**PROFESSIONAL INFORMATION FOR**

**TENSOPYN EFFERVESCENT**

**SCHEDULING STATUS**

**S2**

## 1. NAME OF THE MEDICINE

**TENSOPYN EFFERVESCENT,** tablets**.**

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

| | | |
|---|---|---|
| | Caffeine anhydrous | 50 mg |
| | Codeine phosphate | 10 mg |
| | Doxylamine succinate | 5 mg |
| | Paracetamol | 450 mg |
| Preservative: | Sodium Benzoate | 0,001 % *m/m* |

Contains sweetener: (Aspartame 35 mg; Acesulfame-K 10 mg and Sodium cyclamate 15 mg per tablet)

For the full list of excipients, see **section 6.1**.

## 3. PHARMACEUTICAL FORM

Tablets

Round white to off white tablet, with sharp edges and a cherry odour and taste.

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

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

### 4.2 Posology and method of administration

**DO NOT EXCEED THE RECOMMENDED DOSE**.

Adults and children 12 years and older: 1 to 2 tablets dissolved in approximately 200 mL water every 4 hours as needed. Do not exceed 8 tablets per day.

Do not use continuously for longer than 5 days without consulting your doctor.

### 4.3 Contraindications

TENSOPYN EFFERVESCENT is contraindicated:

- In patients with known hypersensitivity to paracetamol, doxylamine succinate, caffeine, or codeine phosphate, or to any of the excipients listed in **section 6.1.**
- In severe liver function impairment.
- In acute intermittent porphyria.
- In patients with respiratory depression, especially in the presence of cyanosis and excessive bronchial secretion.
- After an operation on the biliary tract.
- In acute alcoholism.
- In head injuries and conditions in which intracranial pressure is raised.
- During an attack of bronchial asthma or in heart failure secondary to chronic lung disease.

- In patients taking monoamine oxidase inhibitors or within 14 days of stopping such treatment.
- Pregnancy and lactation (see to **section 4.6**)
- Children under the age of 12 years.
- Children (aged below 18 years) who undergo surgery for the removal of the tonsils or adenoids to treat obstructive sleep apnoea, as these patients are more susceptible to respiratory problems.

## 4.4 Special warnings and precautions for use

**TENSOPYN EFFERVESCENT 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**.

**Exceeding the prescribed dose, together with prolonged and continuous use of TENSOPYN EFFERVESCENT, may lead to dependency and addiction.**

Do not use continuously for longer than 5 days without consulting your doctor.

Dosage in excess of those recommended may cause severe liver damage.

The dosage in renal functional impairment must be reduced.

Should be taken with caution by asthmatics.

Consult a doctor if no relief is obtained from the recommended dosage.

Use with caution in renal disease.

Risk of renal tubular acidosis and hypokalaemia are associated with non-steroidal anti-inflammatory medicine (NSAID) usage.

**Severe cutaneous adverse reactions (SCARs)**

Severe cutaneous adverse reactions (SCARs) such as toxic epidermal necrolysis (TEN), Steven-Johnson syndrome (SJS), acute generalized exanthematous pustulosis (AGEP), eosinophilia and systemic (DRESS)/Drug-induced hypersensitivity syndrome (DIHS) and fixed drug eruptions (FDE) have been reported in patients treated with paracetamol containing medicines. If a patient develops SCAR, treatment with TENSOPYN EFFERVESCENT must immediately be discontinued and appropriate treatment instituted.

**Paracetamol**

Patients suffering from kidney or liver disease should take paracetamol under medical supervision.

**Codeine**

Codeine should be given with caution to patients with hypothyroidism, adrenocortical insufficiency, impaired kidney or liver function, myasthenia gravis, prostatic hypertrophy, or shock. It should be used with caution in patients with inflammatory or obstructive bowel disorders. The dosage should be reduced in elderly and debilitated patients.

The depressant effects of codeine are enhanced by depressants of the central nervous system such as alcohol, anaesthetics, hypnotics, and sedatives and phenothiazines see **section 4.5**.

Prolonged use of high doses of codeine has produced dependence.

Children with conditions associated with respiratory problems should not take codeine, as in TENSOPYN EFFERVESCENT.

