a head injury or a condition in which the pressure exerted on your brain is increased.
- if you have used monoamine oxidase inhibitors or within 14 days of stopping such treatment.

- if you are pregnant or breastfeeding your baby.
- if you suffer from alcoholism.
- if you are known to be a CYP2D6 ultra-rapid metaboliser where you metabolise codeine into morphine very rapidly.

Warnings and Precautions

Take special care with TENSOPYN:

- if you have liver, kidney, thyroid, or hormonal problems and/or are elderly or of a weakened state.
- if you have high blood pressure, low blood pressure, an enlarged prostate, obstructive bowel problems, acute abdominal conditions (e.g. peptic ulcer) or problems passing urine.
- if you have had a recent operation on the gastrointestinal tract.
- if you have gall stones.
- if you are in shock, if you have glaucoma (pressure in the eyes), or a disease called myasthenia gravis (a condition which weakens muscles), or a history of irregular heartbeats or fits.
- if you have asthma.
- if you have a history of mood swings, alcohol or drug abuse or are under psychiatric treatment.
- if you are taking a benzodiazepine (used for treatment of anxiety or sleep disorders), e.g. diazepam, clobazam, lorazepam, chlordiazepoxide, oxazepam, temazepam, nitrazepam, loprazolam, lormetazepam or clonazepam.
- if you are alcohol dependent.

- if you have chronic malnutrition.
- if you are dehydrated.
- if you have a personal or family history of mental health disorders or substance abuse, as TENSOPYN contains codeine which may predispose you to an increased risk of drug misuse and abuse.
- if you are a child with breathing problems, you should not take TENSOPYN.
- Codeine is transformed into morphine in the liver by an enzyme. Morphine is a substance that produces pain relief. Some people have a variation of this enzyme, and this can affect people in different ways. In some people, morphine is not produced or produced in very small quantities, and it will not provide enough pain relief. Other people are more likely to get serious side effects because a very high amount of morphine is produced. If you notice any of the following side effects, you must stop taking this medicine and seek immediate medical advice: slow or shallow breathing, confusion, sleepiness, small pupils, feeling or being sick, constipation, lack of appetite.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking this medicine.

Skin reactions have been reported. If you develop any skin reactions, stop taking TENSOPYN immediately and contact your doctor or go to the nearest hospital.

Tolerance, dependence and addiction

Increased risk of addiction in patients with personal or family history of substance abuse or mental health disorders

TENSOPYN contains codeine, which is an opioid medicine.

Repeated use of TENSOPYN may result in you becoming accustomed to it (needing to take higher doses). Repeated use of TENSOPYN may also lead to dependence, abuse and addiction, which may result in life-threatening overdose.

If you experience any of the following signs whilst taking TENSOPYN, talk to your doctor or pharmacist as it could be an indication that you are dependent or addicted.

• You need to take this medicine for longer than advised

• You need to take more than the recommended dose

• You are using this medicine for reasons other than medical reasons, for instance, 'to stay calm' or to 'help you sleep'

• You have made repeated, unsuccessful attempts to quit or control the use of this medicine

• When you stop taking this medicine you feel unwell, and you feel better once taking this medicine again (withdrawal effects)

Opioid Induced Hyperalgesia

Taking opioid medications for too long can paradoxically induce or sensitise patients to acute pain this condition is called opioid-induced hyperalgesia. The type of pain experienced might be the same as or different from the original underlying pain, and in some cases, patients may experience pain from ordinarily non-painful stimuli (allodynia).

Other medicines and TENSOPYN

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

Do not take TENSOPYN and tell your doctor or pharmacist if you are taking:

- medicines to treat depression called MAOIs (monoamine oxidase inhibitors) or have recently taken them in the last two weeks. MAOIs are medicines such as moclobemide, phenelzine, tranylcypromine (see **Do not take TENSOPYN**).

