

PARACETAMOL-AFT SOLUTION FOR INJECTION

(Paracetamol)

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about PARACETAMOL-AFT. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking PARACETAMOL-AFT against the benefits that are expected. This leaflet does not contain everything about PARACETAMOL-AFT. Your doctor has been provided with full information and can answer any questions you may have. Follow your doctor's advice even if it differs from what is in this leaflet.

Please read this leaflet carefully and keep it in a safe place so you may refer to it later.

What PARACETAMOL-AFT is used for

PARACETAMOL-AFT contains paracetamol an analgesic medicine which relieves pain and reduces fever. PARACETAMOL-AFT is a solution of paracetamol which is given by intravenous infusion (IV) directly into a vein, and is used to relieve pain or reduce fever following surgery.

This medicine is available only with a doctor's prescription.

Before you are given PARACETAMOL-AFT

When you must not be given PARACETAMOL-AFT

You must not be given PARACETAMOL-AFT if you have an allergy to paracetamol or to any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction to PARACETAMOL-AFT may include:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

You must not be given PARACETAMOL-AFT if you have liver failure or severe liver disease.

If you are not sure whether you should be given PARACETAMOL-AFT, talk to your doctor or pharmacist.

Before you are given PARACETAMOL-AFT

Tell your doctor or pharmacist if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes

Tell your doctor or pharmacist if you are pregnant

PARACETAMOL-AFT may be given to pregnant women, but your doctor must be told if you are pregnant.

Tell your doctor or pharmacist if you are breast-feeding

PARACETAMOL-AFT may be given to women who are breast-feeding, but your doctor must be told if you are breastfeeding.

Tell your doctor or pharmacist if you have or have had any medical conditions, especially the following:

- liver disease
- kidney disease
- alcoholism
- suffer from malnutrition
- dehydration
- eating disorders (anorexia, bulimia)
- a wasting syndrome including unexplained weight loss, fatigue, weakness and loss of appetite (cachexia)
- malnutrition (low reserves of glutathione)
- a metabolic condition called glucose-6-phosphate dehydrogenase deficiency (G6PD)
- hypovolaemia (decreased blood volume)

If you have not told your doctor or pharmacist about any of the above, tell them before you are given PARACETAMOL-AFT

Taking other medicines

It is especially important to tell your doctor if you are taking any other medication, including over the counter or pharmacy medication, which contains paracetamol. This may affect the dosage of PARACETAMOL-AFT which you should receive.

Tell your doctor if you drink alcohol.

Your doctor may advise you to avoid alcohol as it may interfere with PARACETAMOL-AFT.

Some medicines and PARACETAMOL-AFT may interfere with each other. These include:

- Pro-Cid (probenecid) - a medicine used to treat gout or given with antibiotics.
- Anticonvulsants - medicines used to treat epilepsy or fits, such as Dilantin (phenytoin), Tegretol or Teril (carbamazepine), amytal sodium, phenobarbitone.
- Other forms of paracetamol, such as tablets, liquid preparations or capsules
- Myleron or Busulfex (busulfan) a cancer drug
- Dolobid (diflunisal) an anti-inflammatory drug
- Barbiturates
- Retrovir (zidovudine) - a HIV drug or other drugs containing zidovudine
- Anticoagulants which are used to stop the blood from clotting
- Isoniazid (isoniazid) a tuberculosis drug
- Antibiotics containing amoxicillin plus clavulanic acid such as Clamoxyl, Clavulan,

These medicines may be affected by PARACETAMOL-AFT, or may affect how well PARACETAMOL-AFT works. You may need different amounts of your medicine, or you may need to take different

medicines. Your doctor or pharmacist will advise you.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while receiving PARACETAMOL-AFT.

How PARACETAMOL-AFT is given

How much is given

Your doctor will decide what dose you will be given, and for how long you will be given PARACETAMOL-AFT. Tell your doctor if you have been taking other forms of Paracetamol (tablets, capsules, liquid preparations) and the quantity that you have been taking

How it is given

PARACETAMOL-AFT is given as a slow infusion (drip) into a vein. PARACETAMOL-AFT must only be given by a doctor or nurse.

Overdose

Your doctor has information on how to recognise and treat an overdose. Ask your doctor or nurse if you have any concerns.

While you are being given PARACETAMOL-AFT

Things you must do

Tell any other doctors, dentists, and pharmacists who are treating you that you are being given PARACETAMOL-AFT.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are being given PARACETAMOL-AFT.

Tell your doctor immediately if you develop a rash or other symptoms of an allergic reaction.

These symptoms may be:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being given PARACETAMOL-AFT.

PARACETAMOL-AFT helps most people with pain and fever, but it may have unwanted side effects in some people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you.

- feeling unwell
- dizziness, light-headedness
- bleeding or bruising more easily than normal
- vomiting, nausea
- constipation

- a faster heart rate
- unusual tiredness or weakness, fatigue
- redness of the skin

These side effects are rare and usually mild.

If any of the following happen, tell your doctor or a nurse immediately.

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

- allergic reaction - shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body, rash, itching or hives on the skin.
- Yellowing of the skin and/or eyes, also called jaundice

Other side effects not listed above may occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.

Do not be alarmed by possible side effects. You may not experience any of them.

Product description

What it looks like

PARACETAMOL-AFT is available in colourless glass vials closed with a dark gray rubber stopper and sealed with an aluminium lever capsule with gold lever. Each vial contains 100 mL of a clear, colourless to slightly yellowish solution.

Each 100 mL vial contains 1 g of paracetamol. AUST R 191802

Ingredients

Active Ingredient: paracetamol 10 mg/mL

Other Ingredients: mannitol, cysteine hydrochloride, dibasic sodium phosphate, sodium hydroxide, hydrochloric acid, water for injections.

Storage

PARACETAMOL-AFT will be stored in the pharmacy or on the ward. The injection should be kept in a cool dry place, protected from light, where the temperature stays below 25 °C.

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