Applicant: Teva Pharmaceuticals (Pty) Ltd	**Product: Acutev** **Film-coated tablets** Each film-coated tablet contains 500 mg paracetamol
Registration date: 2.06.2026 **Reg No: 59/2.7/0652**	**Closing sequence submitted: 1.07.2026** **eCTD 0005**

APPROVED PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET:

SCHEDULING STATUS: S0

ACUTEV (film-coated tablets)

Paracetamol

Sugar free

Read all of this leaflet carefully because it contains important information for you:

- Keep this leaflet. You may need to read it again.
- Do not share ACUTEV 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 after 10 days for adults, or after 3 days for children aged 10 to 15 years of age.

What is in this leaflet:

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

The active ingredient is paracetamol which is a painkiller and also reduces your temperature when you have a fever.

ACUTEV is used for pain relief of headaches, including migraine and tension headaches, toothache, backache, rheumatic and muscle pains. It also relieves sore throat and the feverishness, aches and pains of colds and flu.

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

Do not take ACUTEV if:

- if you are allergic to paracetamol or any of the other ingredients of ACUTEV (listed in **section 6**)
- if you have severe liver problems.

Warnings and precautions:

Take special care with ACUTEV:

- **Do not exceed the recommended daily dose, as it may cause serious harm to your liver. In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.**
- Do not use ACUTEV tablets if you are taking any other prescription or non-prescription medicines containing paracetamol to treat pain, fever, symptoms of cold and flu, or to aid sleep.
- Check with your doctor before use if you:
  - have liver or kidney problems
  - are underweight or malnourished
  - have sepsis (a serious condition that happens when the body's immune system has an extreme response to an infection)
  - regularly drink alcohol.

You may need to avoid using ACUTEV tablets altogether or limit the amount of paracetamol you take, as this may increase the risk of paracetamol-related liver damage.

- Check with your doctor before use if you have a severe infection, are severely malnourished, severely underweight or are a chronic heavy alcohol user as this may increase the risk of metabolic acidosis. Signs of metabolic acidosis include:
  - deep, rapid, difficult breathing
  - feeling sick (nausea), being sick (vomiting)
  - loss of appetite.

Contact a doctor immediately if you get a combination of these symptoms.

Do not use continuously for more than 10 days without consulting your doctor or for more than 3 days for your child, without medical advice.

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

- Serious skin reactions such as Toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome (SJS), Acute generalised 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 receiving paracetamol. If you experience any signs of serious skin reactions such as swelling, itching, red severe rash, stop taking ACUTEV immediately and contact your doctor (see **section 4**).
- If you have severe illnesses, including severe renal impairment or sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), or you suffer from malnutrition, chronic alcoholism or if you are also taking flucloxacillin (an antibiotic). A serious condition called metabolic acidosis (a blood and fluid abnormality) has been reported in patients in these situations when paracetamol is used at regular doses for a prolonged period or when paracetamol is taken together with flucloxacillin. Symptoms of metabolic acidosis may include: serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea) and being sick (vomiting).

Children and adolescents:

ACUTEV is not recommended for children under 10 years of age.

Other medicines and ACUTEV:

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

- Consult your doctor before taking ACUTEV if you are using warfarin or similar medicines used to thin the blood, as this can increase the risk of bleeding.
- The rate of absorption of paracetamol as contained in ACUTEV may be increased by metoclopramide or domperidone.
- The absorption of paracetamol as contained in ACUTEV may be reduced by cholestyramine.
- Inform your doctor if you are taking flucloxacillin (an antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see **section 2**).
- Inform your doctor if you are taking medicines used to treat epilepsy (fits) such as carbamazepine, fosphenytoin, phenytoin, phenobarbital or primidone.
- Plasma (blood) concentrations of ACUTEV may be altered when taken together with probenecid (used to treat gout).
- ACUTEV use with certain antibacterials used for the treatment of tuberculosis (a disease affecting the lungs) such as rifampicin or isoniazid or use with antiviral medicines such as zidovudine can cause severe damage to the liver.
- The antiviral effect of interferon alfa may be increased if taken with ACUTEV.

ACUTEV with food, drink and alcohol:

If you drink large amounts of alcohol you may be more prone to the side effects of ACUTEV. Please talk to your doctor or pharmacist before taking ACUTEV if this apples to you.

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 ACUTEV. Safety and efficacy in pregnancy and breastfeeding have not been established.

Paracetamol is excreted in breastmilk.

Driving and using machines:

It is not always possible to predict to what extent ACUTEV may interfere with the daily activities of a patient. You should ensure that you do not engage in driving a vehicle or use machines until you are aware of the measure to which ACUTEV affects you.

3. HOW TO TAKE ACUTEV:

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

Always take ACUTEV exactly as described in this leaflet or as your doctor or pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

Do not exceed the stated dose.

Do not take with any other product containing paracetamol.

Do not take more than 4 doses in any 24-hour period. Maximum daily dose 4 000 mg (8 tablets).

Do not take more frequently than every 4 hours.

Adults (including the elderly) and children aged 16 years and over:

One to two film-coated tablets every 4 to 6 hours as required.

Do not take more than 8 tablets per 24 hours.