**Opioid use disorder (abuse and dependence)**

Tolerance, physical and psychological dependence and opioid use disorder (OUD) may develop upon repeated administration of opioids such as codeine. Abuse or intentional misuse of TENSOPYN EFFERVESCENT may result in overdose and/or death.

Patients should be informed about the risks and signs of OUD as well as serious clinical outcomes. If these signs occur, patients should be advised to contact their doctor.

Withdrawal symptoms, such as restlessness and irritability may occur once the medicine is stopped. Increased risk of addiction in patients with personal or family history of substance abuse or mental health disorders.

**Opioid-induced Hyperalgesia (OIH) and Allodynia**

Opioid pain medicines have been associated with opioid-induced hyperalgesia (OIH), a condition where opioids cause an increase in pain (called hyperalgesia) or an increased sensitivity to pain (called allodynia). Increases in pain typically occur following a dose increase and resolve quickly following proper diagnosis and management of the condition. Symptoms of OIH include (but may not be limited to) increased levels of pain upon opioid dosage increase, decreased levels of pain upon opioid dosage decrease, or pain from ordinarily non-painful stimuli (allodynia).

**Caffeine**

Large doses may cause restlessness, excitement, muscle tremor, tinnitus, scintillating scotoma, tachycardia and extrasystole. Caffeine increases gastric secretion and may cause gastric ulceration.

Caffeine should be given with care to patients with a history of peptic ulceration. With prolonged use some degree of tolerance and psychic dependence may occur. Give with caution to

patients with hyperthyroidism, cardiac arrythmias or other cardiovascular disease or epilepsy as these conditions may be exacerbated.

**Doxylamine succinate**

Doxylamine succinate has anticholinergic properties and should be used with care in conditions such as glaucoma and prostatic hypertrophy. The effects of atropine and tricyclic antidepressants may be enhanced by doxylamine succinate. Doxylamine succinate may mask the symptoms of damage caused by ototoxic medicine and may affect metabolism of medicine in the liver.

Doxylamine succinate may enhance the sedative effects of central nervous system depressants including alcohol, barbiturates, hypnotics, narcotic analgesics, sedatives, and tranquillisers.

Large doses may precipitate fits in epileptics. Allergy and anaphylaxis may occur. Erythema multiforme and exfoliative or bullous dermatitis may occur. Symptoms of porphyria may be exacerbated (see **section 4.3**).

**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 (60 mg Sodium Chloride) per tablet, equivalent to 1,2 % of the WHO recommended maximum daily intake of 2 g sodium for an adult.

**TENSOPYN EFFERVESCENT contains Macrogol.**

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

## 4.5 Interaction with other medicines and other forms of interaction

(see **"section 4.3"** and **"section 4.8")**.

TENSOPYN EFFERVESCENT may enhance the depressant effects of central nervous system depressants such as alcohol, anaesthetics, hypnotics, and sedatives and phenothiazines.

Prolonged use of high doses of codeine has produced dependence.

## 4.6 Fertility, pregnancy, and lactation

### Pregnancy

TENSOPYN EFFERVESCENT is contraindicated in pregnancy (see **section 4.3**).

### Breastfeeding

TENSOPYN EFFERVESCENT is contraindicated in woman who are breastfeeding their infants (see **section 4.3**).

### Fertility

No data available.

## 4.7 Effects on ability to drive and use machines.

TENSOPYN EFFERVESCENT may lead to drowsiness and impaired concentration, which may be aggravated by simultaneous intake of alcohol, or other central nervous system depressant agents. Patients should be warned against taking charge of vehicles or machinery or performing potentially hazardous tasks where loss of concentration may lead to accidents.

## 4.8 Undesirable effects

### Tabulated summary of adverse reactions

The following adverse reactions have been classified according to the following categories, frequency unknown.

