

Maxigesic[®] Tablet 500mg/150mg

Paracetamol 500 mg and Ibuprofen 150 mg film coated tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Maxigesic[®].

It does not contain all the available information. It does not take the place of talking to your pharmacist or doctor.

All medicines have risks and benefits. Your pharmacist or doctor has weighed the risks of you taking Maxigesic[®] against the benefits they expect it will have for you.

If you have any concerns about taking Maxigesic[®], ask your pharmacist or doctor.

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

What Maxigesic[®] is used for

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 fever.

Maxigesic[®] tablets are indicated for temporary relief of mild to moderate pain associated with headache, dental pain, period pain, migraine, backache, rheumatic pain, muscular pain, pain after vaccination and sore throat, and reduction of fever. This product is especially suitable for pain which requires stronger analgesia than ibuprofen or paracetamol alone.

Maxigesic[®] is not addictive.

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

Before you take Maxigesic[®]

When you must not take it

Do not take Maxigesic[®] if you have an allergy to:

- any medicine containing paracetamol;
- any medicine containing ibuprofen;
- any of the ingredients listed at the end of this leaflet;
- aspirin or any other NSAIDs

Many medicines used to treat headache, period pain and other aches and pains contain aspirin or 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, hives or blisters on the skin
- stomach ache, fever, chills, nausea and vomiting
- fainting

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

Do not take this medicine if:

- you are pregnant or intend to become pregnant. Taking NSAIDs at about 20 weeks of pregnancy or later may harm your unborn baby;
- you are breast-feeding or intend to breast-feed;
- you are (or have previously) bled from the rectum (back passage), have black sticky bowel motions (stools) or bloody diarrhoea;
- you have a peptic ulcer (i.e. stomach or duodenal ulcer), a recent history of one, or have had peptic ulcers before;
- You have, or have a history of, ulcerative colitis or Crohn's Disease.

Do not take Maxigesic[®] if you regularly drink large quantities of alcohol.

Do not take Maxigesic[®] 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 taking Maxigesic[®], talk to your pharmacist or doctor.

Before you start to take Maxigesic[®]

Tell your pharmacist or doctor if:

- you have liver disease, hepatitis, kidney disease or difficulty urinating;
- you are a heavy drinker or drug user;
- you have allergies to any other medicines contain aspirin or other NSAID medicines or any other substances listed at the end of this leaflet;
- you are pregnant or intend to become pregnant. Taking NSAIDs at about 20 weeks of pregnancy or later may harm your unborn baby
- you are breast-feeding or plan to breast-feed;
- you currently are having an infection;
- you plan to have surgery;
- you have or have had other medical conditions including:
 - heart disease or high blood pressure;
 - heartburn, indigestion, stomach ulcer or any other stomach problems;
 - vomiting blood or bleeding from back passage;
 - 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;
 - heart failure, swelling of ankles or feet;
 - diarrhoea.

Taking other medicines

Do not take with other medicines containing paracetamol or ibuprofen.

Many medicines used to treat headache, period pain and other aches and pains contain paracetamol, aspirin or NSAID medicines. These medicines have a range of different trade names. It is important to check the labels of all other medicines you are taking to make sure they do not contain paracetamol or ibuprofen 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.

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

Maxigesic[®] may interfere with some medicines. These include:

- warfarin, a medicine used to prevent blood clots
- medicines to treat epilepsy or fits
- chloramphenicol, an antibiotic used to treat ear and eye infections
- probenecid, a medicine used to treat gout
- zidovudine, a medicine used to treat HIV (the virus that causes AIDs)
- medicines used to treat tuberculosis such as isoniazid
- aspirin, salicylates or other NSAID medicines
- 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

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.

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

How to take Maxigesic®

Follow all directions given to you by your doctor and pharmacist carefully.

These directions may differ from the information contained in this leaflet.

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

How much to take

Adults and Children over 12 years: The usual dosage is 1-2 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 hours period.

If your doctor prescribes a different dose, follow directions given by your doctor.

Do not break the tablet when taking the medicine.

How to take it

Take Maxigesic® tablets with or straight after food 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 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 forget to take it

If it is almost time for your next dose, skip the dose missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking your tablets as you would normally.

Do not take a double dose to make up for the dose that you missed.
If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

If you take too much (overdose)

Immediately telephone your doctor for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Maxigesic®. Do this even if there are no signs of discomfort or poisoning.

Taking too many Maxigesic® tablets can lead to delayed, serious liver and renal damage. You may need urgent medical attention.

If you take too much Maxigesic® you may:

- feel sick or vomit
- have stomach pain
- have convulsions
- feel dizzy or even become unconscious

While you are taking Maxigesic®

Things you must do

If you become pregnant while taking Maxigesic® tell your doctor immediately.

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

Tell all of the doctors, dentists and pharmacist that are treating you 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.

Things you must 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 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.

Things to be careful of

Do not take high doses of Maxigesic® for long periods of time unless your doctor tells you to.

Only drink small quantities of alcohol (beer, wine or spirits) while taking Maxigesic®.

Drinking large quantities of alcohol while taking Maxigesic® may increase the risk of liver side effects.

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

Side effects

Tell your pharmacist or doctor as soon as possible if you do not feel well while you are taking Maxigesic®.

This medicine helps most people, but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them. Tell your pharmacist or doctor if you notice any of the following and they worry you:

- nausea
- loss of appetite
- heartburn or pain in the upper part of your stomach
- cramps, wind, diarrhoea
- skin rashes
- headache
- dizziness
- nervousness

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:

- severe pain or tenderness in the stomach
- signs of frequent or worrying 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
- signs of anaemia, such as tiredness, headaches, being short of breath, and looking pale
- yellowing of the skin and /or eyes, also called jaundice
- unusual weight gain, swelling of ankles or legs
- symptoms of sunburn (such as redness, itching, swelling, blistering) which may occur more quickly than normal.
- Severe or persistent headache
- Fast or irregular heartbeats, also called palpitations.

The above list includes serious side effects that may require medical attention. Serious side effects are rare for low doses of this medicine and when used for a short period of time.

If any of the following happen, stop taking Maxigesic® and tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- vomiting blood or material that looks like coffee grounds;
- 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, shortness of breath;
- 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.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. Other side effects not listed above may also occur in some people.

Tell your pharmacist or doctor if you notice anything that is making you feel unwell.

Ibuprofen may be associated with a small increased risk of heart attack or stroke. Any risk is more likely with high doses or prolonged treatment. Do not exceed the recommended dose and duration.

The lowest effective dose should be taken for the shortest possible time to reduce the risk of side effects.

Check with your pharmacist or doctor before taking this product if you previously have had a heart attack or stroke.

Stop taking the product and contact your doctor immediately if you develop signs and symptoms of heart problems or stroke, such as chest pain, shortness of breath, weakness in one part or side of body, or slurring of speech.

After using Maxigesic®

Storage

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

Keep your medicine in a cool dry place where the temperature stays below 30°C.

Do not store Maxigesic® or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

Ask your pharmacist what to do with any medicine that is left over, or if the expiry date has passed.

Product description

What it looks like

Maxigesic® tablets are white coloured, capsule shaped, film coated tablets with breakline on one side and plain on the other side.

Ingredients

Maxigesic® contains 500 mg of paracetamol and 150 mg of ibuprofen in each tablet. Tablets also contain maize starch, lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, magnesium stearate, talc and Opadry white.

Product owner

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