Approved Patient Information Leaflet for Medicines for Human Use:

ACTAMOL SOLUTION

SCHEDULING STATUS: S0

ACTAMOL SOLUTION 120 mg/5 mL

Paracetamol

Sugar free

Tartrazine free

Each 5 mL contains 10,417 % v/v ethanol.

Each 5 mL contains 0,1 % m/v methylparaben (preservative).

Each 5 mL contains 0,05 % m/v propylparaben (preservative).

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

ACTAMOL is available without a doctor's prescription, for you to treat pain and fever. Nevertheless, you still need to use ACTAMOL carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share ACTAMOL 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 5 days.

What is in this leaflet

1. What ACTAMOL is and what it is used for

2. What you need to know before you take ACTAMOL

3. How to take ACTAMOL

4. Possible side effects

5. How to store ACTAMOL

6. Contents of the pack and other information

1. What ACTAMOL is and what it is used for

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

Paracetamol works by inhibiting prostaglandin synthesis.

ACTAMOL is used for the relief of mild to moderate pain and fever.

2. What you need to know before you take ACTAMOL

Do not take ACTAMOL

- if you or the child are hypersensitive (allergic) to paracetamol or any of the other ingredients of ACTAMOL (listed in section 6).
- if you or the child suffer from serious liver problems.

Warnings and precautions

Take special care with ACTAMOL:

ACTAMOL contains paracetamol which may be fatal in overdose. In the event of overdose or suspected overdose, even if your child may not be showing or experiencing any symptoms, the nearest doctor, hospital or poison centre must be contacted immediately. Prompt specialised treatment

- If you or the child take more than the recommended doses, very serious liver damage may occur. Always take the correct dose of ACTAMOL.
- Excessive and prolonged use of ACTAMOL is dangerous.

- If you or the child still have pain or fever or feel that ACTAMOL is not working, please tell your doctor.
- Do not take ACTAMOL or give ACTAMOL to your child, continuously for 10 days without talking to your doctor first.
- If you or the child suffer from liver or kidney disease, a doctor will monitor your condition while taking ACTAMOL.
- If you or the child suffer from hepatitis (a disease of the liver), or are still recovering from a liver disease, do not take ACTAMOL in large amounts.
- Take ACTAMOL or give ACTAMOL to the child, with caution if you have kidney disease, chronic malnutrition, dehydration, or if you haven't eaten for a few days.
- If you or the child are concomitantly taking a medicine that contains flucloxacillin, you may be at high risk for blood and fluid abnormality (high anion gap metabolic acidosis).
- Serious skin reactions, some of them fatal, including exfoliative dermatitis, Stevens Johnson syndrome (SJS), and toxic epidermal necrolysis (TEN), including Fixed Drug Eruptions (FDE), which are reactions that appear at the same location 1 to 2 weeks after first drug exposure and within 24 hours of repeat exposure, have been reported in patients receiving paracetamol. If you experience any signs of serious skin reactions such as swelling, itching, red severe rash, stop using ACTAMOL immediately and contact your doctor.
- If you develop a fever, skin rash, swelling of the lymph nodes and/or swelling of the face. This is known as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), stop using ACTAMOL immediately and contact your doctor.

- A fixed drug reaction appears at the same location 1 to 2 weeks after first drug exposure and within 24 hours of repeat exposure.

Children

Do not give ACTAMOL to babies under 3 (three) months old.

Other medicines and ACTAMOL

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

The risk of side effects with paracetamol may be increased in patients taking other medicines that may be harmful to the liver or medicines that can influence the functioning of the liver.

- The absorption of paracetamol may be increased by metoclopramide.
- Excretion of paracetamol may be affected and plasma (blood) concentrations altered when taken together with probenecid.
- Cholestyramine reduces the absorption of paracetamol.
- Prolonged concurrent use of ACTAMOL with salicylates (e.g. aspirin) increases the risk of adverse kidney effects.
- If you or the child are taking warfarin or other blood thinning medicines (anticoagulants), ACTAMOL may increase the anticoagulant effect and there is an increased risk of bleeding if you are taking regular or high doses of paracetamol while on an oral anticoagulant.
- Use of ACTAMOL and certain antibacterials used for the treatment of tuberculosis (a disease affecting the lungs) such as rifampicin or isoniazid can cause toxic damage to the liver.
- Taking ACTAMOL together with certain antiviral medicines such as zidovudine can cause severe toxic damage to the liver.

