PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

ACTATENSE (tablets)

Paracetamol, Doxylamine succinate, Caffeine, Codeine phosphate

Sugar free

Please read this leaflet carefully before you take ACTATENSE

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- ACTATENSE 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 ACTATENSE is and what it is used for

ACTATENSE has analgesic (to relieve pain), antipyretic (to prevent or reduce fever) and antihistaminic (allergy treatment) properties.

ACTATENSE tablets are used for the relief of mild to moderate pain and pain associated with

tension and fever.

2. What you need to know before you take ACTATENSE

Do not take ACTATENSE

- if you are hypersensitive (allergic) to paracetamol, codeine phosphate, caffeine or doxylamine succinate or any of the other ingredients of ACTATENSE (listed in section 6).
- if you have impaired liver function.
- if you have problems with breathing and impaired lung function.
- if you have heart failure as a result of chronic lung disease.
- if you are having an asthma attack.
- if you had an operation on your bile ducts.
- if you recently had a head injury or have increased pressure in the brain (possibly after a head injury or brain disease).
- if you have used monoamine oxidase inhibitors (certain medicines used for treatment of depression) or within 14 days of stopping such treatment.
- if you are pregnant or breastfeeding your baby.
- if you are alcohol dependent.
- in children under the age of 12 years.

Warnings and precautions

Paracetamol may be fatal in overdose.

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

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

Do not take together with any other paracetamol or codeine containing products.

Special care should be taken with ACTATENSE

Tell your doctor or health care provider

- if you are an asthmatic.
- if you have kidney or liver or disease.
- if you have weakness in skeletal muscles (myasthenia gravis).
- if you are in shock.
- if you have enlarged prostate (prostatic hypertrophy).
- if you have inflammatory or obstructive bowel disorders or obstruction of the gastric outlet.
- if you have hyperthyroidism or hypothyroidism (over or under active thyroid).
- if your adrenal glands do not produce adequate amounts of steroid hormones (adrenocortical insufficiency).
- if you have a history of sores that develop in the lining of the stomach (peptic ulceration).
- if you have high pressure in your eye (glaucoma).
- if you have heart rhythm problems or heart and blood vessel disease (cardiac arrhythmias or other cardiovascular disease).
- if you have epilepsy.
- if you have urinary retention.
- if you are malnourished or dehydrated.

Children

ACTATENSE tablets should NOT be used in children under 12 years of age.

Other medicine and ACTATENSE

Always tell your healthcare professional if you are taking any other medicines (this includes complementary or traditional medicines).

ACTATENSE can interfere with medicines:

- which is toxic to the liver or induce liver enzymes – it increases risk of toxicity.
- which make you drowsy or sleepy (CNS depressants) (e.g. barbiturates, anaesthetics, hypnotics, other opioid analgesics, anxiolytic sedatives, antipsychotics, tricyclic

antidepressants and phenothiazines – it enhances the depressant effects.

- to thin the blood such as warfarin (or other coumarins).
- to stop you feeling sick (nausea) or being sick (vomiting) (e.g. metoclopramide) – it accelerates the absorption of paracetamol.
- for lowering blood cholesterol levels (cholestyramine) – It reduces absorption of paracetamol.
- to treat irregular heartbeat (mexiletine).
- to treat stomach ulcers (cimetidine).
- to treat irregular heart rate (quinidine) – it can inhibit the pain effect.
- for oral contraception.
- for the treatment of epilepsy (carbamazepine; phenobarbital; phenytoin; primidone).
- for treatment of gout - it may affect the excretion of ACTATENSE.
- it may affect the metabolism of medicine in the liver.
- it may mask the symptoms of damage by medicine toxic to the ears.

ACTATENSE should be used with care if you concomitantly use alcohol, antivirals, antibacterials, lithium (to treat bipolar disorders), methoxsalen (to treat skin diseases) theophylline (to treat respiratory diseases), sympathomimetics (antihypertensives).

ACTATENSE with food drink and alcohol

ACTATENSE tablets can be taken without regard to food or drink intake.

Do NOT drink alcohol whilst taking ACTATENSE.

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 ACTATENSE.

ACTATENSE should not be used during pregnancy or while breastfeeding.

Driving and using machines

Do not drive or operate machinery until you know how ACTATENSE tablets affect you. It may make you feel drowsy or sleepy which may be increased when taking alcohol or central nervous system depressants simultaneously. If these tablets affect you in this way, DO NOT drive or operate machinery.

ACTATENSE contains Quinoline Yellow CI 47005

ACTATENSE contains Quinoline Yellow CI 47005 which may cause allergic reactions.

