PATIENT INFORMATION LEAFLET FOR

TENSOPYN EFFERVESCENT

Scheduling Status

S2

TENSOPYN EFFERVESCENT, tablets

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

Contains sweetener: (aspartame 35 mg; acesulfame-K 10 mg and sodium cyclamate 15 mg per tablet)

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

TENSOPYN EFFERVESCENT tablets are available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use TENSOPYN EFFERVESCENT tablets carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share TENSOPYN EFFERVESCENT 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 EFFERVESCENT is and what it is used for
2. What you need to know before you take TENSOPYN EFFERVESCENT
3. How to take TENSOPYN EFFERVESCENT

4. Possible side effects
5. How to store TENSOPYN EFFERVESCENT
6. Contents of the pack and other information.

1. What TENSOPYN EFFERVESCENT tablet is and what it is used for

TENSOPYN EFFERVESCENT contains paracetamol, codeine phosphate, caffeine and doxylamine succinate as actives.

TENSOPYN EFFERVESCENT belongs to a class of medicine with the following known properties: analgesic (painkiller), antipyretic (lowers body temperature) and antihistamine (prevents allergy).

TENSOPYN EFFERVESCENT tablets are indicated for the relief of mild to moderate pain associated with tension.

2. What you need to know before you take TENSOPYN EFFERVESCENT tablets

Do not take TENSOPYN EFFERVESCENT tablets if you:

- Are hypersensitive (allergic) to paracetamol, codeine phosphate, caffeine or doxylamine succinate or any of the other ingredients of TENSOPYN EFFERVESCENT tablets (listed in **section 6**).
- Are a child under the age of 12 years.
- Are pregnant or breastfeeding your baby.
- 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.
- Have impaired liver or kidney function.
- Have been told by your doctor that you have a metabolic disorder called porphyria.
- Have problems with breathing and impaired lung function.

- Have heart failure as a result of chronic lung disease.
- Are having an asthma attack.
- Had an operation on your bile ducts.
- Had a brain or head injury.
- Have used monoamine oxidase inhibitors or within 14 days of stopping such treatment.
- Are alcohol dependent.
- Have chronic malnutrition.
- Are dehydrated.

Warnings and precautions

TENSOPYN EFFERVESCENT contains codeine, which is an opioid medicine.

Repeated use of TENSOPYN EFFERVESCENT may result in you becoming accustomed to it (needing to take higher doses). Repeated use of TENSOPYN EFFERVESCENT 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 EFFERVESCENT, 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’).

Take special care with TENSOPYN EFFERVESCENT:

- If you have high or low blood pressure or any heart conditions,
- if you are a child with breathing problems, you should not take TENSOPYN EFFERVESCENT,
- if you have thyroid or hormonal conditions,
- if you have an enlarged prostrate,
- if you have trouble to pass urine,
- if you have pressure in the eyes,
- if you are in shock, or if you have a history of drug abuse or are emotionally not stable,
- if you have any bowel or abdominal problems (e.g., stomach ulcer),
- if you have had a recent operation on the gastrointestinal tract,
- if you have gall stones,
- if you have a condition known as myasthenia gravis which weakens the muscles,
- if you suffer from seizures,
- if you have asthma,
- if you have a fever (high temperature),
- if you are an elderly.

Risk of renal impairment and low potassium levels are associated with non-steroidal anti-inflammatory medicine (NSAID) usage**.**

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

Opioid Induced Hyperalgesia

Taking a high dose of opioid medications as TENSOPYN EFFERVESCENT 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).

Children and adolescents

Do not give TENSOPYN EFFERVESCENT to children 12 years old and younger.

Other medicines and TENSOPYN EFFERVESCENT tablets

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

Take care when taking TENSOPYN EFFERVESCENT tablets concomitantly with the following:

- Medicines which are toxic to the liver or have an influence on liver enzymes.
- Metoclopramide, medicine used to treat nausea and vomiting.
- Probenecid, medicines used to treat gout.
- Cholestyramine, medicine used for lowering blood cholesterol levels.
- Antibacterials, medicines used to treat bacterial infection.
- Anticoagulants, medicine used to treat or prevent clotting of blood.
- Antiepileptics, medicine used to treat epilepsy.
- Antivirals, medicine used to treat different viral infections.
- Medicines which make you drowsy or sleepy (CNS depressants) e.g., alcohol, anaesthetics, hypnotics, and sedatives, phenothiazines, antidepressants.
- Antiarrhythmics, medicines used to treat heart diseases.

- Antifungals, medicines used to treat fungal infections.
- Medicines used to treat gastrointestinal diseases.
- Lithium, medicines used to treat people with bipolar.
- Methoxsalen, medicines used to treat skin sensitivity.
- Sex hormones.
- Sympathomimetics medicines used to treat cardiac arrest and low blood pressure.
- Theophylline medicines used to treat asthma and other breathing problems.

Please consult your doctor, pharmacist, or other healthcare provider for advice if you are not sure whether the above-mentioned medicines are ingredients in the medicines you are taking.

TENSOPYN EFFERVESCENT with food, drink, and alcohol

TENSOPYN EFFERVESCENT tablets can be taken without regard to food or drink.

TENSOPYN EFFERVESCENT tablets should not be taken with alcohol.

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 TENSOPYN EFFERVESCENT**.**

TENSOPYN EFFERVESCENT should not be used during pregnancy or while breastfeeding (see **Do not take TENSOPYN EFFERVESCENT**).

