

## PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

### Ibuprofen & Paracetamol 200mg/500mg tablets

Read all of this leaflet carefully because it contains important information for you.

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

- Keep this leaflet. You may need to read it again
- Ask your pharmacist if you need more information or advice
- You **should not take the product for longer than 3 days**
- If symptoms persist or worsen consult your doctor
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

#### In this Leaflet:

1. **What Ibuprofen & Paracetamol 200mg/500mg tablets are and what they are used for**
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1. ***What Ibuprofen & Paracetamol 200mg/500mg tablets are and what they are used for***

Ibuprofen & Paracetamol 200mg/500mg tablets contain 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 temperatures.

Paracetamol is an analgesic which works in a different way from ibuprofen to relieve pain and fever.

Ibuprofen & Paracetamol 200mg/500mg tablets are used for the temporary relief of mild to moderate pain associated with migraine, headache, backache, period pain, dental pain, rheumatic and muscular pain, pain of non-serious arthritis, cold and flu symptoms, sore throat and fever.

2. ***Before you take Ibuprofen & Paracetamol 200mg/500mg tablets***

**Do not take Ibuprofen & Paracetamol 200mg/500mg tablets if you:**

- are already taking **any other paracetamol containing product.**
- are taking **any other pain relieving products** including **ibuprofen, high dose aspirin** (above 75mg per day) or **other non-steroidal anti-inflammatory drugs** (NSAIDs) including cyclo-oxygenase-2 (COX-2) specific inhibitors
- are **allergic to ibuprofen, paracetamol** or any other ingredients in Ibuprofen & Paracetamol 200mg/500mg tablets
- are **allergic to aspirin or other NSAID painkillers**
- have or ever had an **ulcer or bleeding in your stomach or duodenum** (small bowel)
- have **blood clotting (coagulation) disorder**
- suffer from **heart, liver or kidney failure**
- are in the **last 3 months of pregnancy**
- are **under 18** years old

**Take special care and check with a doctor or pharmacist before taking Ibuprofen & Paracetamol 200mg/500mg tablets if you:**

- are **elderly**
- have **asthma** or have suffered from asthma
- have **kidney, heart, liver or bowel** problems
- 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 **breastfeeding**
- are **planning to become pregnant**

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 [Invented name] 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 of 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.

### **Taking Ibuprofen & Paracetamol 200mg/500mg tablets with other medicines:**

#### **Do not take Ibuprofen & Paracetamol 200mg/500mg tablets with:**

- other **paracetamol containing** products
- other **NSAID containing products** such as aspirin, ibuprofen.

Special care is required as some medicines may interact with Ibuprofen & Paracetamol 200mg/500mg tablets, for example:

- **corticosteroid** tablets
- **antibiotics** (e.g. chloramphenicol or quinolones)
- **anti sickness** medicines (e.g. metoclopramide, domperidone)
- **heart stimulants** (e.g. glycosides)
- medicines for **high cholesterol** (e.g. cholestyramine)
- **diuretics** (to help you pass water)
- medicines to **suppress the immune system** (e.g. methotrexate, ciclosporine, tacrolimus)
- medicines for **mania or depression** (e.g. lithium or SSRI's)
- **mifepristone** (for pregnancy termination)
- **HIV medicines** (e.g. zidovudine)

Ibuprofen & Paracetamol 200mg/500mg tablets 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 that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan)

**Some other medicines may also affect or be affected by the treatment of take Ibuprofen & Paracetamol 200mg/500mg tablets. You should therefore always seek the advice of your doctor or pharmacist before you use Ibuprofen & Paracetamol 200mg/500mg tablets with other medicines.**

### **Taking Ibuprofen & Paracetamol 200mg/500mg tablets with food**

To reduce the likelihood of side effects, take Ibuprofen & Paracetamol 200mg/500mg tablets with food.

### **Pregnancy and breastfeeding**

Ask your doctor or pharmacist for advice before taking any medicine. Do not take if you are in the last 3 months of your pregnancy. Take special care if you are in the first 6 months of pregnancy.

Ibuprofen & Paracetamol 200mg/500mg tablets may make it more difficult to become pregnant. Ibuprofen belongs to a group of medicines which may impair fertility in women. This is reversible on stopping the medicine. You should inform your doctor if you are planning to become pregnant or if you have problems becoming pregnant.

