

Package leaflet: Information for the user

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

Ibuprofen/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 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.

What is in this leaflet

1. What Ibuprofen/Paracetamol Haleon 200 mg/500 mg film-coated tablets is and what it is used for
2. What you need to know before you take Ibuprofen/Paracetamol Haleon 200 mg/500 mg film-coated tablets
3. How to take Ibuprofen/Paracetamol Haleon 200 mg/500 mg film-coated tablets
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1. What Ibuprofen/Paracetamol Haleon 200 mg/500 mg film-coated tablets is and what it is used for

The medicine is called Ibuprofen/Paracetamol Haleon 200 mg/500 mg film-coated tablets.

Ibuprofen/Paracetamol Haleon 200 mg/500 mg film-coated tablets 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 temperatures.

Paracetamol is an analgesic which works in a different way from ibuprofen to relieve pain and fever. Ibuprofen/Paracetamol Haleon 200 mg/500 mg film-coated tablets is 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. What you need to know before you take Ibuprofen/Paracetamol Haleon 200 mg/500 mg film-coated tablets

Do not take Ibuprofen/Paracetamol Haleon 200 mg/500 mg film-coated tablets if you

- are already taking any other paracetamol containing product
- are taking any other pain relieving products including ibuprofen, high dose acetylsalicylic acid (above 75 mg per day), or other non-steroidal antiinflammatory drugs (NSAIDs) including cyclooxygenase-2 (COX-2) specific inhibitors
- are allergic to ibuprofen, paracetamol or any other ingredients in Ibuprofen/Paracetamol Haleon 200 mg/500 mg film-coated tablets

- are allergic to acetylsalicylic acid 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.

Warnings and precautions

Talk to your doctor or pharmacist before taking Ibuprofen/Paracetamol Haeon 200 mg/500 mg film-coated tablets if you:

- You have an infection - please see heading “Infections” below.
- 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.

Infections

Ibuprofen/Paracetamol Haeon 200 mg/500 mg film-coated tablets may hide signs of infections such as fever and pain. It is therefore possible that Ibuprofen/Paracetamol Haeon 200 mg/500 mg film-coated tablets 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.

Serious skin reactions have been reported in association with Ibuprofen/Paracetamol Haeon 200 mg/500 mg film-coated tablets treatment. You should stop taking Ibuprofen/Paracetamol Haeon 200 mg/500 mg film-coated tablets 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 section 4.

Anti-inflammatory/pain-killer medicines such as 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 Ibuprofen/Paracetamol Haeon 200 mg/500 mg film-coated tablets 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.

Other medicines and Ibuprofen/Paracetamol Haeon 200 mg/500 mg film-coated tablets

Do not take Ibuprofen/Paracetamol Haeon 200 mg/500 mg film-coated tablets with

- other paracetamol containing products
- other NSAID containing products such as aspirin/acetylsalicylic acid, ibuprofen.

Ibuprofen/Paracetamol Haeon 200 mg/500 mg film-coated tablets may affect or be affected by some other medicines. Please inform your doctor or pharmacist if you are taking:

- corticosteroid tablets

- antibiotics (e.g. chloramphenicol or quinolones)
- 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 (to help you pass water)
- medicines to 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 system (e.g. methotrexate, ciclosporine, tacrolimus)
- medicines for mania or depression (e.g. lithium or SSRIs)
- mifepristone (for pregnancy termination)
- HIV medicines (e.g. zidovudine)
- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (high anion gap metabolic acidosis) that must have urgent treatment and which may occur particularly in case of severe renal impairment, sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), malnutrition, chronic alcoholism, and if the maximum daily doses of paracetamol are used.

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

Ibuprofen/Paracetamol Haleon 200 mg/500 mg film-coated tablets with food and drink

To reduce the likelihood of side effects, take Ibuprofen/Paracetamol Haleon 200 mg/500 mg film-coated tablets with food.

Pregnancy, breastfeeding 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 Ibuprofen/Paracetamol Haleon 200 mg/500 mg film-coated tablets if you are in the last 3 months of 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 Ibuprofen/Paracetamol Haleon 200 mg/500 mg film-coated tablets 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, Ibuprofen/Paracetamol Haleon 200 mg/500 mg film-coated tablets 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.

Ibuprofen/Paracetamol Haleon 200 mg/500 mg film-coated 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 have problems becoming pregnant.

