Approved Patient Information Leaflet for Medicines for Human Use:

ACTAMOL TABLETS

SCHEDULING STATUS: S1

ACTAMOL TABLETS 500 mg

Paracetamol

Methylparaben 0,38 % *m/m* (as preservative)

Propylparaben 0,063 % *m/m* (as preservative)

Sugar free

Contains TARTRAZINE

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

ACTAMOL TABLETS is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use ACTAMOL TABLETS carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share ACTAMOL TABLETS with any other person.
- Ask your health care 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.

What is in this leaflet

1. What ACTAMOL TABLETS is and what it is used for

2. What you need to know before you take ACTAMOL TABLETS

3. How to take ACTAMOL TABLETS

4. Possible side effects

5. How to store ACTAMOL TABLETS

6. Contents of the pack and other information

1. What ACTAMOL TABLETS is and what it is used for

ACTAMOL TABLETS contains the active substance called paracetamol which belongs to the group of medicines called analgesics and antipyretics.

ACTAMOL TABLETS works by inhibiting prostaglandin synthesis.

ACTAMOL TABLETS is used to relieve:

- mild to moderate pain
- fever.

2. What you need to know before you take ACTAMOL TABLETS

Do not take ACTAMOL TABLETS

- if you are hypersensitive (allergic) to paracetamol or any of the other ingredients of ACTAMOL TABLETS (listed in section 6).
- if you have severe renal (kidney) problems.
- if you have severe liver problems.

Warnings and precautions

Take special care with ACTAMOL TABLETS and tell your doctor:

- if you are suffering from liver or kidney disease (including Gilbert's syndrome or acute hepatitis)
- if you have a deficiency of a certain enzyme called glucose-6-phosphatase
- if you have haemolytic anaemia (abnormal breakdown of red blood cells)
- if you regularly take large amounts of alcohol. Never take more than 2000 mg a day.
- if you are asthmatic sensitive to acetylsalicylic acid
- in case of dehydration or chronic malnutrition.

Do not use continuously for longer than ten (10 days) without consulting your doctor. Consult your doctor if no relief is obtained with the recommended dosage.

DO NOT EXCEED THE RECOMMENDED DOSAGE.

Do not use more than one medicine containing paracetamol (such as cold and flu medicines) without talking to your doctor. Dosages more than those recommended may cause sever liver damage.

In cases of high fever, signs of a secondary infection, or persistence of your symptoms for more than three days, consult your doctor or pharmacist.

Headaches caused by overuse of analgesics should not be handled by increasing the dose. In those cases, the use of analgesics should be taken after consulting a doctor.

ACTAMOL TABLETS contains FD & C Yellow No. 5 (Tartrazine) which may cause allergic-type reactions (including bronchial asthma) in certain susceptible individuals. Although the overall incidence of tartrazine sensitivity in the general population is currently thought to be low, it is frequently seen in patients who also have aspirin sensitivity.

Serious skin reactions, some of them fatal, including exfoliative dermatitis, Stevens - Johnson syndrome (SJS), and toxic epidermal necrolysis (TEN), acute generalized exanthematous pustulosis (AGEP), eosinophilia and systemic (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, blisters, hives and sometimes peeling or pain, stop using ACTAMOL TABLETS immediately and contact your doctor (see section 4).

Other medicines and ACTAMOL TABLETS

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

ACTAMOL TABLETS may affect or be affected by other medicines, such as:

- metoclopramide or domperidone (medicines used for nausea and/or vomiting)
- cholestyramine (medicine used to reduce blood fat levels)
- isoniazid or rifampicin (antibiotic medicine used to treat tuberculosis)
- lamotrigine or phenytoin (a medicine used to treat epilepsy)
- barbiturates or carbamazepines (medicines that cause relaxation and sleepiness)
- St. John’s wort (a medicine used to treat depression)

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- probenecid (medicine used for gout)
- aspirin (medicine for pain, inflammation and fever)
- warfarin and other anti-blood clotting medicine or anticoagulants (medicines for prevention of blood clots)
- chloramphenicol (an antibiotic)
- zidovudine (a medicine used to treat AIDS)
- 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.

If you are going to have any laboratory tests (such as a blood test, urine analysis, skin allergy test, etc.), you should tell your doctor that you are taking this medicine as it could affect the results of these tests.

ACTAMOL TABLETS with alcohol

Alcohol should be avoided in patients with alcoholic liver disease when taking paracetamol.

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 health care provider for advice before taking ACTAMOL TABLETS.

Pregnancy

If necessary, paracetamol can be used during pregnancy. You should use the lowest possible dose that reduces your pain and/or your fever and use it for the shortest time possible. Contact your doctor if the pain and/or fever are not reduced or if you need to take the medicine more often.

Breastfeeding

Paracetamol is excreted in breast milk but in insignificant amounts. Therapeutic doses of paracetamol may be used during breastfeeding.

Fertility

No detrimental effects on fertility upon normal use of paracetamol are known.

Driving and using machines

It is not always possible to predict to what extent ACTAMOL TABLETS may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which ACTAMOL TABLETS affects them.

ACTAMOL TABLETS has no or negligible influence on the ability to drive and use machines.

3. How to take ACTAMOL TABLETS

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

Always take ACTAMOL TABLETS exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Do not exceed the recommended dose (see “Take special care with ACTAMOL TABLETS”).

