

Teva Pharmaceuticals (Pty) Ltd

Product name: Acurate

Each tablet contains paracetamol 450 mg, doxylamine succinate 5 mg, caffeine 30 mg, codeine phosphate 10 mg

Reg no: Z/2.8/221

PATIENT INFORMATION LEAFLET:

SCHEDULING STATUS:

S2

ACURATE (tablets)

Paracetamol 450 mg

Doxylamine Succinate 5 mg

Caffeine 30 mg

Codeine Phosphate 10 mg

Sugar free.

Read all of this leaflet carefully before you start taking ACURATE.

ACURATE is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use ACURATE carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share ACURATE with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

WHAT IS IN THIS LEAFLET:

- 1. WHAT ACURATE IS AND WHAT IT IS USED FOR**
- 2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ACURATE**
- 3. HOW TO TAKE ACURATE**
- 4. POSSIBLE SIDE EFFECTS**
- 5. HOW TO STORE ACURATE**
- 6. CONTENTS OF THE PACK AND OTHER INFORMATION**

1. WHAT ACURATE IS AND WHAT IT IS USED FOR:

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ACURATE has pain relieving, fever reduction and allergic reaction reduction properties. ACURATE can be used for mild to moderate pain associated with tension such as tension headache or muscle contraction, neuralgia (a sharp, shocking pain that follows the path of a nerve and is due to irritation or damage to the nerve), period pain and for pain relief following surgery or injury.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ACURATE:

Do not take ACURATE:

- If you are hypersensitive (allergic) to paracetamol, doxylamine succinate, caffeine, codeine phosphate or any of the other ingredients of ACURATE.
- If you suffer from severe liver and kidney function impairment.
- If you suffer from acute intermittent porphyria.
- If you are experiencing inadequate ventilation, especially if you are experiencing bluish coloration of your skin, secretion of phlegm in your lungs, head injury or a condition in which the pressure exerted on your brain is increased. ACURATE should not be taken during an attack of bronchial asthma or in heart failure caused by long term lung disease.
- If you suffer from acute alcoholism.
- If you are taking monoamine oxidase inhibitors or within 14 days of stopping such treatment.
- If you are pregnant.
- If you are known to be a CYP2D6 ultra-rapid metaboliser where you metabolise codeine into morphine very rapidly.

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Warnings and precautions:

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

If you use ACURATE along with alcohol or central nervous system depressants, you may experience drowsiness and impaired concentration.

If you take more ACURATE than is prescribed, it may cause severe liver damage.

If you suffer from liver or kidney disease you should take ACURATE under medical supervision.

If you suffer from high blood pressure, hypothyroidism, adrenocortical insufficiency (hormonal problems), myasthenia gravis (a condition which weakens muscles), an enlarged prostate, problems with passing urine, shock, inflammatory or obstructive bowel syndrome.

If you have acute abdominal (stomach) conditions (e.g. peptic ulcer), recent gastrointestinal surgery, gallstones, a history of irregular heartbeats or fits.

If you have a history of drug abuse, mood swings or are under psychiatric treatment.

If you have asthma.

If you are elderly or debilitated.

If you suffer from porphyria, glaucoma or prostatic hypertrophy.

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

Other medicines and ACURATE:

Always tell your healthcare provider if you are taking any other medicine.

(This includes complementary or traditional medicines.)

Do not take ACURATE if you are taking:

- medicines to treat depression called MAOIs (monoamine oxidase inhibitors) or if you have recently taken them in the last two weeks. MAOIs are medicines such as moclobemide, phenelzine, tranylcypromine (see **section 2**).

Please inform your doctor or pharmacist if you are taking the following medicines:

- using ACURATE with alcohol, anaesthetics (medicines that induce sleep), medicines used for calmness and

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neuroleptic antipsychotic medicines may cause depressing effects such as drowsiness.

- benzodiazepines (used for treatment of anxiety or sleep disorders), e.g. diazepam, clobazam, lorazepam, chlordiazepoxide, oxazepam, temazepam, nitrazepam, loprazolam, lormetazepam or clonazepam
- metoclopramide or domperidone - used to stop you from feeling sick (nausea) or being sick (vomiting)
- cholestyramine (cholesterol lowering medicine)
- warfarin (blood thinners) especially with prolonged use
- CNS depressants which make you sleepy or drowsy such as alcohol, barbiturates, narcotic analgesics (strong pain medicines), medicines used to help you sleep such as hypnotics, sedatives, tranquilizers and medicines used for depression or mental health problems such as tricyclic antidepressants and phenothiazines
- medicines for the treatment of high blood pressure (diuretics and antihypertensives)
- hydroxyzine - to treat anxiety and tension
- any medicines from the group called neuromuscular blockers (e.g. tubocurarine)
- quinidine (used to treat irregular heart rate)
- kaolin or loperamide (used for the treatment of diarrhea)
- medicines called antimuscarinics (e.g. atropine, hyoscine)
- mexiletine (used to treat irregular heartbeat)
- cisapride (used to treat gastro-oesophageal reflux disease)
- cimetidine (used to treat stomach ulcers)
- naloxone (used to treat a narcotic overdose)
- naltrexone (used as part of a treatment program for drug or alcohol dependence).

