

PACKAGE INFORMATION LEAFLET

Maxigesic PE 500 mg/150 mg/2.5 mg film coated tablets
(Paracetamol, Ibuprofen and Phenylephrine Hydrochloride)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days.
- You should not take this product for longer than 3 days.

This medicine is available without prescription. However, you still need to read this leaflet carefully to get the best results from it.

What is in this leaflet

1. What Maxigesic PE is and what it is used for
2. What you need to know before you take Maxigesic PE
3. How to take Maxigesic PE
4. Possible side effects
5. How to store Maxigesic PE
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1. What Maxigesic PE is and what it is used for

Maxigesic PE contains 500 mg paracetamol, 150 mg ibuprofen and 2.5 mg phenylephrine hydrochloride in each tablet dose.

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 is used for temporary relief of cold and flu symptoms including:

- Headache
- Fever
- Pain
- Nasal congestion

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

You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

2. What you need to know before you take Maxigesic PE

Do not take Maxigesic PE:

- if you are allergic to the active substance(s) or any of the other ingredients of this medicine (listed in section 6);

- if 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;
- with any other medicines containing paracetamol or ibuprofen
- if you regularly drink large quantities of alcohol
- if you have severe heart failure, hepatic failure or renal failure
- if you have active or history of gastrointestinal bleeding or peptic ulceration.
- if you have cerebrovascular or other active bleeding
- if you have blood-formation disturbances
- if you have hypertension
- if you have coronary heart disease and cardiovascular disorders
- if you have asthma, urticaria or allergic-type reactions after taking aspirin/acetylsalicylic acid or other anti-inflammatory medicines
- during the last three months of pregnancy
- with other medicines intended to treat the symptoms of the common cold except on the advice of a healthcare professional

Unless a doctor has told you to, do not give or take Maxigesic PE:

- with other medicines you are taking regularly
- if you have asthma
- for more than a few days at a time
- 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 aged 65 years or over

Talk to your doctor or pharmacist before taking Maxigesic PE

Anti-inflammatory/pain-killer medicines like ibuprofen may be associated with a small increased risk of heart attack or stroke, particularly when used at high doses. Do not exceed the recommended dose or duration of treatment.

Products containing phenylephrine may induce nervousness, irritability, restlessness, excitability, headache, dizziness and insomnia. Special care should be taken when these symptoms are present. See doctor if symptoms persist.

You should discuss your treatment with your doctor or pharmacist before taking Maxigesic PE 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”).
- have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker;
- have hyperthyroidism
- suffer from Raynaud’s phenomenon
- have diabetes mellitus
- have had prostatic enlargement
- have closed angle glaucoma
- are currently receiving or within two weeks of stopping therapy with monoamine oxidase inhibitors (anti-depressant)
- have liver disease, hepatitis, kidney disease or difficulty urinating;
- are heavy drinker or drug user;
- 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;
- are pregnant or intend to become pregnant;
- are breast-feeding or plan to breast-feed;

- currently have an infection;
- plan to have surgery;
- 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

Do not drink alcoholic beverages when taking this medication. Combining alcohol with Maxigesic PE may lead to liver damage.

The product belongs to a group of medicines (NSAIDs) which may impair the fertility in women. This effect is reversible on stopping the medicine.

Taking Maxigesic PE may interfere with the results from the urine analysis test for 5-hydroxyindoleacetic acid (5HIAA), causing false-positive results. To avoid false results do not take Maxigesic PE or other paracetamol containing products for several hours before or during the collection of the urine specimen.

Children under 12 years

This product is not recommended for children under 12 years.

Other medicines and Maxigesic PE

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Maxigesic PE may affect or be affected by some other medicines. For example:

- 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 Maxigesic PE works. You may need different amounts of your medicines, or you may need to take different medicines.

Some other medicines may also affect or be affected by the treatment with Maxigesic PE. You should therefore always seek the advice of your doctor or pharmacist before you use Maxigesic PE with other medicines.

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

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Do not take this medicine during the last 3 months of your pregnancy. Take special care if you are in the first 6 months of pregnancy.

This product may impair female fertility and is not recommended in women attempting to conceive.

Driving and using machines

Be careful driving or operating machines until you know how Maxigesic PE affects you.

3. How to take Maxigesic PE

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. **Do not take for more than 3 days.**

The recommended dose is:

Adults and children over 12 years: The usual dosage is 1-2 two tablets taken every four hours, as required up to a maximum of 8 eight in 24 hours.

Use the lowest effective dose for the shortest time necessary to relieve symptoms. The patient should consult a doctor if the symptoms persist or worsen or if the product is required for more than 3 days.

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.

Take Maxigesic PE tablets with a full glass of water. The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Use in children under 12 years

Maxigesic PE is not recommended for children under 12 years.

If you take more Maxigesic PE than you should

If you have taken more Maxigesic PE than you should, or if children have 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.

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

The symptoms can include nausea, stomach pain, vomiting (may be blood streaked), headache, ringing in the ears, confusion and shaky eye movement. At high doses, drowsiness, chest pain, palpitations, loss of consciousness, convulsions (mainly in children), weakness and dizziness, blood in urine, cold body feeling, and breathing problems have been reported.

If you forget to take Maxigesic PE

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.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. If you get any side effects, talk to your doctor or pharmacist.

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;
- very rare cases of serious skin reactions have been reported including sudden or 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

Other side effects:

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)

Rare (may affect up to 1 in 1,000 people):

- hallucinations and increased nightmare occurrence
- numbness or abnormal skin sensations (e.g. burning, tingling or pricking) in the hands and feet

Very rare (may affect up to 1 in 10,000 people):

- 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
- vertigo
- yellowing of the skin and/or eyes, also called jaundice
- unusual weight gain, swelling of ankles or legs, decreased urine output
- involuntary muscle movements/spasms, tremors and convulsions, slowing of physical and emotional reactions
- temporary vision loss, pain during eye movements
- symptoms of sunburn (such as redness, itching, swelling, blistering) which may occur more quickly than normal
- fast or irregular heartbeats, also called palpitations
- increased sweating

Not known (frequency cannot be estimated from the available data):

- 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).

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.

Reporting of side effects

If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Maxigesic PE

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.

6. Contents of the pack and other information

What Maxigesic PE contains

The active substances are paracetamol, ibuprofen and phenylephrine hydrochloride.

The other ingredients are: maize starch, pregelatinised starch, microcrystalline cellulose (102), croscarmellose sodium, magnesium stearate, purified talc, hydroxy propyl methyl cellulose 5 cps, polyethylene glycol 6000, titanium dioxide and color lake quinoline yellow (Neelilake).

What Maxigesic PE looks like and contents of the pack

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.

Each blister pack contains 8, 10, 16, 20, 24, 30, 32, 50 and 100 film-coated tablets.

Maxigesic PE is distributed in Singapore by:

Apex Pharma Marketing Pte Ltd
4 Loyang Way 1
Level 2
Singapore 508708

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