

Maxigesic[®] IV

Paracetamol 1000 mg/ibuprofen (as sodium dihydrate) 300 mg in 100 mL

Solution for infusion

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you start using Maxigesic[®] IV.

This leaflet answers some common questions about Maxigesic[®] IV. 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 using Maxigesic[®] IV against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine. You may need to read it again.

What Maxigesic[®] IV is used for

Maxigesic[®] IV contains paracetamol, an analgesic medicine which relieves pain and reduces fever. Maxigesic[®] IV also contains ibuprofen, which belongs to a group of medicines called non-steroidal anti-inflammatory drugs

(NSAIDs). Ibuprofen relieves pain, inflammation and fever.

Maxigesic[®] IV is a solution which is given by intravenous (IV) infusion directly into a vein, and is used to relieve pain or reduce fever. Your doctor may have prescribed Maxigesic[®] IV for another reason.

Ask your doctor if you have any questions about why Maxigesic[®] IV has been prescribed for you.

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

Before you are given Maxigesic[®] IV

When you must not be given Maxigesic[®] IV

You must not be given Maxigesic[®] IV if:

1. You have an allergy to:

- paracetamol,
- ibuprofen,
- any of the ingredients listed at the end of this leaflet,
- aspirin or any other NSAIDs.

Symptoms of an allergic reaction may include:

- asthma, wheezing or coughing,
- shortness of breath, difficulty breathing,
- swelling of the face, lips, tongue which may cause difficulty in swallowing or breathing,
- hives, itching or skin rash,
- stomach ache, fever, chills, nausea and vomiting,
- fainting.

2. You regularly drink large quantities of alcohol.

3. You are having heart bypass surgery.

It may increase your chance of a heart attack or a stroke (damage to part of the brain caused by an interruption to its blood supply).

4. You have impaired kidney function, impaired liver function, heart problems or heart failure.

5. You have (or have previously):

- vomited blood or material that looks like ground coffee,
- bled from the rectum (back passage), have black sticky bowel motions (stools) or bloody diarrhoea,
- had a peptic ulcer (i.e. ulcer in the stomach or part of the small intestine), a recent history of one, or

have had peptic ulcers before,

- had ulcerative colitis (inflammation of the colon) or Crohn's disease.

6. You have a spinal cord injury.

It may increase the risk of bleeding in this area.

7. You are pregnant or planning to become pregnant.

8. You are breastfeeding or planning to breastfeed.

If you are not sure whether you should be given Maxigesic® IV, talk to your doctor.

Before you are given Maxigesic® IV

Tell your doctor if:

1. You have allergies to:

- any other medicines including aspirin or any other NSAID,
- any other substances such as, foods, preservatives or dyes.

2. You are pregnant or intend to become pregnant.

Maxigesic® IV should not be used during pregnancy.

3. You are breastfeeding or planning to breastfeed.

It is not known whether Maxigesic® IV passes into breast milk.

4. You have, or have had, any of the following medical conditions:

- liver disease (including Gilbert's syndrome)
- kidney disease
- alcoholism
- heart disease or high blood pressure
- heart failure
- swelling of ankles or feet
- shortness of breath
- fatigue, chest pain, palpitations
- heartburn, indigestion, or an uncomfortable feeling in the stomach or belching after eating
- diarrhoea
- vomiting blood or material that looks like ground coffee
- bled from the back passage, have black sticky bowel motions (stools) or bloody diarrhoea
- a peptic ulcer (i.e. ulcer in the stomach or part of the small intestine), a recent history of one, or have had peptic ulcers before
- ulcerative colitis (inflammation of the colon) or Crohn's disease
- any other stomach or bowel problem
- 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)

- a severe skin rash, flaking or peeling of the skin or reactions such as Stevens-Johnson syndrome
- asthma, breathlessness, wheezing, a cough sometimes brought on by exercise and/or a feeling of tightness in the chest
- vision problems
- liver or kidney disease or impairment
- dehydration
- tendency to bleed, disease of blood clotting or other blood problems
- recent spinal or epidural pain relief
- tiredness, headaches, dizziness and looking pale
- systemic lupus erythematosus (SLE) and/or related connective tissue diseases
- Acute generalized exanthematous pustulosis (AGEP)
- Drug Reaction with eosinophilia and systemic symptoms (DRESS)
- signs or symptoms of an infection.

If you have not told your doctor about any of the above, tell him/her before you are given Maxigesic® IV.

Taking other medicines

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

Some medicines may interfere with Maxigesic® IV. These include:

- aspirin, salicylates or other NSAIDs, medicines used to treat pain, inflammation or swelling,
- aminoglycoside medicines, used to treat certain infections,
- antibiotics, including chloramphenicol, and those containing amoxicillin plus clavulanic acid,
- anticonvulsants, medicines used to treat epilepsy or fits, such as phenytoin or carbamazepine,
- antidiabetic medicines,
- barbiturates, such as amytal sodium or phenobarbitone,
- busulfan, an anti-cancer drug,
- diflunisal, an anti-inflammatory drug,
- warfarin or other anti-coagulant medicines used to prevent blood clots,
- cardiac glycosides, medicines used to treat heart failure such as digoxin,
- medicines used to treat high blood pressure or other heart conditions,
- corticosteroids, such as prednisone or cortisone,
- cyclosporine or tacrolimus, medicines used to treat certain problems with the immune system or to help prevent organ transplant rejection,
- diuretics, may also be called water tablets,
- ginkgo biloba, a herbal medicine,
- isoniazid, an anti-tuberculosis drug,
- lithium, a medicine used to treat some types of depression including bipolar disorder,

- other forms of paracetamol, such as tablets, liquid preparations or capsules,
- methotrexate, a medicine used to treat arthritis and some types of cancer,
- mifepristone, a medicine used for medical abortion,
- probenecid, a medicine used to treat gout, or that is given with antibiotics,
- quinolone antibiotics, medicines used to treat certain infections,
- zidovudine, a medicine used to treat HIV.

