MAXOFEN Paracetamol 500 mg and Ibuprofen 200 mg

Active ingredients: *Paracetamol 500mg and Ibuprofen 200 mg*

Consumer Medicine Information (CMI)

This leaflet provides important information about using MAXOFEN tablet. **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 MAXOFEN Paracetamol 500 mg and Ibuprofen 200 mg.**

Where to find information in this leaflet:

1. Why am I using MAXOFEN Paracetamol 500 mg and Ibuprofen 200 mg?
2. What should I know before I use MAXOFEN Paracetamol 500 mg and Ibuprofen 200 mg?
3. What if I am taking other medicines?
4. How do I use MAXOFEN tablet?
5. What should I know while using MAXOFEN Paracetamol 500 mg and Ibuprofen 200 mg?
6. Are there any side effects?
7. Product details

1. Why am I using MAXOFEN Paracetamol 500 mg and Ibuprofen 200 mg?

MAXOFEN Paracetamol 500 mg and Ibuprofen 200 mg contains the active ingredients paracetamol and Ibuprofen. MAXOFEN is an analgesic (pain reliever). It works to relieve acute (short term) pain and / or inflammation associated with headache, migraine headache, tension headache, sinus pain, toothache, dental procedures, backache, muscular aches and pains, period pain, sore throat, tennis elbow, rheumatic pain and arthritis, and the aches and pains associated with cold and flu. Reduces fever.

Ibuprofen belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). Paracetamol works to stop the pain messages from getting through to the brain.

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

This medicine is not addictive. It is only available from your pharmacist.

Your doctor or pharmacist may have recommended MAXOFEN Paracetamol 500 mg and Ibuprofen 200 mg for another purpose. Ask your doctor or pharmacist if you have any questions about why MAXOFEN Paracetamol 500 mg and Ibuprofen 200 mg has been recommended for you.

2. What should I know before I use MAXOFEN Paracetamol 500 mg and Ibuprofen 200 mg?

Warnings

Do not take more than the recommended dose as it may cause serious harm to your liver.

Do not use MAXOFEN Paracetamol 500 mg and Ibuprofen 200 mg if:

- any medicine containing ibuprofen, aspirin or other NSAIDs,
- any medicine containing paracetamol,
- any of the ingredients listed at the end of this leaflet.
- any other medicine for pain relief
- 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, **Always read and follow the label.**

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start using MAXOFEN Paracetamol 500 mg and Ibuprofen 200 mg, contact your doctor or pharmacist.

Check with your doctor or pharmacist if you:

• asthma,
• a stomach or duodenal ulcer or if you have had either of these conditions or gastric bleeding or other gastrointestinal diseases in the past,
• liver or kidney disease,
• heart problems,
• recently vomited blood or material that looks like coffee grounds,
• recently bled from the back passage (rectum), had black sticky bowel motions or bloody diarrhoea.
Some of the symptoms of liver problems may include:
• nausea,
• feeling tired,
• itching of the skin,
• yellow colouring of your skin,
• flu-like symptoms,
• tenderness in your abdomen

If you develop any of these symptoms or heart problems, talk to your doctor.

Do not take MAXOFEN if you are aged 65 years or older.
Do not give MAXOFEN to children aged under 12 years.

Do not take MAXOFEN if you are taking any other product containing paracetamol, ibuprofen or other NSAIDs or if you are taking any other medication for pain relief.

If you are not sure whether you should start taking MAXOFEN, talk to your pharmacist or doctor.

Pregnancy and breastfeeding

Check with your doctor or pharmacist if you are pregnant or intend to become pregnant. Your doctor or pharmacist can discuss with you the risks and benefits involved.

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

Do not take MAXOFEN if you are pregnant or plan to become pregnant.

Do not take MAXOFEN after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal. Consider taking the lowest effective dose for the shortest period of time.

If you have not told your doctor or pharmacist about any of the above, tell them before you use MAXOFEN Paracetamol 500 mg and Ibuprofen 200 mg.

3. What if I am taking other medicines?

Some medicines and ibuprofen or paracetamol may interfere with each other. These include:

- warfarin, a medicine used to prevent blood clots,
- lithium, a medicine used to treat mood swings and some types of depression,
- medicines used to lower blood pressure,
- methotrexate, a medicine used to treat arthritis and some types of cancer,
- medicines used to treat heart failure
- Flucloxacillin, an antibiotic used to treat skin, bone, and chest infections
- medicines such as prednisone, prednisolone and cortisone, which reduce the activity of your immune system,
- zidovudine, a medicine used to treat HIV infection,
- aspirin, salicylates and other non-steroidal anti-inflammatory drugs (NSAIDs),
- metoclopramide, a medicine used to control nausea and vomiting,
- Medicines used to treat epilepsy or fits,
- Chloramphenicol, an antibiotic used to treat ear and eye infections,
- alcohol,
- medicines used to treat diabetes.

Your pharmacist and doctor will have more information on these and other medicines to be careful with or avoid while using this medicine.