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Pregnancy, breastfeeding and fertility:

- It has not yet been established if it is safe to use ACURATE during pregnancy or breastfeeding.
- If you are pregnant or breastfeeding your baby while taking ACURATE, please consult your doctor, pharmacist or other healthcare provider for advice.

Driving and using machines:

ACURATE may lead to drowsiness and impaired concentration therefore when patients are taking ACURATE, they should not drive a vehicle or operate machinery or perform potentially hazardous tasks where loss of concentration can lead to accidents.

3. HOW TO TAKE ACURATE:

Do not share ACURATE with any other person.

Always use ACURATE exactly as described in this leaflet or as your healthcare provider has told you. Check with your healthcare provider if you are not sure.

The usual dose for adults and children 12 years and older is 2 tablets 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.

If you have the impression that the effect of ACURATE is too strong or too weak, talk to your doctor or pharmacist.

ACURATE tablets must be swallowed.

If you take more ACURATE than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

This product 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.

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Overdosage of ACURATE will cause symptoms listed below under **section 4** in a more severe form.

You may experience sedation.

It may cause drowsiness, coma, convulsions and low blood pressure.

You may experience paleness of your face or palms, nausea, vomiting, eating disorders and abdominal pain within the first 24 hours.

It may be fatal especially in children. Coma, heart failure and death may occur within 18 hours. Prompt treatment is essential. A delay in starting treatment may mean that antidote is given too late to be effective.

If you forget to take ACURATE:

If you miss a dose, take it as soon as you remember. However, if it is almost time for your next dose, skip the missed dose and take only a single dose as usual.

Do not take a double dose to make up for forgotten individual doses.

4. POSSIBLE SIDE EFFECTS:

ACURATE can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing
- itchy, lumpy skin rash (hives) or nettle rash (urticaria)
- rash, fever, swelling, bruising or tiredness
- difficulty in breathing or dizziness

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the

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following:

- severe stomach pain, which may reach to your back, as this could be a sign of inflammation of the pancreas (pancreatitis)
- you get infections or bruise more easily than usual. This could be because of a blood problem (such as agranulocytosis or thrombocytopenia)
- yellowing of the skin or the whites of the eyes.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following frequent side effects which lasts longer than a few days or gets serious:

- drowsiness
- constipation
- headaches, psychomotor impairment (slowed speech, decreased movement and impaired mental function)

Tell your doctor if you notice any of the following which may occur less frequently and lasts longer than a few days or gets serious:

- skin reactions
- loss of appetite
- hallucinations, nightmares, mental depression, confusion, depression, sleep disturbances
- dizziness, fits, uncontrolled muscle movements, muscle stiffness
- blurred or double vision
- irregular heartbeat
- sweating, facial flushing, low blood pressure (causing light-headedness or fainting when standing up)
- shortness of breath
- nausea (feeling sick), vomiting (being sick), dry mouth, stomach cramps
- difficulty passing urine, increased frequency of urination, decreased urine
- feeling unwell, tiredness.

Tell your doctor if you notice any of the following which may also occur:

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- dependence on ACURATE (when you need to take ACURATE for longer periods of time or you need to take more than the recommended dose or if you stop taking ACURATE you feel very unwell but you feel better if you start taking ACURATE again)
- restlessness, excitement
- difficulty sleeping
- ringing in the ears
- increased stomach acid, stomach ulcers
- thick phlegm.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get any side effects, talk to your doctor or pharmacist. 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 ACURATE.

5. HOW TO STORE ACURATE:

KEEP ALL MEDICINES OUT OF REACH AND SIGHT OF CHILDREN.

Store at or below 25 °C in a dry place, in order to protect from moisture.

Do not use after the expiry date stated on the container.

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 ACURATE contains:

The active substances are paracetamol 450 mg, doxylamine succinate 5 mg, caffeine 30 mg and codeine phosphate 10 mg.

The other ingredients are: colloidal silicon dioxide, magnesium stearate, maize starch, povidone, quinolone yellow

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cl no. 47005, sodium starch glycolate, purified talc, purified water.

What ACURATE looks like and contents of the pack:

A round yellow, flat bevel edged tablet with a breakline on one side.

Packaging material and pack size:

Blister packs of 20 or 100 tablets or in securitainers containing 20, 100 or 500 tablets or in a white plastic jar with a screw cap containing 1000 tablets.

Holder of Certificate of Registration:

TEVA PHARMACEUTICALS (PTY) LTD.

Maxwell Office Park,

Magwa Crescent West,

Waterfall City,

Midrand,

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