These medicines may be affected by Maxigesic® IV, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor will advise you.

Your doctor has more information on medicines to be careful with or avoid while being given Maxigesic® IV.

How Maxigesic® IV is given

How it is given

Maxigesic® IV will be given as a slow infusion (drip) into a vein.

Maxigesic® IV must only be given by a doctor or nurse.

How much is given

Your doctor will decide how much Maxigesic® IV you need.

You will usually be given 100 mL of Maxigesic® IV every 6 hours, as necessary.

Your doctor may give you a different amount depending on your condition.

How long is it given for

Your doctor will decide how long you need to be given Maxigesic® IV.

While you are being given Maxigesic® IV

Things you must do

If you are about to be started on any new medicine tell your doctor, pharmacist or dentist that you are taking Maxigesic® IV.

Do not start taking any other medicine including any that you buy without a prescription from your pharmacy, supermarket, health food shop, naturopath or herbalist without first telling your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how Maxigesic® IV affects you.

As with other NSAIDs, Maxigesic® IV may cause dizziness, light-headedness, drowsiness, or blurred vision in some people. If you have any of these symptoms, do not drive, operate machinery or do

anything else that could be dangerous.

Tell your doctor or pharmacist if you drink alcohol.

Your doctor may advise you to avoid alcohol as it may interfere with Maxigesic® IV.

In case of overdose

If you are given too much (overdose)

Maxigesic® IV must only be given by a doctor or nurse so overdose is unlikely.

If you think you have been given too much Maxigesic® IV, immediately telephone your doctor or the National Poisons Centre in New Zealand (telephone 0800 POISON or 0800 764 766) or the Poisons Information Centre in Australia (telephone 13 11 26), or go to Accident and Emergency at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning.

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

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel

well while you are using Maxigesic® IV.

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

Tell your doctor or nurse if you notice any of the following and they worry you:

- feeling unwell,
- nausea or vomiting,
- loss of appetite or changes to the taste of food,
- cramps, wind, constipation or diarrhoea,
- heartburn /indigestion or an uncomfortable feeling in the stomach or belching after eating,
- headache,
- tiredness,
- dizziness or light-headedness,
- numbness or 'pins and needles',
- fever or feeling hot,
- sleeplessness,
- itchy, red or painful skin,
- excessive sweating.

The above list includes the more common side effects of your medicine. They are usually mild.

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,

- severe pain or tenderness in the stomach,
- eye problems such as blurred vision, sore red eyes, itching,
- frequent infections such as fever, severe chills, sore throat or mouth ulcers,
- bleeding or bruising more easily than normal, reddish or purplish blotches under the skin,
- tiredness, headaches, being short of breath when exercising, dizziness and looking pale,
- yellowing of the skin and/or eyes, also called jaundice,
- unusual weight gain, swelling of ankles or legs,
- severe or persistent headache,
- fast or irregular heartbeats, also called palpitations,
- excessive thirst, weakness, tiredness.

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital, if you notice any of the following:

- bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea,
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing,
- asthma, wheezing, breathlessness sudden or severe itching, skin rash, hives,

- severe blisters and bleeding in the lips, eyes, mouth, nose and genitals (Stevens-Johnson Syndrome),
- fever, generally feeling unwell, nausea, stomach ache, headache and stiff neck,
- vomiting blood or material that looks like ground coffee,
- severe nausea, dizziness, numbness, drooping in your mouth or eye, difficulty in speaking or paralysis,
- sudden and oppressive chest pain,
- breathlessness, difficulty breathing when lying down, or swelling of the feet or legs.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

After being given Maxigesic® IV

Storage

Maxigesic® IV is usually stored at the hospital. However, if you need to store Maxigesic® IV:

- keep it where children cannot reach it,
- keep it in the original pack until it is time for it to be given,
- keep it in a cool dry place where the temperature stays below 25°C.

Do not refrigerate or freeze.

Disposal

Maxigesic® IV should not be given to you:

- if the expiry date (EXP) printed on the pack has passed,
- if the package is torn or shows signs of tampering.

Your doctor or nurse will check these things for you.

Product description

What it looks like

Maxigesic® IV is a clear, colourless solution. It is supplied in a clear glass vial that is closed with a stopper and an aluminium flip-off cap.

Ingredients

One 100 mL vial of Maxigesic® IV contains:

Active ingredients:

- Paracetamol 1000 mg (1 g)
- Ibuprofen (as sodium dihydrate) 300 mg

Inactive ingredients:

- Cysteine hydrochloride monohydrate
- Dibasic sodium phosphate dihydrate
- Mannitol
- Hydrochloric acid (for pH adjustment)
- Sodium hydroxide (for pH adjustment)
- Water for injections

This medicine contains 35.06 mg of sodium per 100 mL vial.

Sponsor details

Maxigesic® IV is distributed in Australia by:

AFT Pharmaceuticals Pty Ltd
113 Wicks Road
North Ryde
NSW 2113

Phone: 1800 238 74276

Maxigesic® IV is distributed in New Zealand by:

AFT Pharmaceuticals Ltd
PO Box 33-203
Takapuna
Auckland 0740

Phone: 0800 423 823

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This leaflet was prepared on 5 October 2020.