| Paracetamol | Doxylamine succinate | Codeine phosphate | Caffeine |
|---|---|---|---|
| **Blood and lymphatic system disorders** | | | |
| ***Frequency not known:*** Thrombocytopenia, neutropenia, pancytopenia, leukopenia, agranulocytosis. | ***Frequency not known:*** Blood discrasias including agranulocytosis, eosinophilia, leukopenia, thrombocytopenia and haemolytical anaemia. | | |
| **Immune system disorders** | | | |
| ***Frequency not known:*** Sensitivity reactions. | ***Frequency not known:*** Hypersensitivity reactions such as skin rashes, urticaria, purpura, angioedema, bronchospasm, anaphylaxis. | ***Frequency not known:*** Urticaria. | |
| **Metabolism and nutrition disorders** | | | |
| ***Frequent not known:*** Hypokalaemia | ***Frequency not known:*** Dryness of the mouth. | ***Frequency not known:*** Dry mouth. | |
| **Psychiatric disorders** | | | |
| | ***Frequency not known:*** Sedation (see **section 4.4**), elation or depression, irritability, nightmares, anorexia, insomnia. | ***Frequency not known:*** Drowsiness, confusion restlessness, deepening coma, euphoria, changes of mood, opioid use disorder (OUD). opioid-induced hyperalgesia (OIH) and allodynia (see **section 4.4**) | ***Frequency not known:*** Insomnia. |
| **Nervous system disorders** | | | |

| | | | |
|---|---|---|---|
| | ***Frequency not known:*** Headache, tingling, paraesthesia, nervousness, tremors, muscle twitching, convulsions, fits in epileptics. | ***Frequency not known:*** Raised intracranial pressure. | ***Frequency not known:*** Headache, restlessness, excitement. |
| **Eye disorders** | | | |
| | ***Frequency not known:*** Blurred vision. | ***Frequency not known:*** Miosis. | ***Frequency not known:*** Scintillating scotoma. |
| **Ear and labyrinth disorders** | | | |
| | ***Frequency not known:*** Tinnitus. | ***Frequency not known:*** Vertigo. | |
| **Cardiac disorders** | | | |
| | ***Frequency not known:*** Tachycardia, hypotension. | ***Frequency not known:*** Bradycardia, palpitation, hypotension, orthostatic hypotension, circulatory failure. | ***Frequency not known:*** Tachycardia. |
| **Respiratory, thoracic and mediastinal disorders** | | | |
| | ***Frequency not known:*** Tightness of the chest. | ***Frequency not known:*** Respiratory depression. | |
| **Gastrointestinal disorders** | | | |
| ***Frequency not known:*** Pancreatitis. | ***Frequency not known:*** Gastro-intestinal disturbances, diarrhoea, nausea, vomiting. | ***Frequency not known:*** Nausea, vomiting, constipation. | ***Frequency not known:*** Nausea, increased gastric secretion and gastric ulceration. |
| **Skin and subcutaneous tissue disorders** | | | |

| | | | |
|---|---|---|---|
| ***Frequency not known:*** Reversible skin rashes, erythromatous rash, urticarial, mucosal lesions, risk of fixed drug eruptions (FDE) and drug induced hypersensitivity syndrome (DIHS). | ***Frequency not known:*** Erythema multiforme and exfoliative or bullous dermatitis, porphyria. | ***Frequency not known:*** Pruritus. | |
| **Musculoskeletal and connective tissue disorders** | | | |
| | ***Frequency not known:*** Heaviness and weakness of the hands. | ***Frequency not known:*** Muscle rigidity. | ***Frequency not known:*** Muscle tremor. |
| **Renal and urinary disorders** | | | |
| ***Frequent not known:*** Renal tubular acidosis (RTA) | ***Frequency not known:*** Difficulty in micturition, anuria. | ***Frequency not known:*** Difficult micturition, ureteric or biliary spasms, diuretic effect. | |
| **General disorders and administration site conditions** | | | |
| ***Frequency not known***: Fever | | ***Frequency not known:*** Sweating, facial flushing hyperthermia. | |

## Post-marketing Experience

| **Paracetamol** | **Doxylamine succinate** | **Codeine phosphate** | **Caffeine** |
|---|---|---|---|
| **Skin and subcutaneous tissue disorders** | | | |
| ***Frequency not known:*** Risk of fixed drug eruptions (FDE) and Drug induced hypersensitivity syndrome (DIHS). | | | |

**Reporting of suspected adverse reactions**

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are requested to report any suspected adverse drug reactions 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).

## 4.9 Overdose

**Antihistamines (Doxylamine succinate)**

Overdosage of the doxylamine succinate causes sedation. Overdosage may be fatal, especially in infants and children in whom the main symptoms are central nervous stimulation and antimuscarinic effects, including ataxia, excitement, hallucinations, muscle tremor, 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 depression with drowsiness, coma, and convulsions. Hypotension may also occur. Treatment of antihistamine overdose is symptomatic and supportive.