3. How to take ACTATENSE

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

Always take ACTATENSE exactly as your doctor or pharmacist has told you.

Check with your doctor or pharmacist if you are not sure.

The usual dose for adults and children over 12 years is:

Take 1 to 2 tablets with water every 4 hours, with a maximum of 8 tablets daily.

Do NOT exceed the recommended maximum dose.

Do not use continuously for more than 10 days without consulting your doctor.

If your symptoms worsen or do not improve with treatment, please consult your doctor or pharmacist.

Children

ACTATENSE should not be given to children below the age of 12 years.

Elderly patients

The dosage should be reduced in elderly and debilitated patients.

Patients with liver and kidney impairment

The dosage in renal functional impairment must be reduced and should be taken under medical supervision.

How and when should you take ACTATENSE

ACTATENSE is for oral use.

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

If you take more ACTATENSE than you should

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

ACTATENSE tablets contain 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 2 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. In the event of overdosage, consult your doctor or pharmacist immediately. If neither is available, seek help at the nearest hospital or poison control centre.

If you forget to take ACTATENSE

If you forget to take ACTATENSE tablets, do not take a double dose to make up for the missed dose.

If you stop taking ACTATENSE

ACTATENSE contains codeine and can cause addiction if you take it continuously for many days. When you stop taking it you may get withdrawal symptoms. You should talk to your doctor or pharmacist if you think you are suffering from withdrawal symptoms.

Withdrawal symptoms such as restlessness, difficulty in sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating may occur if you suddenly stop taking ACTATENSE.

4. POSSIBLE SIDE EFFECTS

ACTATENSE may have side effects.

Not all side effects reported for ACTATENSE are included in this leaflet.

Should your general health worsen of if you experience any untoward effects while receiving ACTATENSE, please inform your doctor, pharmacist or other healthcare provider for advice.

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

- symptoms of an allergic reaction such as sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching and feeling unwell.
- nausea and vomiting.
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to ACTATENSE. You may need urgent medical attention or hospitalisation.

Talk to your doctor straight away if you notice the following serious side effects:

- severe stomach pain, which may reach to your back. This could be a sign of inflammation of the pancreas (pancreatitis). This is a very rare side effect.
- you get infections or bruise more easily than usual. This could be because of a blood

problem (such as agranulocytosis or thrombocytopenia).

- you get serious skin reactions (Steven Johnson syndrome or toxic epidermal necrolysis).

The following side-effects have been reported, which may be related to the use of ACTATENSE:

Frequent side effects:

- gastrointestinal symptoms such as difficulty in emptying the bowels (constipation), feeling sick (nausea) or being sick (vomiting), drowsiness.

Less frequent side effects:

- hypersensitivity (allergy) which can be severe
- gastrointestinal disturbances
- excitement
- restlessness
- sleeplessness (insomnia)
- nightmares
- loss of appetite (anorexia)
- nervousness
- dizziness
- spinning sensation (vertigo)
- confusion
- facial flushing
- dry mouth
- sweating
- tinnitus (ringing in the ear)
- irregular heartbeat
- irregular and difficult breathing

- diarrhoea
- rashes
- sudden decrease in amount of urine
- unusual tiredness or weakness
- visual disturbances including blurred vision
- difficulty passing urine
- shortness of breath
- tremor and fits
- low blood pressure (lightheadedness or fainting when standing up)
- tingling sensation in hands
- increased pressure in the head
- high body temperature
- headache.

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 or pharmacist or nurse. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of ACTATENSE.

5. How to store ACTATENSE

Store all medicines out of reach of children.

Store at or below 25 °C and protect from light.

Keep ACTATENSE in the outer container until required for use.

Do not use after the expiry date stated on the label/carton.

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 ACTATENSE contains

The active ingredients per tablet are paracetamol, doxylamine succinate, caffeine, codeine phosphate

The other ingredients are colloidal silicon dioxide, magnesium stearate, maize starch, micro-crystalline cellulose, Povidone K25, Quinoline Yellow CI 47005, sodium starch glycolate, purified talc.

What ACTATENSE looks like and contents of the pack

A round yellow flat bevelled edge tablet, scored on one side.

Cardboard carton containing 20 or 40 tablets (2 or 4 aluminium/PVC blister packs of 10 tablets each).

REGISTRATION NUMBER

38/2.8/0152

HOLDER OF THE CERTIFICATE OF REGISTRATION

Smart Pharmaceuticals (Pty) Ltd

247 Voortrekker Road

Kraaifontein

Cape Town, 7570

The leaflet was last revised in

18 May 2022

Access to corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

ACT/PIL/A