Tell your doctor or pharmacist if you are taking or have recently taken any of the following medicines:

- medicines which make you drowsy or sleepy (CNS depressants) (e.g. barbiturates, anesthetics, hypnotics, other opioid analgesics, anxiolytic sedatives, antipsychotics, tricyclic antidepressants and phenothiazines) or a benzodiazepine used to treat anxiety or sleep disorders.
- medicines for the treatment of high blood pressure (diuretics and antihypertensives).
- medicines to treat or prevent clinical depression (antidepressants).
- medicines used to treat mental distress or disorder (antipsychotics).
- Any of the groups are called antimuscarinics (e.g. atropine, hyoscine).
- any of the groups are called neuromuscular blockers (e.g. tubocurarine).
- medicines used to thin the blood such as warfarin (or other coumarins).
- metoclopramide or domperidone - used to stop you feeling sick (nausea) or being sick (vomiting).
- cholestyramine - for lowering blood cholesterol levels.
- hydroxyzine - to treat anxiety and tension.
- Mexiletine used to treat irregular heartbeat.
- kaolin or loperamide - for the treatment of diarrhea.
- naloxone - to treat a narcotic overdose.
- naltrexone - used as part of a treatment program for drug or alcohol dependence.
- cimetidine - to treat stomach ulcers.
- cisapride - to treat gastro-oesophageal reflux disease.

- quinidine - to treat irregular heart rate.
- carbamazepine, phenytoin, phenobarbital and primidone (used to treat epilepsy). If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking TENSOPYN.

Concomitant use of opioids and benzodiazepines increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, you should only take these together if prescribed by a doctor. Please follow your doctor's dosage recommendation closely. It could be helpful to inform friends or relatives to be aware of signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

TENSOPYN with food, drink and alcohol

TENSOPYN can be taken without regard to food or drink.

TENSOPYN should not be taken with alcohol.

Pregnancy, breastfeeding and fertility

Do not take TENSOPYN if you are pregnant or breastfeeding your baby (see **Do not take TENSOPYN**).

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 TENSOPYN**.**

Driving and using machines

- TENSOPYN tablets may make you feel drowsy or sleepy or impair your concentration.

- Do not drive because TENSOPYN tablets can interfere with your ability to drive safely.
- Do not operate any tools or machines while taking TENSOPYN tablets.

It is not always possible to predict to what extent TENSOPYN 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 TENSOPYN affects them.

3. How to take TENSOPYN

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

Always take TENSOPYN exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are unsure.

The usual dose for adults and children over 12 years is: take one to two tablets with water every 4 hours, with a maximum of 8 tablets daily.

TENSOPYN may be taken when necessary for the relief of pain and does not have to be taken regularly.

Do not take TENSOPYN for more than 5 days. If you need to use this medicine for more than 5 days, you must speak to your doctor or pharmacist.

This medicine contains codeine and can cause addiction if you take it continuously for more than five days. When you stop taking it you may get withdrawal symptoms. You should talk to your doctor or pharmacist if you think you are suffering from withdrawal symptoms.

DO NOT EXCEED THE RECOMMENDED DOSE.

If you take more TENSOPYN than you should

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

Prompt treatment is essential. A delay in starting treatment may mean that the antidote is given too late to be effective.

TENSOPYN 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, contact the nearest doctor, hospital or Poison Centre immediately.

Symptoms of paracetamol overdosage in the first 24 hours include pallor, nausea, vomiting, anorexia and possibly abdominal pain. Mild symptoms during the first two days of acute poisoning do not reflect the potential seriousness of the overdosage.

Liver damage may become apparent 12 to 48 hours, or later after ingestion. Acute renal failure may develop even in the absence of severe liver damage.

Symptoms of codeine phosphate overdosage produce central stimulation with exhilaration, in children, convulsions, followed by vomiting, drowsiness, respiratory depression and cyanosis, and coma. Symptoms in decreasing order of frequency included somnolence, rash, miosis, vomiting, itching, ataxia, swelling of the skin and respiratory failure.

Opioid toxicity may occur in adults after overdoses of codeine tablets. Get emergency help immediately if any of the following symptoms occur:

Cold, clammy skin, confusion, convulsions, severe dizziness, low blood pressure, severe nervousness or restlessness, pinpoint pupils of eyes, slow heartbeat, slow or troubled breathing, severe weakness.

Overdose of caffeine may cause restlessness, excitement, muscle tremor, tinnitus, scintillating scotoma, tachycardia and extrasystoles.

Overdosage of doxylamine succinate causes sedation. Overdosage may be fatal, especially in infants and children in whom the main symptoms are central nervous system stimulation, and antimuscarinic effects, including ataxia, excitement, hallucinations, muscle tremors, convulsions, dilated pupils, dry mouth, flushed face and hyperpyrexia. Deepening coma, cardiorespiratory collapse and death may occur within 18 hours.