**Paracetamol**

**Prompt treatment is essential**. In the event of an overdosage, consult a doctor immediately, or take the person directly to a hospital. A delay in starting treatment may mean that antidote is given too late to be effective. Evidence of liver damage is often delayed until after the time for effective treatment has lapsed.

Susceptibility to paracetamol toxicity is increased in patients who have taken repeated high doses (greater than 5 to 10 g/day) of paracetamol for several days, in chronic alcoholism,

chronic liver disease, AIDS, malnutrition, and with the use of drugs that induce liver microsomal oxidation such as barbiturates, isoniazid, rifampicin, phenytoin and carbamazepine.

Symptoms of paracetamol overdosage in the first 24 hours are pallor, nausea, vomiting, anorexia, and 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 after ingestion, initially by elevation of the serum transaminase and lactic dehydrogenase activity, increased serum bilirubin concentration and prolongation of the prothrombin time. Liver damage may lead to encephalopathy, coma, and death.

Acute renal failure with acute tubular necrosis may develop even in the absence of severe liver damage. Abnormalities of glucose metabolism and metabolic acidosis may occur. Cardiac arrhythmias have been reported.

**Treatment for paracetamol overdosage**:

Although evidence is limited it is recommended that any adult person who has ingested 5 to 10 grams or more of paracetamol (or a child who has had more than 140 mg/kg) within the preceding four hours, should have the stomach emptied by lavage (emesis may be adequate for children) and a single dose of 50 g activated charcoal given via the lavage tube. Ingestion of amounts of paracetamol smaller than this may require treatment in patients susceptible to paracetamol poisoning (see above). In patients who are stuporose or comatose endotracheal intubation should precede gastric lavage in order to avoid aspiration.

**N-acetylcysteine** should be administered to all cases of suspected overdose as soon as possible preferably within eight hours of overdosage, although treatment up to 36 hours after ingestion may still be of benefit, especially if more than 150 mg/kg of paracetamol was taken. An initial dose of 150 mg/kg N-acetylcysteine in 200 mL dextrose injection given intravenously

over 15 minutes, followed by an infusion of 50 mg/kg in 500 mL dextrose injection over the next four hours, and then 100 mg/kg in 1 000 mL dextrose injection over the next sixteen hours. **The volume of intravenous fluid should be modified for children**.

Although the oral formulation is not the treatment of choice, 140 mg/kg dissolved in water may be administered initially, followed by 70 mg/kg every four hours for seventeen doses.

