Package leaflet: Information for the user

Ibuprofen & Paracetamol 200 mg/500 mg film-coated tablets

Ibuprofen and paracetamol

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 have told you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- **This medicine is intended for temporary relief of mild to moderate pain which has not been relieved by either ibuprofen or paracetamol individually. See section 3.**
- **You should not take this medicine if your pain has been relieved by using either ibuprofen or paracetamol individually.**
- 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.

What is in this leaflet

1. What this medicine is and what it is used for
2. What you need to know before you take this medicine
3. How to take this medicine
4. Possible side effects
5. How to store this medicine
6. Contents of the pack and other information

1. What this medicine is and what it is used for

This medicine contains two active ingredients (which make the medicine work). These are **Ibuprofen** and **Paracetamol.**
Ibuprofen belongs to a group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs work by reducing pain, reducing swelling and lowering high body temperature.
Paracetamol is an analgesic which works in a different way from ibuprofen to relieve pain and fever.
This medicine is used for temporary relief of mild to moderate pain which has not been relieved by ibuprofen or paracetamol individually, such as migraine, headache, period pain, dental pain, rheumatic and muscular pain, cold and flu symptoms, sore throat and fever.

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 this medicine

Do not take this medicine if you:
- are already taking **any other paracetamol containing product**
- are taking **any other pain relieving products** including **ibuprofen**, **high dose acetylsalicilic acid** (above 75 mg per day), or **other non-steroidal anti inflammatory drugs** (NSAIDs) including cyclo-oxygenase-2 (COX-2) inhibitors
- are **allergic to ibuprofen**, **paracetamol** or any of the other ingredients of this medicine (listed in section 6)
- are **allergic to acetylsalicilic acid or other NSAID**
- have or have ever had an **ulcer or bleeding in your stomach or duodenum** (small intestine)
- have **blood clotting (coagulation) disorder**
- suffer from **severe heart, liver or kidney failure**
- are **in the last 3 months of pregnancy**
- are **under 18 years old**.

Warnings and precautions
Do not take this medicine if you have not tried using either ibuprofen or paracetamol individually to relieve your pain. See section 3.
Talk to your doctor or pharmacist before taking this medicine if you:
- have an **infection** - please see heading “Infections”
- are **elderly**
- have **asthma** or have suffered from asthma
- have **kidney, heart, liver or bowel disorder**
- have **systemic lupus erythematosus** (sle) – a condition of the immune system affecting connective tissue resulting in joint pain, skin changes and disorder of other organs **or other mixed connective tissue disease**
- have **gastrointestinal disorders or chronic inflammatory bowel disease** (e.g. ulcerative colitis, crohn’s disease)
- are in the **first 6 months of pregnancy** or are **breast-feeding**
- are **planning to become pregnant**.

If you are taking this medicine for longer than the recommended time or at higher than recommended doses you are at risk of serious harms. These include serious harms to the stomach/gut and kidneys, as well as very low levels of potassium in your blood. These can be fatal (see section 4).

Signs of an allergic reaction to this medicine, including breathing problems, swelling of the face and neck region (angioedema), chest pain have been reported with ibuprofen. Stop immediately this medicine and contact immediately your doctor or medical emergencies if you notice any of these signs.

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.

You should discuss your treatment with your doctor or pharmacist before taking this medicine 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 blood circulation in the legs 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.

<u>Infections</u>
This medicine may hide signs of infections such as fever and pain. It is therefore possible that this medicine may delay appropriate treatment of infection, which may lead to an increased risk of complications. This has been observed in pneumonia caused by bacteria and bacterial skin infections related to chickenpox. If you take this medicine while you have an infection and your symptoms of the infection persist or worsen, consult a doctor without delay.

<u>Skin reactions</u>
Serious skin reactions including exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS), acute generalised exanthematous pustulosis (AGEP) have been reported in association with ibuprofen treatment. Stop using this medicine and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

During treatment with this medicine, tell your doctor straight away if:
you have severe illnesses, including severe renal impairment or sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), or you suffer from malnutrition, chronic alcoholism or if you are also taking flucloxacillin (an antibiotic). A serious condition called metabolic acidosis (a blood and fluid abnormality) has been reported in patients in these situations when paracetamol is used at regular doses for a prolonged period or when paracetamol is taken together with flucloxacillin. Symptoms of metabolic acidosis may include: serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea) and being sick (vomiting).

Other medicines and this medicine
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
You should not use this medicine with:
- other **paracetamol containing** products
- other **NSAID containing products** such as aspirin, ibuprofen.