Some medicines may be affected by MAXOFEN Paracetamol 500 mg and Ibuprofen 200 mg or may affect how well it works. You may need to use different amounts of your medicine or take different medicines. Your doctor or pharmacist will advise you.

- Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect MAXOFEN Paracetamol 500 mg and Ibuprofen 200 mg.

4. How do I use MAXOFEN Paracetamol 500 mg and Ibuprofen 200 mg?

How much to take

Adults under 65 years and children over 12 years: Take one tablet with fluid every 8 hours, as necessary

Not recommended in children under 12 years.

Follow all directions given to you by your pharmacist or doctor carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your pharmacist or doctor for help.

Do not take more than the recommended dose or for a longer period of time.
Adults: Do not take for more than 3 days at a time, except on medical advice.
Adolescents (12 to 17 years): Do not take for more than 2 days at a time.

Use the smallest dose that you need to treat your symptoms and use the medicine for the shortest period of time necessary.

How to take MAXOFEN Paracetamol 500 mg and Ibuprofen 200 mg

Swallow the tablets whole with water or other fluid.

Do not crush the tablets. They can be taken with or without food.

Try to space the doses at equal intervals throughout the day.

How long to take MAXOFEN Paracetamol 500 mg and Ibuprofen 200 mg

Do not take more than the recommended dose or for a longer period of time.

Adults: Do not take for more than 3 days at a time, except on medical advice.

Adolescents (12 to 17 years): Do not take for more than 2 days at a time.

If you use too much MAXOFEN Paracetamol 500 mg and Ibuprofen 200 mg

If you think that you have used too much MAXOFEN Paracetamol 500 mg and Ibuprofen 200 mg, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling telephone Australia 13 11 26 or New Zealand 0800 766 764**), 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 MAXOFEN Paracetamol 500 mg and Ibuprofen 200 mg?

Things you should do

- 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 MAXOFEN Paracetamol 500 mg and Ibuprofen 200 mg.

Things you should not do

- Do not give this medicine to children 12 to 17 years for more than 72 hours (3 days) unless a doctor has told you to.
- Do not use for more than a few days at a time unless your doctor tells you to.
- Do not take more than the recommended dose unless your doctor tells you to.
- Do not use MAXOFEN Paracetamol 500 mg and Ibuprofen 200 mg to treat any other complaints unless your pharmacist or doctor tells you to.
- Do not take with other products containing paracetamol or Ibuprofen.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how MAXOFEN Paracetamol 500 mg and Ibuprofen 200 mg affects you. This medicine may cause dizziness in some people. If this happens, do not drive or operate machinery.

Drinking alcohol

Tell your doctor or pharmacist if you drink alcohol.

Drinking large quantities of alcohol whilst taking MAXOFEN Paracetamol 500 mg and Ibuprofen 200 mg may increase the risk of liver side effects. Only drink small quantities of alcohol (beer, wine or spirits) while using MAXOFEN Paracetamol 500 mg and Ibuprofen 200 mg.

Looking after your medicine

- Keep MAXOFEN Paracetamol 500 mg and Ibuprofen 200 mg in a cool, dry place where the temperature stays below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place 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.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it. A locked cupboard at least one and half metres above the ground is a good place to store medicines.

When to discard your medicine

If your doctor or pharmacist tells you to stop using MAXOFEN Paracetamol 500 mg and Ibuprofen 200 mg or it has passed its expiry date, ask your pharmacist what to do with any that is left over. Return any unused medicine to your pharmacist.

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 side effects

Less serious side effects	What to do
• Acid buildup in the blood • Nervousness • Dizziness	**Speak to your doctor if you have any of these less**

	serious side effects and they worry you.

Serious/rare side effects

Serious side effects	What to do
• Shortness of breath • Wheezing or difficulty breathing • Swelling of the face, lips, tongue or other parts of the body • Rash, peeling, itching or hives on the skin or mouth ulcers • Unexplained bruising or bleeding • Severe blisters and bleeding in the lips, eyes, mouth, nose and genitals	**Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

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

Active ingredients (main ingredients)	paracetamol 500mg Ibuprofen 200mg
Other ingredients (inactive ingredients)	colloidal anhydrous silica, croscarmellose sodium, dichloromethane, isopropyl alcohol, magnesium stearate, Povidone, maize starch, microcrystalline cellulose, Purified water, Opadry White, stearic acid.

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

What MAXOFEN Paracetamol 500 mg and Ibuprofen 200 mg looks like

MAXOFEN Paracetamol 500 mg and Ibuprofen 200 mg
White coloured, film coated capsule-shaped tablet, plain on one side & break line on other side.

Who distributes MAXOFEN Paracetamol 500 mg and Ibuprofen 200 mg

Sponsor

Nova Pharmaceuticals Australasia Pty Ltd
Suite 305, 10 Norbrik Drive
Bella Vista, NSW 2153
Australia

Toll free (Australia): 1800 002 171

This leaflet was prepared in July 2025.