SCHEDULING STATUS

S5

1. NAME OF THE MEDICINE

TENSTON SA CAPSULES, 150 mg/10 mg/200 mg/30 mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:

Meprobamate 150 mg

Codeine phosphate 10 mg

Paracetamol 200 mg

Caffeine 30 mg

Sugar free.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Capsules, hard.

Opaque, blue capsules imprinted with “COVAN” on the capsule shell.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For the symptomatic relief of mild to moderate pain and fever.

4.2 Posology and method of administration

Posology

DO NOT EXCEED THE RECOMMENDED DOSE.

Adults

1 to 2 capsules four times daily.

Paediatric population

Children12 years and older: 1 capsule four times daily.

Method of administration:

For oral administration.

4.3 Contraindications

TENSTON SA CAPSULES are contraindicated in:

- Patients with hypersensitivity to meprobamate, codeine phosphate, opioid analgesics, paracetamol, caffeine or to any excipients in TENSTON SA CAPSULES (see section 6.1).
- Patients who must remain alert.
- Patients who have acute intermittent porphyria or severe kidney or liver dysfunction.
- Patients during an attack of bronchial asthma.
- Patients with respiratory depression especially in the presence of cyanosis and excessive bronchial secretion, after operations on the biliary tract, acute alcoholism, head injuries and conditions in which intracranial pressure is raised.
- Heart failure, secondary to chronic lung disease, a history of cardiac disease, epilepsy and all convulsive states.
- Patients taking monoamine oxidase inhibitors or within 14 days of stopping such treatment.
- Children under the age of 12 years.
- In women who are breastfeeding (see section 4.6).
- During third trimester of pregnancy (see section 4.6).
- Children (0 - 18 years of age) who undergo tonsillectomy or adenoidectomy surgery for obstructive sleep apnoea syndrome due to an increased risk of developing serious and life-threatening adverse reactions.

4.4 Special warnings and precautions for use

Do not use continuously for more than ten days without consulting your doctor.

Consult your doctor if no relief is obtained with the recommended dosage.

Paracetamol, as in TENSTON SA CAPSULES

TENSTON SA CAPSULES contain 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.

Care is advised in the administration of paracetamol to patients with renal or hepatic impairment. Dosages in excess of those recommended may cause severe liver damage. The hazard of overdose is greater in those with noncirrhotic alcoholic liver disease.

Paracetamol should be administered only with particular caution under the following circumstances:

- Hepatocellular insufficiency, including Gilbert's Syndrome (familial non-haemolytic jaundice).
- Glucose-6-phosphatase dehydrogenase deficiency which may lead haemolytic anaemia.
- Severe renal insufficiency (creatinine clearance ≤ 30 ml/min).
- Chronic alcoholism, excessive alcohol intake.
- Chronic malnutrition, anorexia, bulimia, cachexia (low reserves of hepatic glutathione).
- Dehydration, hypovolaemia.
- Concomitant treatment with medicinal products affecting hepatic function.
- Glutathione deficiency.
- The elderly, adults and adolescents weighing less than 50 kg.

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), Drug Reaction with eosinophilia and systemic symptoms (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 TENSTON SA CAPSULES must immediately be discontinued and appropriate treatment instituted (see section 4.8).

Flucloxacillin

Caution is advised if paracetamol is administered concomitantly with flucloxacillin due to increased risk of high anion gap metabolic acidosis (HAGMA), particularly in patients with severe renal impairment, sepsis, malnutrition and other sources of glutathione deficiency (e.g. chronic alcoholism), as well as those using maximum daily doses of paracetamol. Close monitoring, including measurement of urinary 5-oxoproline, is recommended (see section 4.5).

Salicylates

Salicylates in prolonged treatments together with paracetamol significantly increased the risk of analgesic nephropathy, renal papillary necrosis, end-stage renal diseases, and cancer of the urinary bladder. Do not exceed the recommended individual dosages for salicylates and paracetamol, as in TENSTON SA CAPSULES (see section 4.5).

Anticoagulants

The anticoagulant effect could be increased when high doses of paracetamol is used together with anticoagulants, such as warfarin (see section 4.5).

Hepatotoxic medicines

The risk of paracetamol toxicity may be increased in patients receiving potentially hepatotoxic medicines or medicines that induce liver microsomal enzymes (see section 4.5).

Codeine, as in TENSTON SA CAPSULES

Exceeding the prescribed dose, together with prolonged and continuous use of this medication, may lead to dependency and addiction.

