Maxigesic®

Active ingredients: Paracetamol 500 mg and Ibuprofen 150 mg

Consumer Medicine Information (CMI)

This leaflet provides important information about using Maxigesic*. 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 Maxigesic*.

Where to find information in this leaflet:

- Why am I using Maxigesic[®]?
- 2. What should I know before I use Maxigesic®?
- 3. What if I am taking other medicines?
- 4. How do I use Maxigesic®?
- 5. What should I know while using Maxigesic®?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using Maxigesic®?

Maxigesic® contains paracetamol and ibuprofen.

Paracetamol works to stop the pain messages from getting through to the brain. It also acts in the brain to reduce fever. Ibuprofen belongs to a group of medicines called non-steroidal anti-inflammatory drugs (or NSAIDs). It relieves pain and reduces inflammation (swelling, redness or soreness).

Maxigesic® is used for temporary relief of pain, including pain where inflammation is present, associated with: headache, migraine headache, tension headache, sinus pain, toothache, dental procedures, backache, sore throat, arthritis, tennis elbow, period pain, muscular pain, rheumatic pain, aches and pains associated with colds and flu. Reduces fever.

Maxigesic® is not addictive.

Ask your pharmacist or doctor if you have any questions about this medicine.

2. What should I know before I use Maxigesic®?

Warnings

Do not take Maxigesic®if:

- you regularly drink large quantities of alcohol
- 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
- you have a peptic ulcer (e.g. stomach or duodenal ulcer), a recent history of one, or have had peptic ulcers before, or any other stomach disorders

- you are pregnant or trying to become pregnant
- you have impaired kidney function, impaired liver function or heart problems
- you have heart failure
- you are undergoing treatment of perioperative pain in setting of coronary artery bypass surgery (CABG)
- you are allergic to paracetamol, ibuprofen, aspirin, NSAIDs or any of the ingredients listed at the end of this leaflet

Always check the ingredients to make sure you can use this medicine.

Many medicines used to treat headache, period pain and other aches and pains contain paracetamol, aspirin, ibuprofen or other NSAID medicines. If you are not sure if you are taking any of these medicines, ask your pharmacist.

Some of the 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
- · stomachache, fever, chills, nausea and vomiting
- fainting

If you are allergic to aspirin or NSAID medicines and take Maxigesic®, these symptoms may be severe.

Check with your doctor or pharmacist if you:

- you have difficulty urinating
- you currently have an infection
- you plan to have surgery
- you are breastfeeding or planning to breastfeed
- you are aged 65 years or over
- you have or have had other medical conditions including
- high blood pressure
- severe skin reactions such as Stevens-Johnson syndrome
- asthma
- vision problems
- tendency to bleed or other blood problems
- bowel or intestinal problems such as ulcerative colitis
- swelling of ankles or feet
- diarrhoea
- take any medicines for any other condition
- have a severe illness, including blood infection, are severely malnourished or are a chronic heavy alcohol user, as this may increase the risk of metabolic acidosis (a blood and fluid abnormality). Signs of metabolic acidosis include:
 - deep, rapid, difficult breathing
 - o feeling sick (nausea), being sick (vomiting)
 - o loss of appetite

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drowsiness

Contact a doctor immediately if you think you may be affected.

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 or pharmacist if you are pregnant or intend to become pregnant.

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

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.

Do not take Maxigesic® with other medicines containing paracetamol, ibuprofen, aspirin or other NSAIDs unless under the advice of a doctor.

Many medicines used to treat headache, period pain and other aches and pains contain paracetamol, aspirin, ibuprofen or other NSAID medicines. These medicines have a range of different trade names. It is important to check the labels of all the other medicines you are taking to make sure they do not contain paracetamol or ibuprofen, aspirin or any other NSAIDs. Taking too much paracetamol or ibuprofen may cause serious side effects. If you are not sure if you are taking any of these medicines, ask your pharmacist.

Maxigesic® may interfere with some medicines. These include:

- medicines to prevent blood clots such as warfarin
- medicines to treat epilepsy or fits
- chloramphenicol, an antibiotic used to treat ear and eye infections
- metoclopramide, a medicine that increases gastric emptying
- propantheline, a medicine used for treating cramps or spasms of the stomach, intestines (gut) or bladder
- cholestyramine, a medicine used as a bile acid sequestrant
- probenecid, a medicine used to treat gout
- zidovudine, a medicine used to treat HIV (the virus that causes AIDs)
- co-trimoxazole, an antibacterial medicine
- medicines used to treat tuberculosis such as isoniazid
- medicines to treat high blood pressure or other heart conditions
- diuretics, also called fluid tablets
- lithium, a medicine used to treat some types of depression
- methotrexate, a medicine used to treat arthritis and some types of cancer
- corticosteroids, such as prednisone, cortisone

- phenylephrine, a medicine used as a decongestant
- flucloxacillin (an antibiotic)

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

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

4. How do I use Maxigesic®?

How much to take

- Adults and children over 12 years: The usual dosage is one to two tablets taken every six hours, as required, up to a maximum of eight tablets in 24 hours.
- Children under 12 years: Maxigesic® is not recommended for children under 12 years.
- Do not take more than 8 tablets in a 24-hour period.
- If your doctor prescribes a different dose, follow directions given by your doctor.
- Maxigesic® should not be used for more than a few days at a time unless a doctor has told you to.

How to take it

• Take Maxigesic® tablets with a full glass of water.