Driving and using machines

Undesirable effects such as dizziness, drowsiness, fatigue and visual disturbances are possible after taking NSAIDs. If affected patients should not drive or operate machinery.

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

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 and minimise undesirable effects. 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 Ibuprofen/Paracetamol Haleon 200 mg/500 mg film-coated tablets for longer than 3 days. If your symptoms worsen or persist, consult your doctor.

Take 1 tablet with water and food, 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 three times a day.

Do not take more than six 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 Ibuprofen/Paracetamol Haleon 200 mg/500 mg film-coated tablets than you should

If you have taken more Ibuprofen/Paracetamol Haleon 200 mg/500 mg film-coated tablets than you should, or if children have taken 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. Talk to a doctor at once if you take too much of this medicine even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage.

If you forget to take Ibuprofen/Paracetamol Haleon 200 mg/500 mg film-coated 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, this medicine 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, difficult breathing, worsening of asthma)
- severe skin reactions such as blistering - see also information below
- 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)
- heart failure (causing breathlessness, swelling)
- severe skin reaction known as DRESS syndrome (frequency not known). Symptoms of DRESS include: skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cells).

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)
- excessive sweating.

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

- headache and dizziness, wind and constipation, skin rashes, swelling of the face, itching
- 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.

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

- 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 generalised exanthematous pustulosis). Stop using Ibuprofen/Paracetamol HALEON 200 mg/500 mg film-coated tablets if you develop these symptoms and seek medical attention immediately. See also section 2.
- skin becomes sensitive to light.

Medicines such as Ibuprofen/Paracetamol HALEON 200 mg/500 mg film-coated tablets 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 [the national reporting system listed in Appendix V](#).* By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ibuprofen/Paracetamol HALEON 200 mg/500 mg film-coated tablets

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

This medicine does not require any special storage conditions.

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

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 Ibuprofen/Paracetamol Haleon 200 mg/500 mg film-coated tablets contains

- The active substances are ibuprofen and paracetamol. Each film-coated tablet contains ibuprofen 200 mg and paracetamol 500 mg.
- The other ingredients are croscarmellose sodium; hydroxypropylcellulose; microcrystalline cellulose; silica, colloidal anhydrous; stearic acid; magnesium stearate.
Film-coating: macrogol polyvinyl alcohol grafted copolymer; talc; mica-based pearlescent pigment (Mica/Titanium dioxide (E 171)); glycerol monocaprylocaprate; polyvinyl alcohol; titanium dioxide (E 171); iron oxide black (E 172).

What Ibuprofen/Paracetamol Haleon 200 mg/500 mg film-coated tablets looks like and contents of the pack

Ibuprofen/Paracetamol Haleon 200 mg/500 mg film-coated tablets is in form of grey, oval film-coated tablets with a sheen and with engraving “200 M 500” on one side. Size of the film-coated tablet - length: 18.9-19.4 mm, width: 8.9-9.3 mm.

Ibuprofen/Paracetamol Haleon 200 mg/500 mg film-coated tablets are packed:

- in Aluminium/PVC/PVDC blisters. Packs contain 10, 20 film-coated tablets.
- in HDPE bottle with LDPE cap with desiccant and shock absorber; Packs contain 30 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Haleon Ireland Limited, 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland

Manufacturer

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This medicinal product is authorised in the Member States of the EEA under the following names:

Latvia: Metafenex, 200mg/500mg, apvalkotā tabletes

Bulgaria: Метафен Макс, 200 mg/500 mg, филмирани таблетки

Lithuania: Metafenex, 200mg/500mg, plėvele dengta tabletės

Cyprus: Panadol Duo 500 mg/200 mg επικαλυμμένα με λεπτό υμένιο δισκία

Czechia: Panadol Duo

Greece: Panadol Plus 200 mg/500 mg επικαλυμμένα με λεπτό υμένιο δισκία

Hungary: Panadol Duo 200 mg/500 mg filmtabletta

Ireland: Ibuprofen/Paracetamol Haleon 200 mg/500 mg film-coated tablets

Malta: Panadol Duo 500 mg/200 mg film-coated tablets

Poland: Excedrin Duo

Romania: Panadol Duo 200 mg/500 mg comprimate filmate

Slovakia: Panadol Duo

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