In adults, the usual symptoms are central nervous system depression with drowsiness, coma and convulsions. Hypotension may also occur. Treatment of antihistamine overdose is symptomatic and supportive.

As TENSOPYN tablets are taken when necessary for the relief of pain, they do not have to be taken regularly, and a missing dose does not matter.

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

If you stop taking TENSOPYN

This medicine contains codeine and can cause addiction if you take it continuously for more than 5 days. When you stop taking it you may get withdrawal symptoms. You should talk to your doctor or pharmacist if you think you are suffering from withdrawal symptoms.

4. Possible Side Effects

TENSOPYN can have side effects**.**

Not all side effects reported for TENSOPYN are included in this leaflet. Should your general

health worsen or if you experience any untoward effects while taking TENSOPYN, please consult your health care provider for advice.

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

- rash, fever, swelling, bruising or tiredness.
- difficulty in breathing or you feel dizzy.
- swelling of the hands, feet, ankles, face, lips or throat which may cause difficulty in swallowing or breathing. You could also notice an itchy, lumpy rash (hives) or nettle rash (urticaria). This may mean you are having an allergic reaction.
- Yellowing of the skin and eyes, also called jaundice.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to TENSOPYN. You may need urgent medical attention or hospitalization.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- severe stomach pain, which may reach your back. This could be a sign of inflammation of the pancreas (pancreatitis).
- You get infections or bruises more easily than usual. This could be because of a blood problem (such as agranulocytosis or thrombocytopenia).

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:

- constipation.
- feeling sick (nausea).
- being sick (vomiting).
- drowsiness, confusion.
- slowing down of the central nervous system. Signs include slower heart rate and breathing, extreme confusion and memory loss and poor judgement.
- *Less frequent side effects:*
- low blood pressure (causing light-headedness or fainting when standing up).
- high blood pressure.
- excitement, nervousness, irritability, depression.
- feelings of unreality.
- irregular heartbeat.
- stomach pain.
- diarrhoea, stomach ulcer or cramps, heartburn, bloody or black, tarry stools.
- sore throat.
- sweating.
- dry mouth.
- sores in the mouth.
- facial flushing or redness.
- general discomfort.
- loss of appetite (anorexia).
- very slow or shallow breathing.

- shortness of breath.
- nightmares.
- muscle cramps or stiffness.
- trembling or uncontrolled muscle movements or weakness, coordination problems, weakness of the hands.
- bloody or cloudy urine, sudden decrease in amount of urine.
- headache, increased pressure in the head.
- vertigo (sensation of spinning or swaying).
- increased body temperature.
- tingling or numbness of your hands and feet (pins and needles).
- seeing flickering lights that obstruct your vision.

Side effects with unknown frequency:

- fixed drug eruptions (FDE) (fever, nausea, anorexia, malaise, itching, burning or stinging sensation).
- thick phlegm.
- muscle pain.
- urinary difficulty, inability to empty all the urine from your bladder, increased frequency of urination.
- hair loss.
- ringing in your ears.
- blurred vision, constricted pupils.
- hallucinations.
- changes in the way you move, talk or do regular activities (psychomotor impairment).

- restlessness, changes in mood, euphoria.
- decreased libido (sex drive).
- difficulties sleeping.
- shaking, fits.
- anxiety.
- sensitivity to light.
- sudden drop in body temperature (hypothermia).
- 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 TENSOPYN.

5. How to store TENSOPYN

- Store at or below 25 °C.
- Store in the original container.
- Keep the container in the outer carton.
- Protect from light and moisture.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the label.

- Store all medicines out of reach of children.
- 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 TENSOPYN contains

- The active substances are paracetamol 450,0 mg, codeine phosphate 10,0 mg, caffeine anhydrous 30,0 mg, doxylamine succinate 5,0 mg.
- The other ingredients are quinoline yellow supra, magnesium stearate, microcrystalline cellulose, povidone, silicon dioxide, sodium croscarmellose.

What TENSOPYN looks like and contents of the pack

Yellow, practically odourless flat faced bevelled edges, round tablets embossed with a triangle on one side.

TENSOPYN is presented in:

- Blister strips of 10 tablets packed in a cardboard carton containing 20 or 40 tablets.
- 40 tablets packed into white plastic containers with white plastic caps.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

CIPLA MEDPRO (PTY) LTD.

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