This medicine may affect or be affected by some other medicines. For example:
- **corticosteroids**
- **antibiotics** (e.g. chloramphenicol or quinolones)
- flucloxacillin **(antibiotic)**, due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).
- **anti sickness** medicines (e.g. metoclopramide, domperidone)
- medicines that are **anti-coagulants** (i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, ticlopidine)
- **heart stimulants** (e.g. glycosides)
- medicines for **high cholesterol** (e.g. cholestyramine)
- **diuretics** (facilitating the excretion of excess water)
- 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 to **suppress the immune response** (e.g. methotrexate, ciclosporine, tacrolimus)
- medicines for **phobia or depression** (e.g. lithium or SSRIs- selective serotonin reuptake inhibitors)
- **mifepristone** (for pregnancy termination)
- **HIV medicines** (e.g. zidovudine).

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

This medicine with food and drink
To reduce the likelihood of side effects, take this medicine with food.

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 if you are in the last 3 months of your pregnancy as it could harm your unborn child or cause problems at delivery. It can cause kidney and heart problems in your unborn baby. It may affect your and your baby’s tendency to bleed and cause labour to be later or longer than expected. You should not take this medicine during the first 6 months of pregnancy unless absolutely necessary and advised by your doctor. If you need treatment during this period or while you are trying to get pregnant, the lowest dose for the shortest time possible should be used.

If taken for more than a few days from 20 weeks of pregnancy onward, this medicine can cause kidney problems in your unborn baby that may lead to low levels of amniotic fluid that surrounds the baby (oligohydramnios) or narrowing of a blood vessel (ductus arteriosus) in the heart of the baby. If you need treatment for longer than a few days, your doctor may recommend additional monitoring.

This medicine may make it more difficult to become pregnant. Ibuprofen belongs to a group of medicines which may impair fertility in women. This is reversible after discontinuation of the medicine. You should inform your doctor if you are planning to become pregnant or if you have problems becoming pregnant.

Driving and using machines
This medicine may cause dizziness, drowsiness, fatigue and visual disturbances in some people. This should be taken into consideration on occasions when high alertness is required, e.g. driving. Be careful driving or operating machines until you know how this medicine affects you.

This medicine contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

3. How to take this medicine

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

For oral use and for short term use only.
The lowest effective dose should be used for the shortest duration necessary to relieve symptoms.
If you have an infection, consult a doctor without delay if symptoms (such as fever and pain) persist or worsen (see section 2).
You should not take this medicine for longer than 3 days. If your symptoms worsen or persist, consult your doctor.
For the first day of treatment, try a pain relief medication which contains a single active ingredient (either ibuprofen or paracetamol) in accordance with product instructions. **If during the first day of treatment with such medication your pain has not been relieved, then the next day you can take this medicine, following the instructions below.**
Adults: Take 1 tablet **with food or water**, up to 3 times a day. Leave at least 6 hours between doses. If one tablet does not control symptoms, then a maximum of 2 tablets may be taken up to 3 times a day. **Do not take more than 6 tablets in any 24 hour period** (equivalent to 3000 mg Paracetamol, 1200 mg Ibuprofen a day).

Use in children and adolescents
Not for use by children under 18 years.

If you take more of this medicine than you should
If you have taken more of this medicine 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.
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 have taken more of this medicine than you should, contact your doctor immediately, even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage.

If you forget to take this medicine
Do not take a double dose to make up for a forgotten dose.
If you forget to take a dose, take it as soon as you remember it and then take the next dose at least 6 hours later.

Further information overleaf

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
STOP TAKING the medicine and tell your doctor if you experience:
- **heartburn, indigestion;**
- **symptoms of intestinal bleeding** (severe stomach pain, bloody vomiting or vomiting containing dark-coloured particles that resemble coffee granules, blood in the stools, black tarry stools);
- **symptoms of inflammation of the brain lining such as**: stiff neck, headache, feeling or being sick, fever or feeling disorientated;
- **symptoms of a severe allergic reaction** (swelling of the face, tongue or throat, difficult breathing, worsening of asthma, chest pain, which can be a sign of a potentially serious allergic reaction e.g. anaphylaxis, Kounis Syndrome);
- **shortness of breath**
- **reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes.** These serious skin rashes can be preceded by fever and flu-like symptoms [exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis];
- **widespread rash, high body temperature and enlarged lymph nodes** (DRESS syndrome);
- **a red, scaly widespread rash with bumps under the skin and blisters accompanied by fever.** The symptoms usually appear at the initiation of treatment (acute generalised exanthematous pustulosis);
- **liver, kidney problems or difficulty urinating**. This medicine, especially when taken at higher than recommended doses or for a prolonged period of time, can cause damage to your kidneys and affect them removing acids properly from your blood into the urine (renal tubular acidosis). It can also cause very low levels of potassium in your blood (see section 2). This is a very serious condition and will require immediate treatment. Signs and symptoms include muscle weakness and light-headedness.
- **symptoms of a reduction in blood cells** (causing sore throat, mouth ulcers, flu-like symptoms, severe exhaustion, unexplained bleeding, bruising and nosebleeds);
- **heart failure** (causing breathlessness, swelling).

