SCHEDULING STATUS: **S5**

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

Meprobamate, Codeine phosphate, Paracetamol and Caffeine anhydrous

Sugar free

Read all of this leaflet carefully before you start taking TENSTON SA CAPSULES

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist, nurse or other health care provider.
- TENSTON SA CAPSULES has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What TENSTON SA CAPSULES is and what it is used for
2. What you need to know before you take TENSTON SA CAPSULES
3. How to take TENSTON SA CAPSULES
4. Possible side effects
5. How to store TENSTON SA CAPSULES
6. Contents of the pack and other information

1. What TENSTON SA CAPSULES is and what it is used for

TENSTON SA CAPSULES contain the active ingredients Paracetamol 200 mg, Codeine phosphate 10 mg, Caffeine 30 mg and Meprobamate 150 mg.

TENSTON SA CAPSULES are used for the symptomatic relief of mild to moderate pain and fever.

2. What you need to know before you take TENSTON SA CAPSULES

Do not take TENSTON SA CAPSULES

- if you have ever had an allergic reaction to paracetamol, codeine phosphate, opioid analgesics caffeine, meprobamate or any of the other ingredients in the capsules (these are listed in section 6),
- if you need to remain alert,
- if you have porphyria (a rare inherited blood disorder),
- if you have severe kidney or liver problems,
- if you are experiencing an asthma attack or heart failure (secondary to a chronic lung disease),
- if you suffer from a head injury or any conditions in which intracranial pressure is raised (a rise in the pressure around your brain),
- if you had an operation on the biliary tract (liver, gall bladder and bile ducts),
- if you have any lung/airway (respiratory) problems, especially in the presence of cyanosis (condition where your skin or lips turn blue due to an insufficient level of oxygen in the blood) and excessive mucus and fluid secretion in the airways,
- if you suffer from acute alcoholism (alcohol poisoning due to rapid and excessive alcohol intake),
- if you have a history of fits (epilepsy),
- if you are taking an antidepressant in the class called monoamine oxidase inhibitors or within fourteen days of stopping such treatment,
- if you are under 12 years old,
- if you are breastfeeding,
- if you are pregnant, do not take codeine containing products, including TENSTON SA CAPSULES later in your pregnancy because these medicines may cause problems in your unborn baby,
- For pain relief in children and adolescents (0-18 years of age) after removal of their tonsils or adenoids due to obstructive sleep apnoea syndrome.

Warnings and precautions

TENSTON SA CAPSULES contains paracetamol which may be fatal in overdose. In the event of overdosage or suspected overdose even if the person may not be showing or experiencing any symptoms, the nearest doctor, hospital or Poison Centre must be contacted immediately. Prompt specialized treatment is essential as soon as possible.

TENSTON SA CAPSULES also contains codeine, which is an opioid medicine.

Repeated use of TENSTON SA CAPSULES may result in you becoming accustomed to it (needing to take higher doses). Repeated use of TENSTON SA CAPSULES may also lead to dependence, abuse and addiction, which may result in life-threatening overdose.

If you are taking TENSTON SA CAPSULES for longer than the recommended time or at higher than recommended doses you are at risk of liver damage.

If you experience any of the following signs whilst taking TENSTON SA CAPSULES, 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 TENSTON SA CAPSULES and tell your doctor

- If your symptoms do not improve within 10 days of continuous use.
- If you have a history of liver or kidney disease including alcoholic liver disease as paracetamol intake must then be carefully monitored and controlled by your doctor.
- If you have a liver condition in which the liver doesn't properly process bilirubin called Gilbert’s syndrome.
- If you suffer from kidney disease.
- If you suffer from chronic alcoholism or excessive alcohol intake.

- If you suffer from dehydration (where your body does not have as much water and fluids as it should) or hypovolaemia (a state of decreased blood volume).
- If you have chronic malnutrition (a condition where your body does not have enough nutrients).
- If you suffer from bulimia or anorexia (eating disorders).
- If you suffer from cachexia or wasting syndrome (is loss of weight, muscle atrophy, fatigue, weakness, and significant loss of appetite in someone who is not actively trying to lose weight).
- If you suffer from glucose-6-phosphate dehydrogenase deficiency (An inherited condition, G6PD deficiency is when someone doesn't have enough of the enzyme G6PD, which protects red blood cells) as this can lead to a condition where the body does not have enough red blood cells.
- If you have glutathione deficiency.
- If you are taking other medicines that can affect liver function.
- If you weigh less that 50 kg.
- If you have serious skin reactions 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) including blistering and peeling of the skin (e.g., Stevens-Johnson syndrome). Stop taking TENSTON SA CAPSULES at the first appearance of skin rash, or any other sign of hypersensitivity and immediately go to your doctor or nearest hospital (See Possible side effects)
- If you take salicylates like aspirin. If taken together with TENSTON SA CAPSULES, it increases the risk of kidney diseases.
- If you are taking blood thinning medicines, such as warfarin.
- If you are taking flucloxacillin (used to treat bacterial infections). If taken together with TENSTON SA CAPSULES, it may cause build up of acid in your body.
- If you are suffering from hypothyroidism (underactive thyroid gland), adrenocortical insufficiency (condition in which the adrenal glands do not produce enough steroid hormones), prostatic hypertrophy (enlarged prostate gland) or shock.
- if you are consuming alcohol or taking other sedatives, TENSTON SA CAPSULES may potentiate the

effect of alcohol and other sedatives (see Other medicines and TENSTON SA CAPSULES).