Children, 10 to ≤ 15 years of age:

One film-coated tablet every 4 to 6 hours as required:

Do not give more than 4 doses in any 24-hour period.

Do not give more than 60 mg per kg body weight in 4 divided doses of 10-15 mg per kg body weight throughout the 24-hour period.

Do not use for longer than 3 days without medical advice.

Children under 10 years:

Not recommended for children under 10 years of age.

If you take more ACUTEV than you should:

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

You may be prone to paracetamol poisoning if you take repeated high doses (greater than 5 to 10 g/day) of paracetamol for several days, in chronic alcoholism, chronic liver disease, AIDS, malnutrition, and if you use medicines such as barbiturates (for anxiety, insomnia and seizures), isoniazid (for tuberculosis), rifampicin (for tuberculosis), phenytoin (for seizures) and carbamazepine (for seizures).

Symptoms of paracetamol overdosage seen in the first 24 hours and likely to remain for a week or more are:

- pale skin
- nausea
- vomiting
- loss of appetite
- abdominal pain

Other symptoms are:

- liver damage or injury 12 to 48 hours after taking ACUTEV
- abnormalities of glucose breakdown
- excess quantity of acid in the blood
- liver damage which may progress to disease of the brain, coma and death
- swelling on the brain
- reduced contractions of the heart muscle may also occur

You may also develop:

- acute kidney failure with acute death of kidney tubule cells even in the absence of severe liver damage
- changes in heart rate or rhythm

If you have taken 5 to 10 grams or more of paracetamol (or if a child has had more than 140 mg/kg) within the preceding 4 hours, you or your child need immediate medical treatment. Contact your medical doctor or go to the nearest hospital or poison control centre without any further delay.

If you forget to take ACUTEV:

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

4. POSSIBLE SIDE EFFECTS

ACUTEV can have side effects.

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

If any of the following happens, stop taking ACUTEV and tell your doctor immediately or go to the casualty department at 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.

These are all very serious side effects. If you have them, you may have had a serious reaction to ACUTEV. 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 following:

- reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson-syndrome, Toxic epidermal necrolysis)
- persistent stomach pain, feeling sick and being sick as these may be symptoms of acute pancreatitis (an inflamed pancreas)
- you have previously experienced breathing problems with aspirin or non-steroidal anti-inflammatories and experience a similar reaction with ACUTEV
- may cause a serious or life-threatening allergic reaction that may affect your skin or other parts of your body such as your liver or blood cells. You may or may not have a rash when you get this type of reaction. It may cause you to be hospitalised or to stop ACUTEV. Call your doctor right away if you have any of the following symptoms:
    - skin rash
    - hives
    - fever
    - swollen glands that do not go away
    - swelling of your lip and tongue
    - yellowing of your skin or of the whites of the eyes

- unusual bruising or bleeding
- severe fatigue or weakness
- unexpected muscle pain
- frequent infections

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

Tell your doctor if you notice any of the following:

Less frequent side effects:

- bleeding problems or clotting disorders, decreased formation of blood cells, severe decrease in white blood cells which may lead to severe infections, frequent infections due to poorly functioning white blood cells or decrease in white blood cells, reduction in blood platelets, which increases the risk of bleeding or bruising abnormal breakdown of red blood cells, which may cause weakness or pale skin, decrease in blood count, reduced neutrophil count in blood
- decrease in red blood cells
- abnormal liver function
- cloudy urine, kidney disorders and kidney failure.

After marketing ACUTEV the following side effects have been reported with unknown frequency:

- A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see **section 2**).

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, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found

on the SAHPRA website. By reporting side effects, you can help provide more information on the safety of ACUTEV.

5. HOW TO STORE ACUTEV:

Store all medicines out of reach of children.

Store at or below 25 °C.

Store in the original packaging until required for use.

Do not use ACUTEV after the expiry date which is stated on the label. The expiry date refers to the last day of the month.

Do not store in a bathroom.

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 ACUTEV contains:

The active substance is paracetamol.

The other ingredients are:

Tablet core: alginic acid, calcium carbonate, crospovidone Type B, magnesium stearate, povidone (K-25), starch (pregelatinized) and silica (colloidal anhydrous).

Film-coating: calcium carbonate, caprylic/capric trigliceride, de-oiled sunflower lecithin E322, hypromellose 2910 (3 cp), hypromellose 2910 (6 cp), polydextrose, polyethylene glycol 3350 and polyethylene glycol 400.

What ACUTEV looks like and contents of the pack:

White to off-white, oval shaped biconvex tablet, break-line on one side of the tablet and plain on the

other side.

Dimensions: approx. 7,9 × 17,1 mm. The height of the tablet is approx. 5,0 to 6,5 mm.

ACUTEV is packaged in blister packs (PVC/PVdC-Aluminium or OPA/Alu/PVC-Aluminium). Blisters are packed in an outer carton.

Pack sizes:

The blisters are further packed into cardboard cartons containing 20 film-coated tablets.

Holder of Certificate of Registration:

Teva Pharmaceuticals (Pty) Ltd,

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Access to the corresponding Professional Information:

Website: https://www.teva.co.za/

The Professional Information can also be obtained from:

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