PARACETAMOL KABI

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I being given PARACETAMOL KABI?

PARACETAMOL KABI contains the active ingredient paracetamol. PARACETAMOL KABI is used to relieve pain and reduce fever following surgery. For more information, see Section 1. Why am I being given PARACETAMOL KABI? in the full CMI.

2. What should I know before I am given PARACETAMOL KABI?

Do not use if you have ever had an allergic reaction to PARACETAMOL KABI or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I am given PARACETAMOL KABI? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with PARACETAMOL KABI and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How is PARACETAMOL KABI given?

Your doctor will decide what dose you will be given, and for how long you will be given PARACETAMOL KABI.

Your doctor will inject the medicine as a slow infusion (drip) into a vein. PARACETAMOL KABI must only be given by a doctor or nurse.

More instructions can be found in Section 4. How is PARACETAMOL KABI given? in the full CMI.

5. What should I know after being given PARACETAMOL KABI?

Things you should do	Remind any doctor, dentist or pharmacist you visit that you have been given PARACETAMOL KABI.
Driving or using machines	Be careful before you drive or use any machines or tools until you know how PARACETAMOL KABI affects you.
Drinking alcohol	Your doctor may advise you to avoid alcohol as it may interfere with PARACETAMOL KABI.

For more information, see Section 5. What should I know after being given PARACETAMOL KABI? in the full CMI.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary.

The most common side effects are feeling unwell, dizziness, light headedness, bleeding or bruising more easily than normal, vomiting, nausea and constipation.

The serious side effects are allergic reaction such as 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.

For more information, including what to do if you have any side effects, see Section <u>6. Are there any side effects?</u> in the full CMI.

PARACETAMOL KABI

Active ingredient: Paracetamol

Consumer Medicine Information (CMI)

This leaflet provides important information about using PARACETAMOL KABI. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using PARACETAMOL KABI.

Where to find information in this leaflet:

- 1. Why am I being given PARACETAMOL KABI?
- 2. What should I know before I am given

PARACETAMOL KABI?

- 3. What if I am taking other medicines?
- 4. How is PARACETAMOL KABI given?
- 5. What should I know after being given PARACETAMOL KABI?
- 6. Are there any side effects?
- 7. Product details

Why am I being given PARACETAMOL KABI?

PARACETAMOL KABI contains the active ingredient paracetamol. 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. Ask your doctor if you want more information.

2. What should I know before I am given PARACETAMOL KABI?

Warnings

Do not use PARACETAMOL KABI if:

- You are allergic to paracetamol, or 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 have the following medical conditions
 - liver failure
 - severe liver disease

Check with your doctor if you:

have or have had any medical conditions such as:

- liver disease (including Gilbert's syndrome)
- o kidney disease
- o alcoholism
- o dehydration
- o 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)
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Your doctor will discuss the risks and benefits of using PARACETAMOL KABI if you are pregnant or breast-feeding.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with PARACETAMOL KABI and affect how it works.

Medicines that may affect the way PARACETAMOL KABI works 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)
- Other forms of paracetamol, such as tablets, liquid preparations or capsules
- Myleran® or Busulfex® (busulfan) a cancer drug
- Dolobid (diflunisal) an anti-inflammatory 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 warfarin)
- Isoniazid® (isoniazid) a tuberculosis drug
- Antibiotics containing amoxicillin plus clavulanic acid (such as Clamoxyl[®]) or flucloxacillin.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect PARACETAMOL KABI.

4. How is PARACETAMOL KABI given?

How much is given

The dosage you will be given will depend on your body size, age and the type of pain relief required. Your doctor will have had a lot of experience using PARACETAMOL KABI and will choose the best dose for you. They will be willing to discuss this decision with you.

How it will be 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 are given too much

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

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

If you think that you have been given too much PARACETAMOL KABI, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning, even if you feel well because of risk of delayed, serious liver damage and abnormal pigment levels.

5. What should I know after being given PARACETAMOL KABI?

Things you should do

Tell any other doctors, dentists, and pharmacists who treat you that you have been given this medicine.

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

Driving or using machines

Be careful before you drive or use any machines or tools until you know how PARACETAMOL KABI affects you.

Drinking alcohol

Tell your doctor or pharmacist if you drink alcohol.

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

Getting rid of any unwanted medicine

Any PARACETAMOL KABI which is not used, and which is left in the container, will be disposed of in a safe manner by your doctor, nurse or pharmacist.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects		What to do
Gut rel Brain a	ated Nausea (feeling sick) Vomiting Constipation nd nervous system related	Speak to your doctor if you have any of these less serious side effects and
•	Dizziness	they worry you.
•	Light headedness	
Genera	ıl	
•	Feeling unwell	
•	Bleeding or bruising more easily than normal	

Serious side effects

Serious side effects		What to do
Lung and upper airways		Tell your doctor
•	Shortness of breath	or nurse straight away,
•	Wheezing	or if you have
• Claire	Difficulty breathing	already left the hospital or
Skin •	Rash	surgery, go straight to the

•	Itching	Emergency Department
•	Hives on the skin	Department
General		at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/safety/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What PARACETAMOL KABI contains

Active ingredient	Paracetamol
(main ingredient)	
Other ingredients	Mannitol
(inactive ingredients)	Cysteine hydrochloride
	Nitrogen (as protective gas)
	Water for injections

Do not take this medicine if you are allergic to any of these ingredients.

What PARACETAMOL KABI looks like

PARACETAMOL KABI 10mg/mL solution for infusion is a clear and slightly yellowish solution.

PARACETAMOL KABI is available in:

- Glass vials containing 50 mL or 100 mL
- Plastic bags (freeflex[®]) containing 50 mL or 100 mL

AUST R	Presentation
203625	50 mL vial: contains 500 mg paracetamol
203624	100 mL vial: contains 1 g of paracetamol
218688	50 mL free flex [®] bag: contains 500 mg paracetamol
218687	100 mL free flex [®] bag: contains 1 g paracetamol

Who distributes PARACETAMOL KABI

Fresenius Kabi Australia Pty Limited Level 2, 2 Woodland Way Mount Kuring-gai NSW 2080 Australia

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