- If you have taken medicine for depression (monoamine oxidase inhibitor) within preceding two weeks should not take this medicine.
- *Opioid Induced Hyperalgesia*

  Taking high dose of opioid medications 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).

Other medicines and TENSTON SA CAPSULES

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

Please consult your doctor or pharmacist for advice and information if you are taking any of the following and wish to use TENSTON SA CAPSULES as problems may occur if you use both products at the same time:

- *Hepatotoxic medicines (medicines that affect the liver) e.g. carbamazepine:* May increase the risk of liver damage.
- *Medicines containing metoclopramide or domperidone (used for nausea):* Absorption of TENSTON SA CAPSULES may be accelerated.
- *Medicines used to treat gout and high blood levels of uric acid*, such as probenecid, can decrease the elimination of TENSTON SA CAPSULES from the body.
- *Medicines containing colestyramine (used for reducing cholesterol in the blood):* Absorption of TENSTON SA CAPSULES is reduced if given within one hour of colestyramine.
- *Salicylates (used for pain and inflammation):* Prolonged concurrent use of TENSTON SA CAPSULES with salicylates increases the risk of adverse kidney effects.
- *Chronic use of isoniazid and/or rifampicin, antibiotic medicines often prescribed for tuberculosis:* These medicines may increase the risk of liver damage when combined with TENSTON SA CAPSULES, even at recommended doses.

- *Warfarin (used to prevent blood clots from forming):* TENSTON SA CAPSULES may increase the anticoagulant effect and there is an increased risk of bleeding if you take regular or high doses of paracetamol while on an oral anticoagulants.
- *Zidovudine used to treat viral infections and co-trimoxazole used to treat bacterial infections:* These medicines together with TENSTON SA CAPSULES can cause damage to the liver.
- The effect of Interferon alfa used to treat cancers and viral infections, can be increased when used together with TENSTON SA CAPSULES and your doctor might change the dose.
- *Flucloxacillin (antibiotic)*, due to a serious risk of blood and fluid abnormality (high anion gap metabolic acidosis) that must have urgent treatment, and which may occur particularly in case of severe renal impairment, sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), malnutrition, chronic alcoholism, and if the maximum daily doses of paracetamol are used.
- *Phenobarbitone, tricyclic antidepressants, alcohol, carbamazepine, phenytoin, primidone, rifampicin, St John's Wort (Hypericum perforatum*). These medicines interact with paracetamol in the same pathway causing toxic to liver should not administered with TENSTON SA CAPSULES.
- Central nervous system depressants such as anaesthetics, hypnotics and sedatives.
- *Monoamine oxidase inhibitors (used to treat depression):* if you are taking or have taken within the last 2 weeks medicines prescribed by your doctor for the treatment of depression or anxiety, or medicines known as tranquilisers (including monoamine oxidase inhibitors-MAOIs).

TENSTON SA CAPSULES with food, drink and alcohol

Alcohol may increase the effects of TENSTON SA CAPSULES, and your doctor may wish to monitor you carefully if you are using alcohol regularly or have a problem with alcohol abuse.

Avoid excessive intake of caffeine containing products such as coffee, tea and some canned drinks.

Pregnancy, breast-feeding 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 TENSTON SA CAPSULES.

TENSTON SA CAPSULES is, however, not recommended for use by pregnant or breastfeeding women (see Do not take TENSTON SA CAPSULES).

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

If you use TENSTON SA CAPSULES during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.

Do not take TENSTON SA CAPSULES while you are breastfeeding. Codeine and Morphine passes into breast milk and will affect your baby.

Driving and using machines

It is not always possible to predict to what extent TENSTON SA CAPSULES may interfere with your daily activities. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which TENSTON SA CAPSULES affects them. TENSTON SA CAPSULES, however, may cause drowsiness and care should be taken when driving or operating machinery.

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'.

3. How to take TENSTON SA CAPSULES

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

Always take TENSTON SA CAPSULES exactly as your doctor has instructed you. Your doctor will decide which dose is applicable to you. You should check with your doctor or pharmacist if you are unsure.

The usual adult dose of TENSTON SA CAPSULES is 1 to 2 capsules four times daily.

Children: 12 years and older is 1 capsule four times daily.

Your doctor will tell you how long your treatment with TENSTON SA CAPSULES will last. However, it is not recommended to use continuously for more than ten days.

If you have the impression that the effect of TENSTON SA CAPSULES is too strong or too weak, tell your doctor or pharmacist.