How long to take it

- Adults and children over 12 years: Only take
 Maxigesic® tablets for a few days at a time for adults,
 or 48 hours at a time for children and adolescents
 aged 12-18 years, unless your doctor tells you to take
 it for longer.
- Children under 12 years: Maxigesic® is not recommended for children under 12 years.
- Do not take Maxigesic® for longer than your doctor says.

Maxigesic® only helps to control pain but will not cure your condition.

If your symptoms persist, worsen or new symptoms develop, talk to your doctor or pharmacist.

If you use too much Maxigesic®

Taking too many Maxigesic® tablets can lead to delayed, serious liver and renal damage. You may need urgent medical attention. Excessive use can be harmful and increase the risk of heart attack, stroke or liver damage.

If you take too much Maxigesic® you may:

- feel sick or vomit
- have stomach pain
- feel fatigued or lethargic
- feel itchy
- your skin takes on a yellow tinge
- have convulsions
- feel dizzy or even become unconscious.

If you think that you have used too much Maxigesic®, 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.

5. What should I know while using Maxigesic[®]?

Things you should do

- If you become pregnant while taking Maxigesic®, stop taking it and tell your doctor immediately.
- If you are about to start on any new medicine, tell your doctor and pharmacist that you are taking Maxigesic®.
- Talk to your pharmacist or doctor if your symptoms do not improve.
- Your pharmacist or doctor will assess your condition and decide if you should continue to take the medicine.
- Remind any doctor, dentist or pharmacist you visit that you are using Maxigesic[®].

Things you should not do

- Do not take any other medicines to relieve pain and reduce inflammation while you are taking Maxigesic® without first telling your doctor. This includes:
 - aspirin (also called acetylsalicylic acid)
 - other medicine containing paracetamol (also called acetaminophen)
 - other medicine containing ibuprofen and other NSAIDs.
- Do not take for more than a few days at a time for adults or more than 48 hours at a time for children and adolescents aged 12-18 years, unless your doctor tells you to.
- Do not take more than the recommended dose unless your doctor tells you to.
- Do not take Maxigesic® to treat any other complaints unless your doctor tells you to. Do not give Maxigesic® to anyone else, even if they have the same conditions as you. Do not take Maxigesic® if you regularly drink large quantities of alcohol.

Driving or using machines

 Be careful before you drive or use any machines or tools until you know how Maxigesic® affects you.

Drinking alcohol

- Tell your doctor or pharmacist if you drink alcohol.
- Avoid alcohol while taking Maxigesic[®].
- Drinking large quantities of alcohol while taking
 Maxigesic® may increase the risk of liver side effects.

Looking after your medicine

Keep your medicine in the original pack until it is time to take.

Heat and dampness can destroy some medicines.

Keep your medicine in a cool dry place where the temperature stays below 30 °C, away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines. Follow the instructions in the carton on how to take care of your medicine properly.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

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.

Less serious/common side effects

Less serious side effects	What to do
 Gastrointestinal related nausea or vomiting heartburn or pain the upper part of your stomach cramps, wind, constipation or diarrhoea 	Speak to your doctor or pharmacist if you have any of these less serious side
Body as a whole Ioss of appetite skin rashes headache dizziness fatigue and/or lethargy sleeplessness change in mood, for example depression, confusion, nervousness.	effects and they worry you.

Serious/rare side effects

Serious side effects	What to do
severe pain or tenderness in the stomach	Call your doctor straight away, or go straight

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- vomiting blood or material that looks like coffee grounds
- bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea

Body as a whole

- fever, generally feeling unwell, nausea, stomach ache, headache and stiff neck
- eye problems such as blurred vision, sore red eyes, itching
- signs of frequent or worrying infections such as fever, severe chills, sore throat or mouth ulcers
- yellowing of the skin and /or eyes, also called jaundice
- serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea) and being sick (vomiting)

Blood related

- bleeding or bruising more easily than normal, reddish or purplish blotches under the skin
- signs of anaemia, such as tiredness, headaches, being short of breath, and looking pale

Heart or kidney related

- unusual weight gain, swelling of ankles or legs
- fast or irregular heartbeats, also called palpitations

Nervous system related

- tingling of the hands and feet
- severe or persistent headache

Allergy related

- symptoms of sunburn (such as redness, itching, swelling, blistering) which may occur more quickly than normal
- sudden or severe itching, skin rash, hives
- severe blisters and bleeding in the lips, eyes, mouth, nose and genitals (Stevens Johnson Syndrome)
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- asthma, wheezing, shortness of breath

that may be making you feel unwell.

to the
Emergency
Department at
your nearest
hospital if you
notice any of
these serious
side effects.

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/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

This medicine is available over-the-counter without a doctor's prescription.

What Maxigesic®contains

Active ingredient (main ingredient)	Paracetamol Ibuprofen
Other ingredients	Maize starch
(inactive ingredients)	Microcrystalline cellulose
	Croscarmellose sodium
	Magnesium stearate
	Opadry white (HMPC 2910/Hypromellose 15cP (E464)
	Lactose monohydrate
	Titanium dioxide (E171)
	Trisodium citrate (E331)
	Macrogol/PEG 4000)
	Talc
Potential allergens	Lactose

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

What Maxigesic®looks like

Maxigesic® is a white coloured, capsule shaped, film coated tablet with breakline on one side and plain on the other side (Aust R 218785).

Who distributes Maxigesic®

AFT Pharmaceuticals Pty Ltd 113 Wicks Road North Ryde

NSW 2113, AUSTRALIA

This leaflet was prepared in June 2025.

Tell your doctor or pharmacist if you notice anything else

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