Codeine should be given with caution to patients with hypothyroidism, adrenocortical insufficiency, impaired liver function, 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, sedatives, and phenothiazines.
The prolonged use of high doses of codeine has produced dependence of the morphine type.

Patients with a history of cholecystectomy should consult a doctor before using TENSTON SA CAPSULES as it may cause acute pancreatitis in some patients.

Patients taking, or who have taken, monoamine oxidase inhibitors (MAOIs) within the preceding two weeks should not take TENSTON SA CAPSULES (see section 4.3 and 4.5).

Drug dependence, tolerance and potential for abuse
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 TENSTON SA CAPSULES 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.

Codeine, as in TENSTON SA CAPSULES should be used with caution in patients with personal or family history of substance abuse or mental health disorders because the risk of addiction is increased.

Drug withdrawal syndrome
Addiction can cause drug withdrawal syndrome upon abrupt cessation of therapy or dose reduction.
The opioid drug withdrawal syndrome is characterised by some or all of the following: restlessness, lacrimation, rhinorrhoea, yawning, perspiration, chills, myalgia, mydriasis and palpitations. Other symptoms may also develop including irritability, agitation, anxiety, hyperkinesia, tremor, weakness, insomnia, anorexia, abdominal cramps, nausea, vomiting, diarrhoea, increased blood pressure, increased respiratory rate or heart rate.

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, as in TENSTON SA CAPSULES

Caffeine should be given with care to patients with a history of peptic ulceration.

Excessive intake of caffeine (e.g. coffee, tea and some canned drinks) should be avoided while taking TENSTON SA CAPSULES (see section 4.9).

Meprobamate, as in TENSTON SA CAPSULES

Patients receiving meprobamate should be warned that their tolerance to ingested alcohol and other depressants of the central nervous system may be lowered with consequent impairment of judgement and co-ordination. Symptoms of porphyria may be exacerbated (see section 4.3).

Prolonged use of meprobamate may lead to the development of dependence of the barbiturate-alcohol type.

Meprobamate may induce the hepatic microsomal enzymes involved in drug metabolism.

TENSTON SA CAPSULES contains sodium

TENSTON SA CAPSULES contains less than 1 mmol sodium (23 mg) per table, that is to say essentially ‘sodium-free’.

4.5 Interactions with other medicines and other forms of interaction

Paracetamol, as in TENSTON SA CAPSULES

Hepatotoxic medicines

Increased risk of hepatotoxicity (see section 4.4).

Enzyme-inducing medicines

Increased risk of hepatotoxicity and possible decrease in therapeutic effects of paracetamol (see section 4.4).

Metoclopramide

Absorption of paracetamol may be accelerated.

Domperidone

Absorption of paracetamol may be accelerated.

Probenecid

Pre-treatment with probenecid can decrease paracetamol clearance and increase its half-life. Although urinary excretion of the sulphate and glucuronide conjugates of paracetamol are reduced, that of paracetamol is unchanged.

Colestyramine

Absorption of paracetamol is reduced if given within one hour of cholestyramine.

Salicylates

Prolonged concurrent use of paracetamol with salicylates increases the risk of adverse renal effects (see section 4.4).

Antibiotics

Chronic use of isoniazid, an antibiotic medicine often prescribed for tuberculosis, may increase the risk of liver damage when combined with paracetamol, even at recommended doses.

Warfarin and anticoagulants

Concurrent, chronic, high-dose administration of paracetamol may increase the anticoagulant effect (see section 4.4).

Paracetamol is recommended as the general analgesic and antipyretic of choice in patients on oral anticoagulant therapy. However, caution is needed since, although it has no effect on the gastric mucosa

or on platelet function, some studies (with warfarin, anisindione, dicoumarol, or phenprocoumon) and isolated reports have found an increased risk of bleeding in patients taking regular doses of paracetamol while on an oral anticoagulant. An increase in INR has also been reported in controlled studies of the use of paracetamol in patients stabilised on warfarin. Increased monitoring of anticoagulant therapy may be appropriate for those also taking paracetamol regularly.

Antibacterials

The plasma-paracetamol concentrations considered an indication for antidote treatment should be halved in patients receiving enzyme inducing drugs such as rifampicin. Severe hepatotoxicity at therapeutic doses or moderate overdoses of paracetamol has been reported in patients receiving isoniazid, alone or with other medicines for tuberculosis.

Antivirals

Severe hepatotoxicity has occurred after use of paracetamol in a patient taking zidovudine and co-trimoxazole. However, neither short-term nor long-term studies (the latter also in an individual patient) have shown any alteration of zidovudine elimination in patients taking zidovudine and paracetamol.