Other possible side effects
Common (may affect up to 1 in 10 people):
- stomach pain or discomfort, feeling or being sick, diarrhoea;
- higher levels of some liver enzymes (ALT, GGT), blood creatinine and urea (shown in blood tests).

Uncommon (may affect up to 1 in 100 people):
- headache and dizziness;
- wind and constipation;
- exacerbation of colitis and Crohn's disease;
- indigestion, heartburn or feeling sick (gastritis);
- inflammation of the pancreas accompanied by severe pain in the upper abdomen extending towards the back and vomiting (pancreatitis);
- inflammation of the lining of the mouth;
- skin rashes, pruritus, hives and swelling of the face;
- higher levels of a liver enzyme (AST), increased level of ALP and CPK (shown in blood tests);
- reduction in red blood cells number or increase in platelets (blood clotting cells) number.

Very rare (may affect up to 1 in 10,000 people):
- visual disturbances, ringing in the ears, spinning sensation;
- confusion, depression, hallucinations;
- numbness, itching, and a feeling of pins and needles on your skin, inflamation of the optic nerve and drowsiness;
- asthma or worsening of asthma;
- fatigue, generally feeling unwell;
- high blood pressure, water retention;
- liver problems (causing yellowing of the skin and white of eyes);
- kidney problems (causing increased or decreased urination, swelling of the legs);
- excessive sweating;
- purpura;
- increased skin sensitivity to sunlight.

Frequency not known (frequency cannot be estimated from the available data):
- decreased appetite;
- low blood potassium levels which can cause weakness, muscle cramps, tingling and heart rhythm disturbance;
- a serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2).

Medicines such as this medicine may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke. (See section 2)

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. You can also report side effects directly via Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store this medicine

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

Do not use this medicine after the expiry date which is stated on the carton (EXP). The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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 this medicine contains
- The active substances are ibuprofen and paracetamol.
- The other ingredients are:
  Tablet core: maize starch, povidone K-30 (E1201), croscarmellose sodium (E468), cellulose microcrystalline (E460), silica colloidal anhydrous (E551), glycerol dibehenate (E471).
  Film-coating: opadry white (polyvinyl alcohol-partially hydrolysed, talc, titanium dioxide (E171), glyceryl monocaprylocaprate, sodium laurilsulfate).

What this medicine looks like and contents of the pack
This tablet is white to off white, oblong, biconvex film-coated tablets with dimensions of (21 mm x 10.5 mm) ± 0.5 mm and marked with a double circle mark on one side.

The film-coated tablets are blister-packed in:
Blister: White PVC/PVDC/ Aluminium hard foil, each blister containing proper number of film-coated tablets *or* Child resistant blister: White PVC/PVDC/ Aluminium push through foil, fortified by polyester layer, each blister containing proper number of film-coated tablets.

The child resistant blister may require an extra effort to push-through the tablet.

Cardboard box with 8, 10 or 16 tablets and instruction leaflet inside. Not all pack sizes may be marked.

Marketing Authorisation Holder
Galpharm Healthcare Limited, Wrafton, Braunton, Devon,
EX33 2DL, United Kingdom

Manufacturer
ALKALOID-INT d.o.o., Šlandrova ulica 4,
Ljubljana-Črnuče, 1231, Slovenia
and
TERAPIA S.A.,124 Fabricii Street, Cluj-Napoca, 400 632, Romania
PL 16028/0186

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Version Information
Version: 2
Operator: NH
Date: 18 / FEB / 25

Job Information
Product Name: Generic Ibuprofen & Paracetamol 200 mg/500 mg film-coated tablets
Project Name: 000111_Paracetamol PRAC 2024 - PL 16028/0186 Safety update to leaflet text for all paracetamol containing products including leaflet cutter increase
Program No.: 002399
Component No.: F7V0000J2
Licence No.: PL 16028/0186
Supplier: Alkaloid
Cutter Ref.: L6029
Dimensions: 172 x 560mm

Colours

Process	Pantone	Technical
N/A	N/A	Cutter
N/A	N/A	N/A
N/A	N/A	N/A
Black	N/A	N/A
	N/A	N/A
	N/A	N/A

MINIMUM TYPE SIZE 9pt