## **3. How to take Ibuprofen & Paracetamol 200mg/500mg tablets**

For oral use and for short term use only.

Only use the minimum effective dose for the shortest time necessary to relieve your symptoms. **You should not take Ibuprofen & Paracetamol 200mg/500mg tablets for longer than 3 days.** If your symptoms worsen or persist, consult your doctor.

Take 1 tablet to be taken with **water and food**, up to three times a day.

Leave at least **6 hours between doses.**

If one tablet dose not control symptoms, then a maximum of 2 tablets may be taken up to three times a day.

**Do not take more than six tablets in any 24 hour period** (equivalent to 3000mg paracetamol, 1200mg ibuprofen a day).

**Not for use by children under 18 years.**

**If you take more Ibuprofen & Paracetamol 200mg/500mg tablets than you should**

Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage.

**If you forget to take Ibuprofen & Paracetamol 200mg/500mg tablets**

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.

#### **4. Possible side effects**

Like all medicines, Ibuprofen & Paracetamol 200mg/500mg tablets can cause side effects, although not everybody gets them.

**STOP TAKING the medicine and tell your doctor if you experience:**

- **Heartburn, indigestion**
- **Signs of intestinal bleeding** (severe stomach pain, vomiting blood or liquid with what looks like coffee granules, blood in the stools/motions, black tarry stools)
- **Signs of Inflammation of the brain lining such as:** stiff neck, headache, feeling or being sick, fever or feeling disorientated
- **Signs of a severe allergic reaction** (swelling of the face, tongue or throat, difficulty breathing or worsening of asthma).

#### **Other possible side effects**

**Common** (occurs in less than 1 in 10 people):

- stomach pain or discomfort, feeling or being sick, diarrhoea
- higher levels of liver enzymes (shown in blood tests)

**Uncommon** (occurs in less than 1 in 100 people):

- headache and dizziness, wind and constipation, skin rashes, swelling of the face.
- reduction in red blood cells number or increase in platelets (blood clotting cells) number.

**Very Rare** (occurs in less than 1 in 10,000 people):

- reduction in blood cells (causing sore throat, mouth ulcers, flu-like symptoms, severe exhaustion, unexplained bleeding, bruising and nose bleeds)
- visual disturbances, ringing in the ears, spinning sensation,
- confusion, depression, hallucinations
- fatigue, generally feeling unwell
- severe skin reactions such as blistering
- high blood pressure, water retention
- liver problems (causing yellowing of the skin and whites of the eyes)
- kidney problems (causing increased or decreased urination, swelling of the legs)
- heart failure (causing breathlessness, swelling)

Medicines such as Ibuprofen & Paracetamol 200mg/500mg tablets may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke. (See section2).

#### **Reporting of side effects:**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard).

By reporting side effects, you can help provide more information on the safety of this medicine.

#### **5. How to store Ibuprofen & Paracetamol 200mg/500mg tablets?**

Keep out of the reach and sight of children. This medicinal product does not require any special storage conditions.

Do not use Ibuprofen & Paracetamol 200mg/500mg tablets after the expiry date which is stated on the blister and the carton. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

#### **6. Further information**

##### **What Ibuprofen & Paracetamol 200mg/500mg tablets contain**

- The active substances are ibuprofen and paracetamol. Each film-coated tablet contains 200 mg of ibuprofen and 500 mg of paracetamol
- The other ingredients are croscarmellose sodium, microcrystalline cellulose, colloidal anhydrous silica, magnesium stearate, stearic acid. Film coating: polyvinyl alcohol, titanium dioxide, talc, macrogol, potassium aluminium silicate (E555), polysorbate.

**What Ibuprofen & Paracetamol 200mg/500mg tablets look like**

Ibuprofen & Paracetamol 200mg/500mg tablets are white to off-white, oval shaped, film-coated pearlescent tablets marked with an identifying helix. They are available in blister packs containing 4, 6, 8, 10, 12, 16, 20, 24, 32 tablets. Not all pack sizes may be marketed.

**Marketing Authorisation Holder and manufacturer**

Licence holder: Reckitt Benckiser Healthcare (UK) Ltd, Slough, SL1 3UH, United Kingdom

Manufactured by Reckitt Benckiser Healthcare International Ltd, Nottingham, NG90 2DB  
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