Interferon alfa

Paracetamol has also been found to enhance the antiviral effect of interferon alfa.

Flucloxacillin

Caution should be taken when paracetamol is used concomitantly with flucloxacillin as concurrent intake has been associated with high anion gap metabolic acidosis, especially in patients with risks factors (see section 4.4).

Other medicines

Paracetamol is metabolized in the liver and can therefore interact with other medicines that follow the same pathway or may inhibit or induce this route (e.g. barbiturates, such as phenobarbitone, tricyclic antidepressants, alcohol, carbamazepine, phenytoin, primidone, rifampicin, St John's Wort (*Hypericum perforatum*) or other drugs that induce liver enzymes), causing hepatotoxicity (see section 4.4), particularly

in overdose (see section 4.9).

Caffeine, as in TENSTON SA CAPSULES

Caffeine, a CNS stimulant, has an antagonistic effect towards the action of sedatives and tranquilizers. Caffeine may enhance the tachycardia effect of some decongestants.

Codeine, as in TENSTON SA CAPSULES

Metoclopramide and domperidone

Codeine may antagonize the effects of metoclopramide and domperidone on gastrointestinal motility.

Central nervous system medicines

Codeine potentiates the central depressive effects of central nervous system depressants including alcohol, anaesthetics, hypnotics, sedatives, tricyclic antidepressants and phenothiazines.

MAOIs

Opioid analgesics should be given with care to patients receiving monoamine oxidase inhibitors. The effect of CNS depressants (including alcohol) may be potentiated by codeine; these interactions are unlikely to be significant at the dosage involved.

MAOIs taken with pethidine have been associated with severe CNS excitation or depression (including hypertension or hypotension). Although this has not been documented with codeine, it is possible that a similar interaction may occur and therefore the use of codeine should be avoided while the patient is taking MAOIs and for 2 weeks after MAOI discontinuation.

Opiate analgesics may interact with monoamine oxidase inhibitors (MAOI) and result in serotonin syndrome. It is recommended that the product should not be taken concurrently or within two weeks of stopping treatment with a MAOI.

Sedative medicines such as benzodiazepines or related drugs:

The concomitant use of opioids with sedative medicines such as benzodiazepines or related drugs increase the risk of sedation, respiratory depression, coma and death because of additive CNS depressant effect. The dose and duration of concomitant use should be limited.

4.6 Fertility, pregnancy and lactation

Pregnancy

TENSTON SA CAPSULES should not be used during pregnancy (see section 4.3). This includes maternal use during labour because of the potential for respiratory depression in the neonate.

Due to the caffeine content of this product, it should not be used during pregnancy.

Regular use during pregnancy may cause drug dependence in the foetus, leading to withdrawal symptoms in the neonate.

The patient should be advised of the risk of neonatal opioid withdrawal syndrome, and it should be ensured that appropriate treatment will be available.

Breastfeeding

Codeine, as in TENSTON SA CAPSULES, should not be used during breastfeeding (see section 4.3), as codeine may be secreted in breast milk and may cause respiratory depression in the infant.
At normal therapeutic doses, codeine and its active metabolite may be present in breast milk at very low doses and is unlikely to adversely affect the breast fed infant. However, if the patient is an ultra-rapid metaboliser of CYP2D6, higher levels of the active metabolite, morphine, may be present in breast milk and on very rare occasions may result in symptoms of opioid toxicity in the infant, which may be fatal.
Although significant caffeine toxicity has not been observed in breastfed infants, caffeine may have a stimulating effect on the infant.

Due to the caffeine content of this product, it should not be used during breastfeeding.

Fertility

No information available.

4.7 Effects on ability to drive and use machines

TENSTON SA CAPSULES may cause drowsiness and patients should not drive vehicles or operate machinery where loss of attention could lead to accidents.

4.8 Undesirable effects

Tabulated list of adverse reactions

Paracetamol

System Organ Class	Frequency	Undesirable effects
Blood and lymphatic system disorders	*Less frequent*	Agranulocytosis, thrombocytopenia, leukopenia, pancytopenia, neutropenia, anaemia.
Immune system disorders	*Frequency not known*	Drug-induced hypersensitivity syndrome (DIHS)**, hypersensitivity reactions characterised by urticaria, dyspnoea, and hypotension (see Section 4.4).
Metabolism and nutrition disorders	*Less frequent*	Pyroglutamic aciduria (5-oxoprolinuria) and high-anion gap metabolic acidosis.
Ear and labyrinth disorders	*Frequency not known*	Hearing loss.
Cardiac disorders	*Frequency not known*	Possible increase in the risk of hypertension.
Gastrointestinal disorders	*Less frequent*	Pancreatitis
Hepatobiliary disorders	*Less frequent*	Hepatitis.
Skin and subcutaneous tissue disorders	*Less frequent*	Cutaneous hypersensitivity reactions including skin rashes, pruritus, sweating, purpura, urticaria and angioedema, severe cutaneous adverse reactions (SCARs) such as toxic epidermal necrolysis (TEN), Stevens–Johnson syndrome (SJS), acute generalized