- The antiviral effect of interferon alfa may be increased if taken with ACTAMOL.

ACTAMOL with alcohol

Do not drink alcohol if you suffer from alcoholic liver disease when taking ACTAMOL.

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.

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

Driving and using machines

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

It is not always possible to predict to what extent ACTAMOL 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 affects them.

3. How to take ACTAMOL

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

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

DO NOT TAKE MORE THAN THE RECOMMENDED DOSE.

Dose

Infants

3 months to 1 year: 2,5 mL to 5 mL (60 mg to 120 mg).

Children

1 to 5 years: 5 mL to 10 mL (120 mg to 240 mg).

6 to 12 years: 10 mL to 20 mL (240 mg to 480 mg).

Duration of administration

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

Method of administration

ACTAMOL may be taken orally using a medicine measure or a syringe.

If you take more ACTAMOL than you should

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

If you have overdosed with ACTAMOL, you might experience (within 24 hours):

- Feeling nauseous
- Vomiting
- Loss of appetite
- Looking pale
- Stomach pain.

Even though these initial symptoms may appear mild, paracetamol overdosage is a serious condition, as liver damage may only become apparent 12 to 48 hours after the paracetamol overdose.

If you forget to take ACTAMOL

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

4. Possible side effects

ACTAMOL can have side effects.

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

If any of the following happens, stop taking ACTAMOL 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. 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:

- nausea, vomiting, upper stomach pain, itching, loss of appetite

- liver failure
- dark urine, clay-coloured stools
- jaundice (yellowing of the skin and eyes).

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:

- Blood disorders (low white blood cell count or low red blood cells or low red cell blood count).
- 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.
- Inflammation of the pancreas (pancreatitis).
- A liver condition called hepatitis.
- Cloudy urine and acute kidney failure with acute damage to the kidney tubular cells (tubular necrosis).
- Sudden pain in the back or side which moves to the lower abdomen and groin (renal colic).
- Allergic skin reactions known as Stevens-Johnson syndrome (a severe life-threatening skin disorder), Toxic Epidermal Necrolysis (a severe life-threatening condition that causes a fever and flu symptoms), Acute Generalised Exanthematous Pustulosis (AGEP (pustular rashes).

Side effects with frequency unknown:

- Blood disorders (platelet disorders (clotting disorders) and stem cell disorders (disorders of the blood forming cells in bone marrow).
- Hearing issues.
- Increased blood pressure.

- Nausea and vomiting.
- Liver failure (after taking paracetamol for a year).
- Fixed drug eruptions (FDE).
- Drug-induced hypersensitivity syndrome (DIHS).
- If you have a sudden decrease in the amount of urine or cloudy urine.
- Skin rashes with low blood pressure and difficulty breathing.

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 ACTAMOL.

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

5. How to store ACTAMOL

Store all medicines out of reach of children.

Store at or below 25 °C.

Store in the original container.

Keep the container tightly closed.

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

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 contains

- The active substance is paracetamol.
- The other ingredients are Propylene glycol, cherry essence no.1, saccharin sodium, carmoisine red (CI 14720) and purified water.

ACTAMOL SOLUTION 120 mg/5 mL

Each 5 mL contains 120 mg paracetamol.

What ACTAMOL looks like and contents of the pack

ACTAMOL SOLUTION 120 mg/5 mL

Packed in 50 mL or 100 mL amber/white PVC or HDPE bottles.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Shanur Healthcare (Pty) Ltd

Loch House Unit 003

3A Eton Road, Parktown

Johannesburg, 2193

This leaflet was last revised in

Registration number

ACTAMOL SOLUTION 120 mg/5 mL: Y/2.8/360

Access to the corresponding Professional Information

Professional Information for this medicine is available on the following URL:

https://shanur.co.za/product-info/

Shanur Healthcare (Pty) Ltd

Tel: +27 87 405 9660