Driving and using machines

- TENSOPYN EFFERVESCENT tablets may make you feel drowsy or sleepy.
- Do not drive because TENSOPYN EFFERVESCENT tablets could interfere with your ability to drive safely.

- Do not operate any tools or machines while taking TENSOPYN EFFERVESCENT tablets.

TENSOPYN EFFERVESCENT contains Aspartame.

Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

TENSOPYN EFFERVESCENT contains Sodium Chloride.

This medicine contains 24 mg sodium (main component of cooking/table salt) in each tablet. This is equivalent to 1,2 % of the recommended maximum daily dietary intake of sodium for an adult.

TENSOPYN EFFERVESCENT contains Macrogol.

This medicine contains macrogol, which may cause stomach upset and diarrhoea.

3. How to take TENSOPYN EFFERVESCENT

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

Always take TENSOPYN EFFERVESCENT tablets exactly as described in this leaflet or as your doctor or pharmacist or nurse 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 EFFERVESCENT tablets may be taken when necessary for the relief of pain and do not have to be taken regularly.

DO NOT EXCEED THE RECOMMENDED DOSE.

Do not take TENSOPYN EFFERVESCENT tablets for longer than 5 days without consulting your doctor. If your symptoms worsen or do not improve within 5 days of treatment, please consult your

doctor or pharmacist.

TENSOPYN EFFERVESCENT tablets are not recommended for children under the age of 12 years.

If you take more TENSOPYN EFFERVESCENT tablets than you should

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

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

TENSOPYN EFFERVESCENT tablets contains 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.

If you forget to take TENSOPYN EFFERVESCENT tablets

As TENSOPYN EFFERVESCENT 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.

4. Possible Side Effects

TENSOPYN EFFERVESCENT tablets can have side effects.

Not all side effects reported for TENSOPYN EFFERVESCENT tablets are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this TENSOPYN EFFERVESCENT, please consult your doctor, pharmacist, or other healthcare provider for advice.

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

- Serious skin disease causing rash, skin peeling and sores (Stevens–Johnson syndrome).
- Skin disease causing rash, skin peeling and sores (epidermal necrolysis).
- Skin rash with blisters and fever (acute generalised exanthematous pustulosis).
- Fixed drug eruption (may look like round or oval patches of redness and swelling of the skin).
- Swelling of the hands, feet, ankles, face, lips, mouth, or throat, which may cause difficulty in swallowing or breathing,
- Rash or itching.
- Fainting.
- 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 [PRODUCT NAME]. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Constipation,
- nausea and

- vomiting.

Less frequent side effects:

- Blood disorders,
- hypersensitivity (allergy) which can be severe,
- pancreatitis,
- excitement,
- elation,
- sedation,
- restlessness,
- sleeplessness,
- deepening coma,
- irritability,
- nightmares,
- loss of appetite,
- nervousness,
- convulsions,
- drowsiness,
- dizziness,
- confusion,
- dry mouth,
- sweating,
- facial flushing,
- vertigo,
- small pupils in the eye, a visual aura, blurred vision,

- ringing in the ears,
- fast, slow, or pounding heartbeat,
- high or low blood pressure,
- high temperature,
- irregular breathing,
- shortness of breath
- wheezing or troubled breathing,
- tightness of the chest,
- diarrhoea,
- stomach ulcers,
- gastro- intestinal disturbances,
- rashes,
- skin eruptions,
- pinpoint red spots on skin,
- hives or itching,
- and unusual tiredness,
- trembling or uncontrolled muscle movements or muscle rigidity,
- muscular weakness and incoordination,
- weakness of the hands,
- difficult urination,
- headache.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Side effects with unknown frequency

- fixed drug eruptions (FDE) (fever, malaise, nausea, diarrhoea, abdominal cramps, anorexia, and dysuria)
- low potassium levels (hypokalaemia)
- renal impairment (renal tubular acidosis).
- opioid use disorder (OUD) an uncontrollable desire to use opioids, leading to dependence, abuse and addiction, and withdrawal syndrome (feeling unwell when opioids are discontinued) see "**Warnings and precautions"** section.
- opioid-induced hyperalgesia (OIH) medical condition where the medication amplifies pain signals instead of bringing relief, Your pain may worsen or spread to new areas.
- allodynia a medical condition where you feel pain from a normally non-painful stimulus, see "**Warnings and precautions"** section.

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 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 EFFERVESCENT.

5. How to store TENSOPYN EFFERVESCENT

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

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 EFFERVESCENT contains

The active substances are paracetamol 450,0 mg, codeine phosphate 10,0 mg, caffeine 50,0 mg, doxylamine succinate 5,0 mg.

The other ingredients are acesulfame-K, adipic acid, aspartame, black berry flavour liquid, black currant flavour liquid, citric acid, copovidone, macrogol – 6000, malto- dextrin, silicon dioxide, sodium benzoate 0,001 % *m/m*, sodium bicarbonate, sodium carbonate, sodium chloride, sodium cyclamate.

What TENSOPYN EFFERVESCENT looks like and contents of the pack

TENSOPYN EFFERVESCENT tablet is a round white to off white tablet, with sharp edges and a cherry odour and taste.

TENSOPYN EFFERVESCENT tablet is presented in a white plastic tube with a white plastic cap, containing 18 effervescent tablets, packed in a carton.

Holder of certificate of registration

CIPLA MEDPRO (PTY) LTD.

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