Usual adult dose:

One tablet every 3 hours or one to two tablets (0,5 to 1 g) every 4 - 6 hours up to a maximum of 4 g daily (8 tablets).

Usual paediatric dose (6 to 12 Years):

250 - 500 mg (half to one tablet) three to four times a day as required. Not suitable for children under

6 years of age.

Duration of administration

Unless prescribed otherwise, ACTAMOL TABLETS should be taken for a period of not more than 10 days.

Talk to your doctor if the symptoms persist longer than 3 days with high fever or signs of infection, worsen or recur periodically.

Method of administration

The tablet should be swallowed with a large amount of water.

If you take more ACTAMOL TABLETS than you should

ACTAMOL TABLETS 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, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

A delay in starting treatment may mean that an antidote is given too late to be effective. Evidence of liver damage is often delayed until after the time for effective treatment has lapsed.

Symptoms of paracetamol overdosage in the first 24 hours include:

- nausea
- vomiting
- anorexia (eating disorder-weight loss)
- possible abdominal pain.

Liver damage may become apparent 12 to 48 hours, or later after ingestion, and may lead to abnormal brain function (encephalopathy), coma and death.

Acute kidney failure with damage to the kidney tubular cells (acute tubular necrosis) may develop even in the absence of severe liver damage.

Abnormalities of glucose metabolism and too much acid in body fluids (metabolic acidosis) may occur.

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Irregular heartbeat (cardiac arrhythmias) has been reported.

If you forget to take ACTAMOL TABLETS

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

4. Possible side effects

ACTAMOL TABLETS can have side effects.

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

If any of the following happens, stop taking ACTAMOL TABLETS 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 very serious side effects. If you have them, you may have had a serious reaction to ACTAMOL TABLETS. You may need urgent medical attention or hospitalisation.

Less frequent side effects:

- feeling or being sick (nausea, vomiting), stomach pain or cramps, diarrhoea, loss of appetite
- liver problems (toxicity and failure)
- jaundice (with symptoms like yellowing of the skin and eyes), hepatic necrosis (death of liver cells)
- gastrointestinal tract bleeding, inflammation of the pancreas (pancreatitis)
- depression, confusion, hallucination

- tremor, headache, convulsions, respiratory depression, cerebral swelling, coma
- skin rashes and other allergic reactions. The skin rash is usually red or hives but it is sometimes more serious and may be accompanied by fever and mucosal lesions.
- low level of blood glucose in the blood
- disturbed vision
- blood disorders (changes in numbers and types of blood cells), platelet disorders (clotting disorders) and stem cell disorders (disorders of the blood forming cells In bone marrow)
- oedema (abnormal accumulation of fluid under the skin) and irregular heartbeat (cardiac arrhythmias)
- bronchospasm (difficulty in breathing) in patients sensitive to aspirin and other anti-inflammatory medicines
- cloudy urine and acute kidney failure with acute damage to the kidney tubular cells (tubular necrosis)
- hematuria (blood in urine) and enuresis (inability to urinate)
- dizziness, generally feeling unwell (malaise), fever, sedation, interactions with medicines
- Overdose and poisoning.

Side effects with frequency unknown:

- Fixed drug eruptions (FDE) – skin rash as a result of systemic exposure to a drug
- Drug-induced hypersensitivity syndrome (DIHS) or drug reaction with eosinophilia and systemic symptoms (DRESS) – (an allergic type of reaction in which you may develop fever, skin rash, and abnormalities in blood and liver function tests - these may be signs of a multi-organ sensitivity disorder).
- acute generalized exanthemateus pustulosis - drug eruption characterized by numerous small, primarily non-follicular, sterile pustules
- Stevens-Johnson syndrome (a severe life-threatening skin disorder) - a severe rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals.

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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 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 ACTAMOL TABLETS.

Suspected side effects can also be reported directly to the Holder of the Certificate of Registration via medsafety@shanur.co.za

5. How to store ACTAMOL TABLETS

Store at or below 25 ºC, protected from light.

Keep the blister packs in the outer carton until required for use.

Store all medicines out of reach of children.

Do not use after the expiry date stated on the 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 ACTAMOL TABLETS contains

The active substance is paracetamol.

Each tablet contains 500 mg paracetamol.

Methylparaben 0,38 % *m/m* (as preservative).

Propylparaben 0,063 % *m/m* (as preservative).

Sugar free.

Contains TARTRAZINE.

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The other ingredients are:

Maize starch

Croscarmellose sodium

Povidone

Purified Water

Apple green (koelron green) colour consisting of:

- brilliant blue: Cl 42090
- tartrazine: Cl 19140

Magnesium stearate

Colloidal silicon dioxide

Talc

What ACTAMOL TABLETS looks like and contents of the pack

ACTAMOL TABLETS 500 mg

Green coloured, round flat uncoated tablets with bevelled edges scored on one side and plain on the other side.

ACTAMOL TABLETS are packed in blisters, packed into a carton. Pack sizes is of 10, 20 and 10 x 10 tablets.

ACTAMOL TABLETS are packed in HDPE bottles. Pack size is of 100, 500 and 1 000 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Shanur Healthcare (Pty) Ltd.

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Access to the corresponding Professional Information

Professional Information for this medicine is available on the following URL: https://shanur.co.za/product-info/

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