If you take more TENSTON SA CAPSULES than you should

TENSTON SA CAPSULES contains paracetamol, which may be fatal in overdose. In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Immediate medical attention is critical. Even if you do not show symptoms of an overdose, go immediately to your nearest hospital or poison centre. Symptoms of paracetamol overdosage in the first 24 hours include pallor (unhealthy pale appearance), nausea, vomiting, loss of appetite 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 lead to brain damage, coma and death. Kidney failure may develop even in the absence of severe liver damage and heart rhythm problems (dysrhythmias) have also been reported.

.Additional symptoms resulting from codeine, meprobamate and caffeine may include restlessness, muscle tremor (involntary shaking or movement), diuresis (an increase in the amount of urine), palpitations, drowsiness, insomnia, excitement, agitation, jitteriness (jumpiness, nervousness, restiveness), stupor (state of speechlessness, motionlessness, and unresponsiveness to stimulation, but are otherwise completely conscious), coma, convulsions (fits), difficulty urinating, bluish or greyish colour of the skin, nails, lips due to lack of oxygen in blood (cyanosis), shock, coma, problems with your blood vessels (circulatory collapse) and breathing (respiratory system/respiratory collapse).

If you forget to take TENSTON SA CAPSULES

If you miss a dose, take it as soon as possible. However, if it is almost time for the next dose, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for forgotten individual

doses.

If you stop taking TENSTON SA CAPSULES

TENSTON SA CAPSULES contain codeine (one of the active ingredients). When you stop taking it you may get withdrawal symptoms.

Withdrawal symptoms can include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling of being sick, diarrhoea, loss of appetite, shaking, shivering or sweating. You should talk to your doctor if you think you are suffering from withdrawal symptoms.

4. Possible side effects

TENSTON SA CAPSULES can have side effects.

Not all side effects reported for TENSTON SA CAPSULES are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking TENSTON SA CAPSULES, please consult your healthcare provider for advice.

If any of the following happens, stop taking TENSTON SA CAPSULES and tell your doctor immediately or go to the casualty department of your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- Rash or itching
- Fainting
- Blistering of the skin, mouth, eyes and genitals as these may be due to a serious allergic reaction known as Stevens-Johnson Syndrome (SJS), severe cutaneous adverse reactions (SCARS) such as toxic epidermal necrolysis (TEN), acute generalised exanthematous pustulosis (AGEP), Drug reaction with eosinophilia and systemic symptoms (DRESS)/Drug-induced hypersensitivity syndrome (DIHS) and fixed drug eruptions (FDE)

These are all very serious side effects. If you have them, you may have had a serious reaction to TENSTON SA

CAPSULES. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent:

Drowsiness (a feeling of being sleepy and lethargic)

Less frequent:

- Blood disorders including agranulocytosis (lowered white blood cell count), leukopenia (low level of white blood cells) and thrombocytopenia (low blood platelet count).
- No bacteria in urine (Sterile pyuria)
- Abdominal pain including risk of inflammation of pancreas, which causes severe pain in the abdomen and back (Acute pancreatitis).
- Inflammation of the liver (you may feel nauseas, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, and dark coloured urine),

Frequency not known:

- Blood disorders including eosinophilia (high level of white blood cells) and aplastic anaemia (a rare condition in which the body stops producing enough new blood cells).
- Hearing loss
- High blood pressure.
- Headache, inability to sleep, restlessness, dizziness, excitement, and muscle tremor (involuntary movements).
- Tinnitus (ringing of the ears)
- Caffeine increases gastric secretions (such as stomach acid) and may cause stomach ulcers
- Drug dependency can occur after prolonged use of codeine
- Codeine may cause nausea, vomiting, constipation, and dry mouth
- Hyperalgesia (a condition where there is an increased sensitivity to pain stimuli, resulting in a heightened perception of pain)

- Kidney problems (you may have blood in your urine, cloudy urine, change in how frequent you want to urinate)
- Sweating
- paraesthesia (tingling or pricking / “pins and needles”), weakness, headache, excitement, dizziness, ataxia (slurred speech, stumbling, falling, and incoordination)
- Scintillating scotoma (visual aura or blind spot that affects a part of your vision), other vision disturbances.
- Tachycardia (rapid heartbeat), extrasystoles (skipped heartbeats). Hypotension (low blood pressure), cardiac dysrhythmias (improper heartbeat)

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, nurse or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of TENSTON SA CAPSULES.
For reporting of side effects directly to Adcock Ingram Limited, contact +27 11 635 0134 or email Adcock.aereports@adcock.com.

5. How to store TENSTON SA CAPSULES

- Store all medicines out of reach of children.
- Store at or below 25 °C. Protect from light and moisture.
- Do not use after the expiry date stated on the bottle.
- 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 TENSTON SA CAPSULES contains

The active substances are paracetamol, codeine phosphate, caffeine and meprobamate.

***The other ingredients are*:**

Capsule fill

Magnesium stearate

Sodium starch glycolate

Starch 1500

Capsule shell

Brilliant blue (E133)

Titanium dioxide (E 171)

Gelatine

What TENSTON SA CAPSULES looks like and contents of the pack

TENSTON SA CAPSULES are opaque, blue capsules imprinted with “COVAN” on the capsule shell.

Capsules are packed in:

- 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 may be marketed.

Holder of Certificate of Registration

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