

PATIENT INFORMATION LEAFLET

Scheduling Status

S2

TENSOPYN (tablets)

Paracetamol, codeine phosphate, caffeine, doxylamine succinate

Sugar free

Read all of 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 tablets:

- 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 have impaired liver or kidney function
- if you have 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 brain injury
- if you have used monoamine oxidase inhibitors or within 14 days of stopping such treatment
- if you are pregnant especially during the first trimester of pregnancy or breastfeeding your baby
- if you are alcohol dependent
- if you have chronic malnutrition
- if you are dehydrated

Warnings and Precautions

Take special care with TENSOPYN:

- if you have liver, kidney, thyroid or heart problems and/or are elderly or

of a weakened state;

- if you have high blood pressure, low blood pressure, problems with the prostate gland, obstructive bowel problems, acute abdominal conditions (e.g. peptic ulcer) or problems passing urine;
- if you are in shock, glaucoma, or a disease called myasthenia gravis (a condition which weakens muscles) or a history of fits;
- 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

Codeine is transformed to morphine in the liver by an enzyme. Morphine is the 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.

Other medicines and TENSOPYN

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.

Do not take this medicine 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.

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, anaesthetics, 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 group called antimuscarinics (e.g. atropine, hyoscine)
- Any of the group 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)
- Colestyramine - for lowering blood cholesterol levels
- Hydroxyzine - to treat anxiety and tension
- Mexiletine used to treat irregular heartbeat.

- Kaolin or loperamide - for the treatment of diarrhoea
- 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

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 tablets can be taken without regard to food or drink.

TENSOPYN should not be taken with alcohol.

Pregnancy, breastfeeding and fertility

Take special care when taking TENSOPYN tablets, during the first trimester of pregnancy.

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking TENSOPYN.

Driving and using machinery

- TENSOPYN tablets may make you feel drowsy or sleepy.
- Do not drive because TENSOPYN tablets could 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. You should 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 tablets 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 control center.

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

TENSOPYN tablets contain paracetamol and codeine 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.

As TENSOPYN tablets are taken when necessary for the relief of pain it does not have to be taken regularly and a missed 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 doctor, pharmacist or other healthcare professional 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 hospitalisation.

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 to your back. This could be a sign of inflammation of the pancreas (pancreatitis).

- You get infections or bruise 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).

Less frequent side effects:

- low blood pressure (causing light-headedness or fainting when standing up)
- Confusion
- Depression
- Difficulties sleeping
- Shaking, fits
- Irregular heart beat
- Stomach pain
- Sweating
- Facial flushing
- General discomfort
- Loss of appetite
- Very slow or shallow breathing
- Shortness of breath
- Hallucinations, nightmares
- Cramps or stiffness.

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> or by e-mail: drugsafety@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

TENSOPYN: Yellow, slightly mottled, practically odourless flat faced bevelled edged round tablets embossed with a triangle on one side.

TENSOPYN is presented in:

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

Holder of Certificate of Registration

CIPLA MEDPRO (PTY) LTD.

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