		exanthematous pustulosis (AGEP), drug reaction with eosinophilia and systemic symptoms (DRESS)/ drug-induced hypersensitivity syndrome (DIHS) and fixed drug eruption (FDE) ** (FDE) (see section 4.4).
Renal and urinary disorders	*Less frequent*	Renal colic, renal failure and sterile pyuria (cloudy urine).

Caffeine

System Organ Class	**Frequency**	**Undesirable effects**
Psychiatric disorders	*Frequency not known*	Nervousness.
Nervous system disorder	*Frequency not known*	Headache, insomnia, restlessness, dizziness excitement and muscle tremor.
Eye disorders	*Frequency not known*	Scintillating scotoma.
Ear and labyrinth disorders	*Frequency not known*	Tinnitus.
Cardiac disorders	*Frequency not known*	Tachycardia and extrasystoles.
Gastrointestinal disorder	*Frequency not known*	Caffeine increases gastric secretions and may cause gastric ulceration.

Codeine phosphate

System Organ Class	**Frequency**	**Undesirable effects**
Psychiatric disorders	*Frequency not known*	Drug dependency can occur after prolonged use of codeine (see section 4.4).
Gastrointestinal disorder	*Less frequent*	Acute pancreatitis***.
	Frequency not	Constipation, nausea, vomiting,

	known	dyspepsia, dry mouth.
Nervous system disorder	*Frequency not known*	Dizziness, drowsiness, hyperalgesia (see section 4.4).
General disorders and administration site conditions	*Less frequent*	Drug withdrawal syndrome.
Renal and urinary disorders	*Frequency not known*	Difficulty with micturition.
Skin and subcutaneous tissue disorder	*Frequency not known*	Skin rashes, pruritus, sweating

Meprobamate

System Organ Class	**Frequency**	**Undesirable effects**
Blood and lymphatic system disorders	*Frequency not known*	Blood disorders including agranulocytosis, eosinophilia, leukopenia, thrombocytopenia, and aplastic anaemia have been reported.
Nervous system disorders	*Frequent*	Drowsiness.
	Frequency not known	Paraesthesia, weakness, headache, excitement, dizziness, ataxia.
Eye disorders	*Frequency not known*	Disturbances of vision.
Cardiac disorders	*Frequency not known*	Hypotension, tachycardia and cardiac dysrhythmias may occur.
Gastrointestinal disorders	*Frequency not known*	Nausea, vomiting, diarrhoea.
Skin and subcutaneous tissue disorders	*Frequency not known*	Hypersensitivity reactions such as skin rashes, urticaria and purpura or may be more severe with angioneurotic oedema, bronchospasm, or

		anuria. Erythema multiforme has been reported.

Post marketing experience

The following less frequent side effects have been reported:

**: Fixed drug eruptions (FDE) and drug-induced hypersensitivity syndrome (DIHS) (See section 4.4).

*** Increased risk of abdominal pain, including pancreatitis has been reported.

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 SAHPRA website.

For reporting of side effects directly to the HCR, contact +27 11 635 0134 or email Adcock.aereports@adcock.com.

4.9 Overdose

In the event of overdosage, consult a doctor or take the patient to the nearest hospital immediately. Specialised treatment is essential as soon as possible. The latest information regarding the treatment of overdosage can be obtained from the nearest poison control centre.

Codeine

The effects in overdosage will be potentiated by simultaneous ingestion of alcohol and psychotropic medicines. Patients should be informed of the signs and symptoms of overdose and to ensure that family and friends are also aware of these signs and to seek immediate medical help if they occur.

Symptoms

An overdose of codeine is characterised, in the first phase, by nausea and vomiting. An acute depression of the respiratory centre can cause cyanosis, slower breathing, drowsiness, ataxia and, more rarely, pulmonary oedema. Respiratory pauses, miosis, convulsion, collapse and urine retention. Signs of histamine release have been observed as well.

