

## PROFESSIONAL INFORMATION FOR TENSOPYN EFFERVESCENT

### SCHEDULING STATUS

S2

#### 1. NAME OF THE MEDICINE

TENSOPYN EFFERVESCENT (Tablets)

#### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Paracetamol 450 mg

Doxylamine succinate 5 mg

Caffeine anhydrous 50 mg

Codeine phosphate 10 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

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 (refer to section **4.6**)

#### 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. <sup>u</sup>

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.

### **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 arrhythmias 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 (section 4.3).

**TENSOPYN EFFERVESCENT contains Aspartame.**

Aspartame is hydrolysed in the gastrointestinal tract when orally ingested. One of the major hydrolysis products is phenylalanine.

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

(Refer to section “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**

The safety of TENSOPYN EFFERVESCENT in pregnant women has not been established.

**Breastfeeding**

The safety of TENSOPYN EFFERVESCENT in lactating women has not been established.

## **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
<b>Blood and lymphatic system disorders</b>			
<b>Frequency not known:</b> Thrombocytopenia, neutropenia, pancytopenia, leukopenia, agranulocytosis.	<b>Frequency not known:</b> Blood discrasias including agranulocytosis, eosinophilia, leukopenia, thrombocytopenia and haemolytical anaemia.		
<b>Immune system disorders</b>			
<b>Frequency not known:</b> Sensitivity reactions.	<b>Frequency not known:</b> Hypersensitivity reactions such as skin rashes, urticaria, purpura, angioedema, bronchospasm, anaphylaxis.	<b>Frequency not known:</b> Urticaria.	
<b>Metabolism and nutrition disorders</b>			
<b>Frequent not known:</b> Hypokalaemia	<b>Frequency not known:</b> Dryness of the mouth.	<b>Frequency not known:</b> Dry mouth.	
<b>Psychiatric disorders</b>			
	<b>Frequency not known:</b> Sedation (see section 4.4), elation or depression, irritability, nightmares, anorexia, insomnia.	<b>Frequency not known:</b> Drowsiness, confusion, restlessness, deepening coma, euphoria, changes of mood.	<b>Frequency not known:</b> Insomnia.
<b>Nervous system disorders</b>			
	<b>Frequency not known:</b> Headache, tingling, paraesthesia, nervousness, tremors, muscle twitching, convulsions, fits in epileptics.	<b>Frequency not known:</b> Raised intracranial pressure.	<b>Frequency not known:</b> Headache, restlessness, excitement.
<b>Eye disorders</b>			

	<b>Frequency not known:</b> Blurred vision.	<b>Frequency not known:</b> Miosis.	<b>Frequency not known:</b> Scintillating scotoma.
<b>Ear and labyrinth disorders</b>			
	<b>Frequency not known:</b> Tinnitus.	<b>Frequency not known:</b> Vertigo.	
<b>Cardiac disorders</b>			
	<b>Frequency not known:</b> Tachycardia, hypotension.	<b>Frequency not known:</b> Bradycardia, palpitation, hypotension, orthostatic hypotension, circulatory failure.	<b>Frequency not known:</b> Tachycardia.
<b>Respiratory, thoracic and mediastinal disorders</b>			
	<b>Frequency not known:</b> Tightness of the chest.	<b>Frequency not known:</b> Respiratory depression.	
<b>Gastrointestinal disorders</b>			
<b>Frequency not known:</b> Pancreatitis.	<b>Frequency not known:</b> Gastro-intestinal disturbances, diarrhoea, nausea, vomiting.	<b>Frequency not known:</b> Nausea, vomiting, constipation.	<b>Frequency not known:</b> Nausea, increased gastric secretion and gastric ulceration.
<b>Skin and subcutaneous tissue disorders</b>			
<b>Frequency not known:</b> Reversible skin rashes, erythematous rash, urticarial, mucosal lesions, risk of fixed drug eruptions (FDE) and drug induced hypersensitivity syndrome (DIHS).	<b>Frequency not known:</b> Erythema multiforme and exfoliative or bullous dermatitis, porphyria.	<b>Frequency not known:</b> Pruritus.	
<b>Musculoskeletal and connective tissue disorders</b>			

	<b>Frequency not known:</b> Heaviness and weakness of the hands.	<b>Frequency not known:</b> Muscle rigidity.	<b>Frequency not known:</b> Muscle tremor.
<b>Renal and urinary disorders</b>			
<b>Frequent not known:</b> Renal tubular acidosis (RTA)	<b>Frequency not known:</b> Difficulty in micturition, anuria.	<b>Frequency not known:</b> Difficult micturition, ureteric or biliary spasms, diuretic effect.	
<b>General disorders and administration site conditions</b>			
<b>Frequency not known:</b> Fever		<b>Frequency not known:</b> Sweating, facial flushing hyperthermia.	

### Post-marketing Experience

Paracetamol	Doxylamine succinate	Codeine phosphate	Caffeine
<b>Skin and subcutaneous tissue disorders</b>			
<b>Frequency not known:</b> 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 asked to report any suspected adverse reactions to SAHPRA via the “**6.04 Adverse Drug Reactions Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8> and to Cipla Medpro (Pty) Ltd at [drugsafetysa@cipla.com](mailto: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.

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 overdose:**

Any adult person who has ingested 5 - 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.

**N-Acetylcysteine**

N-Acetylcysteine should be administered as soon as possible, preferably within 8 hours of overdose.

IV: An initial dose of 150 mg/kg in 200 ml glucose injection, given intravenously over 15 minutes, followed by an intravenous infusion of 50 mg/kg in 500 ml of glucose injection over the next 4 hours, and then 100 mg/kg in 1 000 ml over the next 16 hours. The volume of intravenous fluids should be modified for children.

Orally: 140 mg/kg as a 5 % solution initially, followed by a 70 mg/kg solution every 4 hours for 17 doses.

Acetylcysteine is effective if administered within 8 hours of overdose.

If N-acetylcysteine is not available, methionine 2,5 g may be given immediately, followed by 2,5 g every four hours for three doses. Patients should however preferably be transferred to a facility where N-acetylcysteine can be given.

**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

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

14 March 2005

**10. DATE OF REVISION OF THE TEXT**

05 February 2024