#### **Paracetamol BNM**

### **1000 mg/100 mL solution for infusion** *paracetamol*

#### **Consumer Medicine Information**

#### What is in this leaflet

Please read this leaflet carefully before you are given Paracetamol BNM.

This leaflet answers some common questions about Paracetamol BNM. It does not contain all the available information.

Reading this leaflet 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 giving you Paracetamol BNM against the benefits this medicine is expected to have for you.

# If you have any concerns about being given this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may want to read it again.

#### What Paracetamol BNM is used for

Paracetamol BNM contains paracetamol, an analgesic medicine which relieves pain and reduces fever.

Paracetamol BNM is a sterile solution for infusion which is given by intravenous infusion directly into a vein, and is used to relieve pain or reduce fever following surgery.

Your doctor may have prescribed this medicine for another reason.

#### Ask your doctor if you have any questions about why it has been prescribed for you.

Paracetamol BNM is available only with a doctor's prescription.

Paracetamol BNM is not addictive.

## Before you are given Paracetamol BNM

Paracetamol BNM is not suitable for everyone.

#### When you must not be given it You must not be given Paracetamol BNM if:

- you are allergic to any medicine containing paracetamol or any of the ingredients listed at the end of this leaflet
- you have liver failure or severe liver disease.

Symptoms of an allergic reaction 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.

#### Paracetamol BNM must not be used after the expiry date printed on the pack, or if the packaging is torn or shows signs of tampering. The solution must be clear before use.

If you are not sure whether you should be given this medicine, talk to your doctor.

#### Before you are given it

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

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

- liver disease
- kidney disease
- alcoholism
- malnutrition, including low reserves of glutathione
- dehydration
- eating disorders (anorexia, bulimia)
- cachexia, a wasting syndrome including unexplained weight loss, fatigue and loss of appetite
- a metabolic condition called glucose-6phosphate dehydrogenase deficiency (G6PD)
- an inherited condition called Gilbert's syndrome (also known as familial hyperbilirubinaemia)
- hypovolaemia (decreased blood volume).

### Tell your doctor or pharmacist if you are pregnant or breast-feeding.

Paracetamol BNM may be given to pregnant women and women who are breast-feeding, but your doctor must be told if you are pregnant or breast-feeding.

#### If you have not told your doctor about any of the above, tell them before you are given Paracetamol BNM.

#### Using other medicines

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

It is especially important to tell your doctor if you are taking any other medicines, including over the counter or pharmacy medicines, which contain paracetamol (for example, Panadol®). This may affect the dosage of Paracetamol BNM 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 BNM.

Tell your doctor or pharmacist if you are taking flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (high anion gap metabolic acidosis) that must have urgent treatment and which may occur particularly in case of severe renal impairment, sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), malnutrition, chronic alcoholism, and if the maximum daily doses of paracetamol are used.

Some medicines and Paracetamol BNM may interfere with each other. These include:

- probenecid, a medicine used to treat gout or given with antibiotics
- anticonvulsants, medicines used to treat epilepsy or fits, such as phenytoin, carbamazepine, amytal sodium, and phenobarbitone
- other forms of paracetamol, such as tablets, capsules or liquid preparations
- busulfan, a medicine used in cancer therapy

- diflunisal, a non-steroidal antiinflammatory medicine
- barbiturates
- zidovudine, a medicine for HIV treatment
- anticoagulants, medicines used to stop blood from clotting, such as warfarin
- isoniazid, a medicine used to treat tuberculosis
- antibiotics containing amoxicillin plus clavulanic acid.

The above medicines may be affected by Paracetamol BNM, or may affect how well it works. You may need different amounts of Paracetamol BNM, or you may need to use different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid whilst being given Paracetamol BNM.

#### How Paracetamol BNM is given

#### How it will be given

Paracetamol BNM will be given by slow intravenous infusion (drip) into a vein. This medicine must only be given by a doctor or a nurse.

#### How much will be given

Your doctor will decide how many infusions you need, and how often you should receive them. The need for more doses will depend on how well your body responds to the treatment.

Tell your doctor if you have been taking other forms of paracetamol (tablets, capsules, liquid preparations) and the quantity that you have been taking.

## While you are being given Paracetamol BNM

#### Things you must do

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are being given Paracetamol BNM. Likewise, tell any other doctors, dentists and pharmacists who are treating you that you are being given this medicine. Tell your doctor immediately if you develop a rash or other symptoms of an

#### allergic reaction.

Paracetamol BNM can cause serious skin reactions.

- Symptoms of an allergic reaction 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.

#### In case of overdose

Your doctor has information on how to recognise and treat an overdose.

Ask your doctor or nurse if you have any concerns.

#### Side effects

#### Tell your doctor as soon as possible if you do not feel well while you are being given Paracetamol BNM.

Like all medicines, Paracetamol BNM may occasionally cause side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical attention 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 heartbeat
- 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:

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

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

### Tell your doctor if you notice anything else that is making you feel unwell.

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

### Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After being given Paracetamol BNM

#### Storage

Paracetamol BNM will be stored in the pharmacy or on the ward under the recommended storage conditions.

#### It should be kept in a cool dry place, protected from light, where the temperature stays below 25°C. Do not refrigerate or freeze.

#### Disposal

Any Paracetamol BNM which has passed its expiry date, or is left in the container after use, will be disposed of in a safe manner by your doctor, nurse or pharmacist.

#### Product description

#### What it looks like

Paracetamol BNM is a clear and slightly brownish sterile solution for infusion. It is available in 100 mL transparent plastic bags. A box contains 12 bags. One 100 mL bag contains 1 g of paracetamol. *Ingredients* 

- Active ingredient: • paracetamol
- Inactive ingredients:

- mannitol
- povidone
- sodium hydroxide (for pH adjustment)
- dibasic sodium phosphate dihydrate
- water for injections.

Paracetamol BNM does not contain any preservatives.

#### Sponsor details

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