

# Maxigesic PE

**Paracetamol 500 mg, Ibuprofen 150 mg, Phenylephrine hydrochloride 2.5 mg film coated tablets**

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## What is in this leaflet

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This leaflet answers some common questions about Maxigesic PE. 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 PE 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. Ask your doctor or pharmacist if you have any concerns about this medicine.

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## What Maxigesic PE is used for

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This medicine contains 500 mg paracetamol, 150 mg ibuprofen and 2.5 mg phenylephrine hydrochloride in each tablet.

Paracetamol works to stop the pain messages from getting through to the brain. It also acts 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).

Phenylephrine hydrochloride acts as a decongestant to reduce mucosal lining swelling and suppress the production of mucus.

Maxigesic PE film coated tablets are used for temporary relief of cold and flu symptoms including headache, fever, pain and nasal congestion.

Your doctor may have prescribed Maxigesic PE for another reason. Ask your doctor if you have any questions about why Maxigesic PE has been prescribed for you.

There is no evidence that Maxigesic PE film coated tablet is addictive.

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## Before you use Maxigesic PE

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### Do not take Maxigesic PE:

- If you have a stomach ulcer or other stomach disorders
- If you are allergic to ibuprofen, paracetamol, phenylephrine hydrochloride, aspirin or other anti-inflammatory medicines
- In children under 12 years of age
- If you are in the last 3 months of pregnancy
- If you have impaired kidney function, impaired liver function or heart problems

### Unless doctor tells you to, do not take Maxigesic PE:

- If you are aged 65 years or over
- If you have asthma
- For more than a few days at a time
- With other medicines you are taking regularly
- If you have kidney problems or impaired renal function
- If trying to become pregnant, or during the first 6 months of pregnancy
- If you are a heavy drinker
- If you have high blood pressure
- If you are taking anti-depressant medication
- With other products containing paracetamol, ibuprofen, phenylephrine hydrochloride or other anti-inflammatory medicines.
- With other medicines intended to treat symptoms of the common cold

If you are not sure whether you should start using Maxigesic PE, talk to your doctor.

### Before you start to use Maxigesic PE, tell your doctor or pharmacist:

- If you have heart problems including heart failure, angina (chest pain), or if you have had a heart attack, bypass surgery, peripheral artery disease (poor circulation in the legs or feet due to narrow or blocked arteries), or any kind of stroke (including 'mini-stroke' or transient ischaemic attack "TIA").
- If you have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker
- If you have hyperthyroidism
- If you suffer from Raynaud's phenomenon
- If you have diabetes mellitus
- If you have had prostatic enlargement
- If you have closed angle glaucoma
- If you are currently receiving or within two weeks of stopping therapy with monoamine oxidase inhibitors (antidepressant)
- If you have liver disease, hepatitis, kidney disease or difficulty urinating
- If you are heavy drinker or drug user

- If you have allergies to any other medicines containing aspirin/acetylsalicylic acid or other NSAID medicines or any other substances listed at the end of this leaflet
- If you are pregnant or intend to become pregnant
- If you are breast-feeding or plan to breast-feed
- If you currently have an infection
- If you plan to have surgery
- If you have or have had other medical conditions including:
  - 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 or Crohn's Disease
  - swelling of ankles or feet
  - diarrhoea
  - inherited genetic or acquired disorder of certain enzymes that manifest with either neurological complications or skin problems or occasionally both i.e. porphyria
  - smallpox
  - autoimmune disease such as Lupus erythematosus

### **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. You should also tell any health professional who is prescribing a new medication for you that you are taking Maxigesic PE.

### **Some medicines may interfere with Maxigesic PE. These include:**

- medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, ticlopidine)
- medicines to treat epilepsy or fits such as phenytoin
- monoamine oxidase inhibitors, a class of anti-depressant medication
- 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 acquired immunodeficiency disease)
- medicines used to treat tuberculosis such as isoniazid
- aspirin/acetylsalicylic acid, salicylates or other NSAID medicines
- medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan)
- medicines for other heart conditions such as digoxin
- 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
- metoclopramide, propantheline
- tacrolimus or ciclosporin, immunosuppressive drugs used after organ transplant
- sulphonylureas, a medicine used to treat diabetes
- some antibiotics (such as quinolone antibiotics)

These medicines may be affected by Maxigesic PE, 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 or pharmacist has more information on medicines to be careful with or avoid while taking Maxigesic PE.

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## How to use MAXIGESIC PE

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### How much to take

Always take this medicine exactly as your doctor or pharmacist has told you. These directions may differ from the information contained in this leaflet. Check with your doctor or pharmacist if you are not sure.

Adults and children over 12 years: Take 2 tablets every 4 hours as required, up to a maximum of 8 tablets in 24 hours. Do not halve tablets.

