Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Paracetamol Kabi.

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 Kabi 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.

You may need to read it again.

What Paracetamol Kabi is used for

Paracetamol Kabi is used to relieve pain and reduce fever following surgery.

This medicine belongs to a group of medicines called analgesics.

Ask your doctor if you have any concerns about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

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

Before you are given Paracetamol Kabi

When you must not be given it

You must not be given Paracetamol Kabi 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 Kabi 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 Kabi if you have the following medical conditions.

- · liver failure
- severe liver disease.

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

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor or pharmacist if you have or have had any medical conditions:

- liver disease (including Gilbert's syndrome)
- · kidney disease
- alcoholism
- · 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-6phosphate dehydrogenase deficiency (G6PD)
- hypovolaemia (decreased blood volume)

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above tell him/her before you are given Paracetamol Kabi.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines including:

- · all prescription medicines
- all medicines, vitamins, herbal supplements or natural therapies you buy without a prescription from a pharmacy, supermarket, naturopath or health food shop.

Some medicines may be affected by Paracetamol Kabi or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines. Your doctor will advise you.

Tell your doctor or pharmacist if you drink alcohol.

Your doctor may advise you to avoid alcohol as it may interfere with Paracetamol Kabi.

Tell your doctor or your pharmacist if you are taking any of the following:

- 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)
- Other forms of paracetamol, such as tablets, liquid preparations or capsules
- Myleran® or Busulfex® (busulfan) a cancer drug
- Dolobid (diflunisal) an antiinflammatory drug
- Barbiturates (such as amytal sodium or phenobarbitone)
- Retrovir® (zidovudine) a HIV drug or other drugs containing zidovudine
- Anticoagulants which are used to stop blood from clotting (including warafin)
- Isoniazid® (isoniazid) a tuberculosis drug
- Antibiotics containing amoxicillin plus clavulanic acid (such as Clamoxyl®) or flucloxacillin.

Your doctor and pharmacist have more information on medicines to be careful to avoid while receiving Paracetamol Kabi.

How Paracetamol Kabi is given

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

How much is given

Your doctor will decide what dose you will be given, and for how long you will be given Paracetamol Kabi. 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 Paracetamol Kabi is given

Paracetamol Kabi is given as a slow infusion (drip) into a vein. Paracetamol Kabi must only be given by a doctor or nurse.

If you take too much (Overdose)

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

Adults: keep to the recommended dose. Don't take this medicine for longer than a few days at a time unless advised to by a doctor.

Children and adolescents: keep to the recommended dose. Do not give this medicine for longer than 48 hours at a time unless advised to by a doctor.

If an overdose is taken or suspected, ring the Poisons Information Centre (Australia 131 126; New Zealand 0800 764 766) or go to a hospital straightaway even if you feel well because of risk of delayed, serious liver damage and abnormal pigment levels.

Do not take with other products containing paracetamol, unless advised to do so by a doctor or pharmacist.

While you are being given Paracetamol Kabi

Things you must do

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

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

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 Kabi.

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. It can be difficult to tell whether side effects are the result of being given Paracetamol Kabi, effects of your condition or side effects from other medicines you may be taking. For this reason, it is important to tell your doctor of any change in your condition.

Do not be alarmed by this list of side effects.

You may not experience any of them.

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

Tell your doctor if...

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

The above list includes rare side effects of your medicine. They are usually mild.

Tell your doctor as soon as possible if... Tell your doctor as soon as possible if you notice any of the following:

 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

The above list contains serious side effects that may require medical attention.

Tell your doctor or pharmacist if you notice anything else that is making you unwell.

Other side effects not listed above may also occur in some people.

After being given Paracetamol Kabi

Storage

Paracetamol Kabi will be stored in the pharmacy or on a hospital ward. The injection should be kept in a dry cool place where the temperature stays below 25°C for the **free**flex® bags and below 25°C for the vials.

What it looks like

Paracetamol Kabi solution for infusion 10 mg/mL is clear and slightly yellowish solution.

Paracetamol Kabi is available in glass vials containing 50 mL or 100 mL, or in plastic bags (freeflex®) containing 50 mL or 100 mL.

Ingredients

Active ingredient: paracetamol 10 mg/mL 50 mL vial: AUST R 203625 contains 500 mg paracetamol

 $100\ mL$ vial: AUST R 203624 contains 1 g of paracetamol.

50 mL**free**flex® bag: AUST R 218687 contains 500 mgparacetamol

100 mL **free**flex® bag: AUST R 218688 contains 1 g paracetamol

Other ingredients: mannitol, cysteine hydrochloride, nitrogen (as protective gas), water for injections.

Supplier

Paracetamol Kabi is supplied in Australia by: Fresenius Kabi Australia Pty Limited Level 2, 2 Woodland Way Mount Kuring-gai NSW 2080

Australia Telephone: (02) 9391 5555

Paracetamol Kabi is supplied in New

Zealand by:

Fresenius Kabi New Zealand Limited

60 Pavilion Drive

Airport Oaks, Auckland 2022

New Zealand

Freecall: 0800 144 892

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