Management

This should include general symptomatic and supportive measures including a clear airway and monitoring of vital signs until stable. Consider activated charcoal if an adult presents within one hour of ingestion of more than 350 mg or a child more than 5 mg/kg. Give naloxone if coma or respiratory depression is present. Naloxone is a competitive antagonist and has a short half-life, so large and repeated doses may be required in a seriously poisoned patient. Observe for at least four hours after ingestion, or eight hours if a sustained release preparation has been taken.

Meprobamate

Acute meprobamate overdosage can produce stupor, coma, convulsions, shock, circulatory and respiratory collapse.

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 – 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

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, 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 dysrhythmias have been reported.

After maternal overdosage during pregnancy, foetal metabolism of paracetamol that crosses the placenta can produce hepatotoxic metabolites, causing foetal hepatotoxicity.

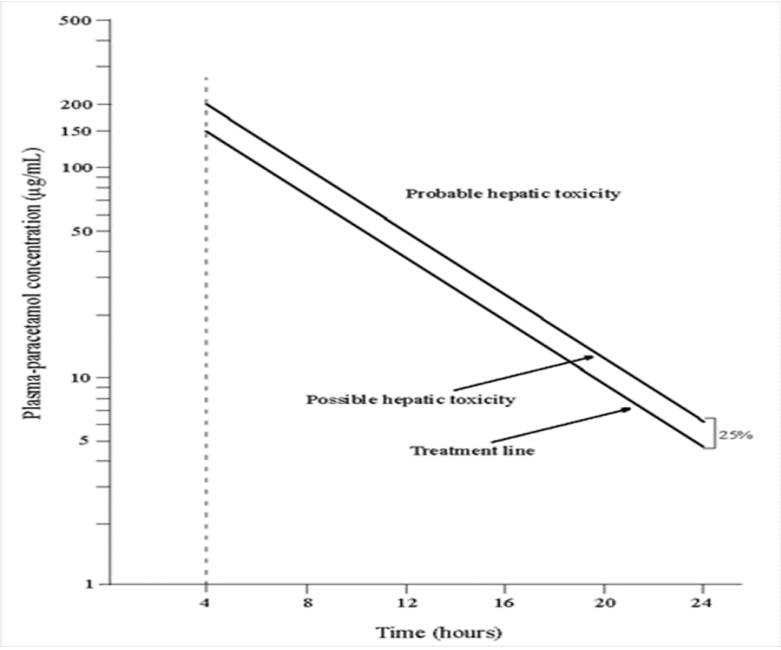
Treatment for paracetamol overdosage:

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.

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



Reference: Martindale, The Complete Drug Reference.

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. Hepatic tests must be carried out at the beginning of treatment and repeated every 24 hours. In most cases hepatic transaminases return to normal in one to two weeks with full restitution of the liver function. In very severe cases, however, liver transplantation may be necessary.

Caffeine

Symptoms

Overdose of caffeine may result in epigastric pain, vomiting, diuresis, tachycardia or cardiac dysrhythmia, CNS stimulation (insomnia, restlessness, excitement, agitation, nervousness, jitteriness, tremors and convulsions).

It must be noted that for clinically significant symptoms of caffeine overdose to occur with this product, the amount ingested would be associated with serious paracetamol related liver toxicity.

Management

Patients should receive general supportive care (e.g. hydration and maintenance of vital signs). The administration of activated charcoal may be beneficial when performed within one hour of the overdose but can be considered for up to four hours after the overdose. The CNS effects of overdose may be treated with intravenous sedatives.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: A 2.9 Other analgesics

Pharmacotherapeutic group: Opioids in combination with non-opioid analgesics, ATC code: N02AJ09.

TENSTON SA CAPSULES have analgesic, antipyretic and muscle relaxing actions.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Capsule fill

Magnesium stearate

Sodium starch glycolate

Starch 1500

Capsule shell

Brilliant blue (E133)

Titanium dioxide (E 171)

Gelatine

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store at or below 25 °C. Protect from light and moisture.

6.5 Nature and contents of container

Securitainers containing 20, 40, 100 and 500 capsules.

White cylindrical screw type HDPE container with screw cap containing 20, 40, 100 and 500 capsules.

Not all pack sizes are necessarily marketed.

6.6 Special precautions for disposal

Not applicable.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Adcock Ingram Limited

1 New Road,

Erand Gardens,

Midrand,

1685

Customer Care: 0860 ADCOCK / 232625

8. REGISTRATION NUMBER

R/2.9/90

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

02 April 1984

10. DATE OF REVISION OF THE TEXT

04 August 2025

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