Package leaflet: Information for the user

[Product name] 500 mg/200 mg film-coated tablets

paracetamol/ibuprofen

[For Rx]
Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, or pharmacistot. This includes any possible side effects not listed in this leaflet. See section 4.

[For OTC]
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 [Product name] is and what it is used for

The medicine is called [Product name].

[Product name] contains two active ingredients (which make the medicine work). These are paracetamol and ibuprofen.

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.

[Product name] is used for the short-term symptomatic treatment of mild to moderate pain associated with migraine, headache, backache, period pain, dental pain, rheumatic and muscular pain, pain in non-serious arthritis, cold and flu symptoms, sore throat and fever.

[Applicable for CZ OTC only and SK if the pack is shared with CZ]:
For relief of rheumatic pain and pain in arthritis, [Product name] should be used only upon medical advice/recommendation.

This product is especially suitable for pain which has not been relieved by ibuprofen or paracetamol alone.

[Product name] is intended for adults over 18 years of age.

2. What you need to know before you take [Product name]

Do not take [Product name] if you
- are allergic to ibuprofen, paracetamol or any of the other ingredients of this medicine (listed in section 6)
- are already taking any other paracetamol containing products
- 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 cyclo-oxygenase-2 (COX-2) specific inhibitors
- have ever had an allergic reaction such as bronchospasm (tightening of the muscles in the lungs that may cause shortness of breath), asthma, runny, itchy and inflamed nose with sneezing, urticaria (an itchy rash), or angioedema (swelling under the skin) when taking acetylsalicylic acid or other NSAIDs
- have an active or history of recurrent ulcer or bleeding in your stomach or duodenum (small bowel) (at least two distinct episodes of confirmed bleeding or an ulcer)
- have ever had perforation or bleeding in your stomach or duodenum, caused by previous NSAID treatment
- have blood clotting (coagulation) disorder
- suffer from severe heart, liver or kidney failure
- are in the last 3 months of pregnancy.

Warnings and precautions
Talk to your doctor or pharmacist before taking [Product name] if 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.

During treatment with [Product name], 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).

Infections
[Product name] may hide signs of infections such as fever and pain. It is therefore possible that [Product name] 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 [Product name] treatment. You should stop taking [Product name] 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 [Product name] if you:
- have heart problems including heart failure, angina pectoris (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 [Product name]
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Do not take [Product name] with
- other paracetamol containing products
- other pain relieving medicines including ibuprofen, high dose acetylsalicylic acid (above 75 mg per day), or other non-steroidal antiinflammatory drugs (NSAIDs) including cyclo-oxygenase-2 (COX-2) selective inhibitors.

Concomitant use of other products containing ibuprofen should be controlled to avoid overdose.

[Product name] may affect or be affected by some other medicines. Please inform your doctor or pharmacist if you are taking:
- corticosteroids
- 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. 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, angiotensin-II receptor antagonists such as losartan)
- medicines to suppress the immune system (e.g. methotrexate, ciclosporin, 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 (called metabolic acidosis) that must have urgent treatment (see section 2).

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

Pregnancy, breastfeeding and fertility

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

Pregnancy
Do not take [Product name] 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 [Product name] 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, [Product name] 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.

Breastfeeding
Only small amounts of paracetamol and ibuprofen and its metabolites pass into breast-milk. This medicine may be taken during breastfeeding if it is used at the recommended dose and for the shortest possible time.

Fertility
[Product name] 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.

[Product name] contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How to take [Product name]

[For Rx]
Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

[For OTC]
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).
If you have liver or kidney disease or are elderly, your doctor will tell you the correct dose which will be the lowest possible. Do not take this medicine if you have severe kidney or liver failure.

You should not take [Product name] for longer than 3 days. If your symptoms worsen or persist, consult your doctor.

Adults

Take one tablet, 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. The single dose of two tablets is intended for patients with a body weight of 60 kg or more.
Leave at least 6 hours between doses.

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

Take [Product name] with a glass of water.
To reduce the likelihood of side effects, take [Product name] with food.

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

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

If you take more [Product name] than you should
If you have taken more [Product name] 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 of overdose can include nausea, stomach pain, vomiting (may be blood streaked), gastrointestinal bleeding (see also part 4 below), diarrhoea, headache, ringing in the ears, confusion and shaky eye movement. Also agitation, somnolence, disorientation or coma may occur. Occasionally patients develop convulsions. At high doses, drowsiness, chest pain, palpitations, loss of consciousness, convulsions (mainly in children), weakness and dizziness, blood in urine, low levels of potassium in your blood, cold body feeling, and breathing problems have been reported. Further, the prothrombin time/INR may be prolonged, probably due to interference with the actions of circulating clotting factors. Acute renal failure and liver damage may occur. Exacerbation of asthma is possible in asthmatics. Furthermore, there may be low blood pressure and reduced breathing.
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 [Product name]
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 (common side effects; may affect up to 1 in 10 people);
  signs of intestinal bleeding (severe abdominal pain, vomiting blood or liquid with what looks like coffee granules, blood in the stools/motions, black tarry stools) (uncommon side effects; may affect up to 1 in 100 people);
- signs of inflammation of the brain lining such as: stiff neck, headache, feeling or being sick, fever or feeling disorientated (very rare side effects; may affect up to 1 in 10,000 people);
- signs of a severe allergic reaction (swelling of the face, tongue or throat, difficult breathing, worsening of asthma) (very rare side effects; may affect up to 1 in 10,000 people);
- severe skin reactions such as blistering - see also information below.

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).

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) (frequency not known). Stop using [Product name] if you develop these symptoms and seek medical attention immediately. See also section 2.

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

Uncommon (may affect up to 1 in 100 people):
- headache and dizziness,
- flatulence (wind) and constipation,
- mouth ulcers, exacerbation of ulcerative colitis and Crohn's disease, inflammation of the stomach or pancreas
- skin rashes, swelling of the face, itching
- higher levels of liver enzymes (AST, ALP) and creatine phosphokinase, decreased hemoglobin level (a protein in red blood cells) or an increase in the number of platelets (cells involved for blood clotting) (according to blood test results).

Very rare (may affect up to 1 in 10,000 people):
- decrease in the number 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, feeling of dizziness
- confusion, depression, hallucinations
- fatigue, generally feeling unwell.
- red or purple colored spots on the skin that do not fade under pressure and are caused by subcutaneous bleeding (purpura)
- high blood pressure, water retention
- liver problems (causing yellowing of the skin and whites of the eyes)
- kidney problems (causing adaptation or reduced urination, leg swelling)
- heart failure (causing shortness of breath, swelling)
- tingling, numbness or itching
- inflammation of the optic nerve
- drowsiness.

Not known (frequency cannot be estimated from the available data):
- skin becomes sensitive to light
- 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 [Product name] 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 [Product name]

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 after: EXP. 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 [Product name] contains

- The active substance are paracetamol and ibuprofen. Each film-coated tablet contains 500 mg of paracetamol and 200 mg of ibuprofen.
- 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; glycerol monocaprylocaprate; polyvinyl alcohol; titanium dioxide (E 171); iron oxide black (E 172).

What [Product name] looks like and contents of the pack
[Product name] is an oval grey film-coated tablet.
[Product name] is available in blisters containing 10 or 20 film-coated tablets or a bottle containing 30 film-coated tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
<[To be completed nationally]>

Manufacturer
<[To be completed nationally]>

This medicine is authorised in the Member States of the European Economic Area under the following names:
<{Name of the Member State}> <{Name of the medicinal product}>

This leaflet was last revised in {MM/YYYY}