#### PARACETAMOL ACTAVIS

Paracetamol

#### **Consumer Medicine Information**

### What is in this leaflet

This leaflet answers some common questions about PARACETAMOL ACTAVIS.

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 or pharmacist has weighed the risks of you receiving PARACETAMOL ACTAVIS against the benefits they expect it will have for you

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

#### Keep this leaflet with the medicine.

You may need to read it again.

# What PARACETAMOL ACTAVIS is used for

PARACETAMOL ACTAVIS contains paracetamol an analgesic medicine which relieves pain and reduces fever.

PARACETAMOL ACTAVIS is a solution of paracetamol which is given by IV infusion 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 ACTAVIS

## When you must not be given PARACETAMOL ACTAVIS

You must not be given PARACETAMOL ACTAVIS 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 ACTAVIS 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 ACTAVIS if you have liver disease.

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

Before you are given PARACETAMOL ACTAVIS

# 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 ACTAVIS 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 ACTAVIS may be given to women who are breast-feeding, but your doctor must be told if you are breast-feeding.

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 and loss of appetite (cachexia)
- a metabolic condition called glucose-6phosphate dehydrogenase deficiency (G6PD)
- hypovolaemi

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

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 Panadol. This may effect the dosage of PARACETAMOL ACTAVIS which you should receive.

Some medicines and PARACETAMOL ACTAVIS 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 epilepy or fits, such as Dilantin (phenytoin), Tegretol or Teril (carbamazepine), Amytal Sodium, Phenobarbitone.
- Other forms of Paracetamol, such as tablets or capsules
- Myleron or Busulfex (busulfan) a cancer drug
- Dolobid (diflusinal) an anti-inflammatory drug
- Barbiturates
- Retrovir (zidovudine) a HIV drug or other drugs containing zidovudine
- Anticoagulants which are used to stop blood from clotting
- Isoniazid, a tuberculosis drug
- Antibiotics containing amoxicillin plus clavulanic acid.

These medicines may be affected by PARACETAMOL ACTAVIS, or may affect how well PARACETAMOL ACTAVIS 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 ACTAVIS.

# How PARACETAMOL ACTAVIS 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 ACTAVIS.

Tell your doctor if you have been taking other forms of Paracetamol (tablets, capsule) and the quantity that you have been taking

#### How it is given

PARACETAMOL ACTAVIS is given as a slow infusion (drip) into a vein. PARACETAMOL ACTAVIS 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 ACTAVIS.

Things you must do

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

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

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 ACTAVIS. PARACETAMOL ACTAVIS helps most people with pain and fever, but it may have unwanted

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

side effects in some people.

- bleeding or bruising more easily than normal
- vomiting, nausea
- constipation.

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.

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 ACTAVIS is a clear solution available in 100 mL glass vials, each containing 1000 mg paracetamol.

### Ingredients

Active Ingredient: paracetamol 1000mg/100 mL

### Other Ingredients:

mannitol, cysteine hydrochloride monohydrate, dibasic dihydrate sodium phosphate, sodium hydroxide, hydrochloric acid, water for injections.

## Storage

PARACETAMOL ACTAVIS 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. Do not refrigerate or freeze.

#### Sponsor

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