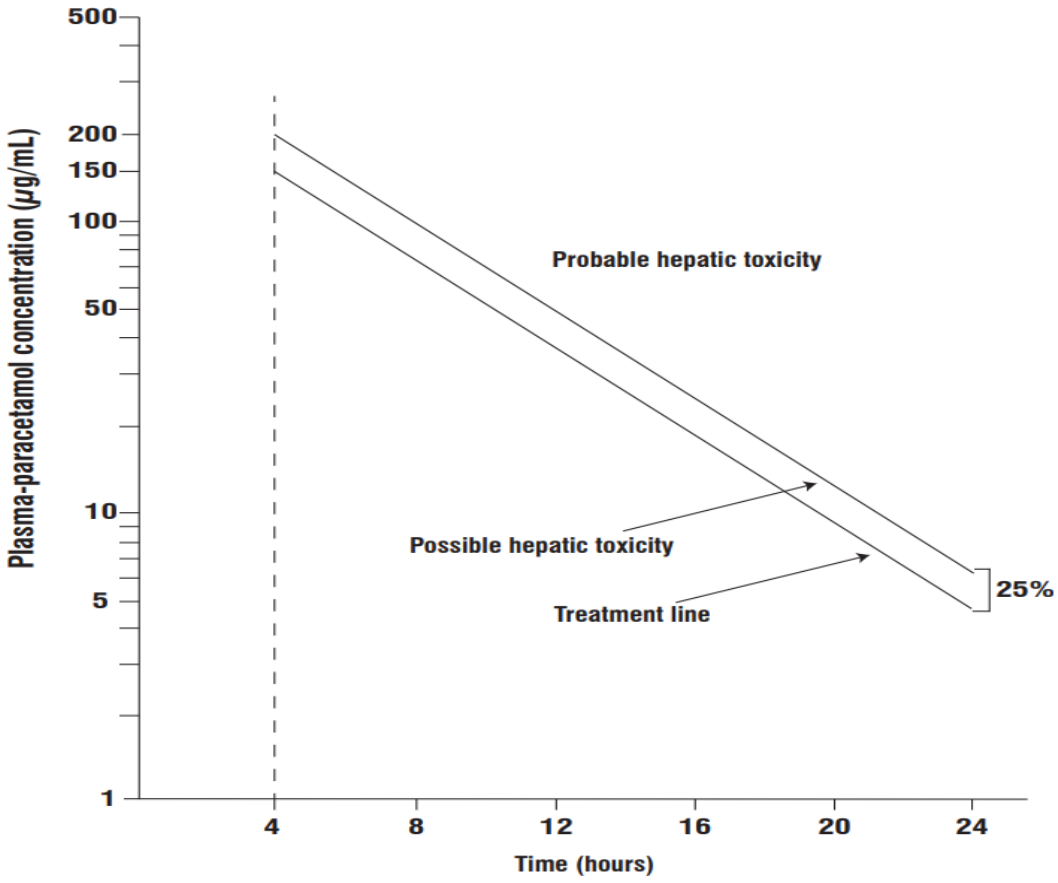
A plasma paracetamol level should be determined four hours after ingestion in all cases of suspected overdosage. Levels done before four hours may be misleading. Patients at risk of liver damage, and hence requiring continued treatment with N-acetylcysteine, can be identified according to their 4-hour plasma paracetamol level. The plasma paracetamol level can be plotted against time since ingestion in the nomogram below. The nomogram should be used only in relation to a single acute ingestion.

Those whose plasma paracetamol levels are above the “normal treatment line”, should continue N-acetylcysteine treatment with 100 mg/kg IV over sixteen hours repeatedly until recovery. Patients with increased susceptibility to liver damage as identified above, should continue treatment if concentrations are above the “high risk treatment line”. Prothrombin index correlates best with survival.

Monitor all patients with significant ingestions for at least ninety-six hours.

A semi-logarithmic plot of plasma-paracetamol concentration against hours after ingestion.

Reference: Martindale, The Complete Drug Reference.




**Codeine phosphate**

Poisoning with codeine produces central stimulation with exhilaration and in children, convulsions, followed by vomiting, drowsiness, respiratory depression and cyanosis and coma. Treatment is symptomatic and supportive.

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Pharmacological classification: A 20.8

Pharmacotherapeutic group: Analgesic combinations.

TENSOPYN EFFERVESCENT has analgesic, antipyretic and antihistaminic properties.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

- Citric acid anhydrous (F.P)
- Citric acid anhydrous (F.G)
- Ascorbic acid
- Aspartame
- Acesulfame-K
- Sodium cyclamate
- Sodium bicarbonate
- Malto-dextrin
- Sodium Chloride
- Sodium Benzoate
- Macrogol – 6000
- Adipic acid
- Sodium carbonate anhydrous
- Silicon Dioxide (Syloid 244)
- Copovidone (kollidon VA-64)
- BC flavour
- Black berry flavour

### 6.2 Incompatibilities

Not applicable

### 6.3 Shelf life

24 months

### 6.4 Special precautions for storage

Store at or below 25 °C in a dry place. Protect from moisture and light.

### 6.5 Nature and contents of container

TENSOPYN EFFERVESCENT tablets are packed in a white polypropylene tube containing 18 tablets each. The tubes are packed in printed cartons together with a package insert.

### 6.6 Special precautions for disposal and other handling

No special requirements.

## 7. HOLDER OF CERTIFICATE OF REGISTRATION

**CIPLA MEDPRO (PTY) LTD.**

Building 9

Parc du Cap

Mispel Street

Bellville

7530

Customer Care: 080 222 6662

## 8. REGISTRATION NUMBER(S)

33/2.8/0380

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|---|
| Namibia: NS2 11/2.8/0040 |

| |
|---|
| Botswana: S3 BOT0901590 |

## 9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

First authorisation: 17 May 2001

Latest renewal: Not applicable.

## 10. DATE OF REVISION OF THE TEXT

26 October 2026