Do not use in children under 12 years old. Keep to the recommended dose.

Use the lowest effective dose for the shortest time necessary to relieve symptoms.

### How long to take it

Do not take this medicine 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 advised to by a doctor. Do not exceed the recommended dose. Excessive use can be harmful and increase the risk of stroke, heart attack or liver damage.

Consult a doctor if the symptoms persist or worsen or if the product is required for more than 3 days.

### If you forget to take it

If it is almost time for your next dose, skip the missed dose 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 a forgotten dose. If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

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## **While you are using MAXIGESIC PE**

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### **Things to be careful of**

Tell all doctors, dentists and pharmacists who are treating you that you are taking Maxigesic PE film coated tablets.

Tell your doctor or pharmacist if you become pregnant while you are taking Maxigesic PE film coated tablets.

Serious skin reactions have been reported in association with Ibuprofen treatment. You should stop taking Maxigesic PE tablet and seek medical attention immediately, if you develop any skin rash, lesions of the mucous membranes, blisters or other signs of allergy since this can be the first signs of a very serious skin reaction. See "Side effects".

Do not give Maxigesic PE film coated tablets to anyone else, even if his or her symptoms seem similar to yours.

Do not use it to treat any other complaints unless your doctor or pharmacist says so.

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## **In case of overdose**

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### **If you take too much (overdose)**

If you have taken more Maxigesic PE than you should, or if you suspect that someone else has taken this medicine by accident always contact a doctor or nearest hospital to get an opinion of the risk and advice on action to be taken. Do this even if there are no signs of discomfort or poisoning.

Immediately telephone your doctor or the New Zealand National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Maxigesic PE.

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

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## Side Effects

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

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.

**If any of these serious side effects happen, stop taking Maxigesic PE and tell your doctor immediately or go to the emergency room 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
- severe itching, skin rash, hives
- severe blisters and bleeding in the lips, eyes, mouth, nose and genitals (Steven Johnson Syndrome)
- fever, generally feeling unwell, nausea, stomach ache, headache and stiff neck.
- Elevated blood pressure
- Abnormal heart palpitations
- Tingling and coolness of the skin

**Common** (may affect up to 1 in 10 people):

- fluid retention, swelling
- ringing in the ears (tinnitus)
- nausea or vomiting
- loss of appetite
- heartburn or pain in the upper part of your stomach
- diarrhoea
- skin rashes
- headache
- dizziness
- change in liver or kidney function (established by blood tests)
- nervousness
- restlessness
- irritability
- insomnia
- excitability

**Uncommon** (may affect up to 1 in 100 people):

- reduction in red blood cell numbers, bleeding episodes such as nosebleeds, abnormal or prolonged bleeding during menstrual periods, increased number of platelets
- eye problems such as blurred or diminished vision, changes to the appearance of colours
- wind and constipation.
- increased sensitivity to allergic reactions, angioedema (symptoms may include itchy, sore red eyes)
- breast enlargement (in males)
- abnormally low blood sugar (hypoglycaemia)
- change in mood, for example, depression, confusion, excessive emotional reactions
- change in the desire to sleep (sleepiness or sleeplessness)
- difficulty urinating
- thickening of respiratory secretions (mucous)

**Not known:**

- A severe skin reaction known as DRESS syndrome can occur. Symptoms of DRESS include: skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cells).
- A red, scaly widespread rash with bumps under the skin and blisters mainly localized on the skin folds, trunk, and upper extremities accompanied by fever at the initiation of treatment (acute generalized exanthematous pustulosis). Stop using Maxigesic PE tablets if you develop these symptoms and seek medical attention immediately.

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.

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## **After using MAXIGESIC PE**

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Keep this medicine out of the sight and reach of children.

Store below 30°C. Store in the original packaging to protect from light.

Do not use this medicine after the expiry date which is stated on the carton label and on the blister after Exp. The expiry date refers to the last day of that month.

Do not use this medicine if you notice packaging is torn or shows signs of tampering.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

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## Product description

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### What it looks like

Maxigesic PE film-coated tablets are pale yellow colored, capsule shaped, film coated tablet with a break line on one side and plain on the other side.

### Ingredients

#### Active ingredient(s):

The active substances are paracetamol, ibuprofen and phenylephrine hydrochloride.

#### Inactive ingredients:

Maize starch, pregelatinised starch, microcrystalline cellulose, croscarmellose sodium, magnesium stearate, purified talc, hydroxy propyl methyl cellulose, polyethylene glycol, titanium dioxide and color lake quinoline yellow.

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## Sponsor Details

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Maxigesic PE is supplied in New Zealand by:

AFT Pharmaceuticals Limited  
P O Box 33203  
Takapuna  
Auckland 0740  
New Zealand

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## Date of Preparation

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This leaflet was revised in October 2020