

Teva Pharmaceuticals (Pty) Ltd  
Product name: Acurate  
Registration no: Z/2.8/221

## PATIENT INFORMATION LEAFLET

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

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **ACURATE** 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.

SCHEDULING STATUS: S2

### PROPRIETARY NAME (and dosage forms)

#### ACURATE TABLETS

Paracetamol	450 mg
Doxylamine Succinate	5 mg
Caffeine	30 mg
Codeine Phosphate	10 mg

#### 1. WHAT ACURATE CONTAIN:

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

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povidone

quinolone yellow ci no. 47005

sodium starch glycollate

talc, purified

water, purified

#### **WHAT ACURATE IS USED FOR:**

**ACURATE** has pain relieving, fever reduction and allergic reaction reduction properties. **ACURATE** can be used for mild to moderate pain associated with tension

#### **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 asthma.

If you suffer from severe liver 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.

If you suffer from acute alcoholism.

If you are taking monoamine oxidase inhibitors or within 14 days of stopping such treatment.

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If you are pregnant.

**Take special care with ACURATE:**

Do not use continuously for longer than 10 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 hypothyroidism, adrenocortical insufficiency, myasthenia gravis, an enlarged prostate, shock, inflammatory or obstructive bowel syndrome.

If you are elderly or debilitated.

If you suffer from porphyria, glaucoma or prostatic hypertrophy.

**Pregnancy and Breastfeeding:**

- 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 professional for advice.

**Driving and using machinery:**

Do not take charge of vehicles or machinery or perform any potential hazardous tasks where loss of concentration can lead to accidents.

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**Taking other medicines with ACURATE:**

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **ACURATE** with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

Using Acurate with alcohol, anaesthetics, drugs that induce sleep, drugs used for calmness and neuroleptic antipsychotic drugs may cause depressing effects.

**HOW TO TAKE ACURATE:**

Always use **ACURATE** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. 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 10 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:**

Overdosage of **ACURATE** will cause symptoms listed below under "**SIDE EFFECT**" 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.

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It may be fatal especially in infants and children. Coma, heart failure and death may occur within 18 hours.

**If you forget to take ACURATE:**

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

**POSSIBLE SIDE EFFECTS:**

**ACURATE** can have the following side effects:

Skin rash or blood disorders

Nausea, vomiting, constipation, drowsiness, confusion, dry mouth, sweating, facial flushing, motion sickness, insufficient ventilation, awareness of the beating of your heart, low blood pressure, head rush, heatstroke, restlessness, coma, a state of very intense happiness and well-being, changes of mood and constriction of pupils, stiffness of muscles, itchiness.

Urinating may be difficult.

Prolonged use may cause you to become dependent on the drug.

Headache, sleeplessness, excitement, involuntary movement of your muscles, ringing sound in your ear, experiencing a ball of light in your field of vision, rapid beating of your heart and may also cause gastric ulcers.

Calmness, gastro-intestinal disturbances, blurred vision, elation or depression, irritability, nightmares, eating disorder, allergy.

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

Not all side effects reported for **ACURATE** are included in this leaflet. Should your general health worsen while taking **ACURATE**, please consult your doctor, pharmacist or other healthcare professional for advice.

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**STORING AND DISPOSING OF 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).

**PRESENTATION OF ACURATE:**

Securitainers containing 20 or 100 tablets.

**IDENTIFICATION OF ACURATE:**

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

**REGISTRATION NUMBER:**

Z/2.8/221

**NAME AND ADDRESS OF REGISTRATION HOLDER:**

TEVA PHARMACEUTICALS (PTY) LTD.

Maxwell Office Park,

**Teva Pharmaceuticals (Pty) Ltd**  
**Product name: Acurate**  
**Registration no: Z/2.8/221**

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**PUBLICATION DATE:**

Registration certificate date: January 1992

Latest package insert: May 2014