Package leaflet: Information for the patient

Parabufin 500 mg/ 200 mg, filmomhulde tabletten

paracetamol en ibuprofen

For adults

[For medicines available without a prescription:]

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 medicine for longer than 3 days.

What is in this leaflet

1. What [Product name] is and what it is used for

[Product name] contains the active substances ibuprofen and paracetamol.

Ibuprofen belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). Paracetamol works in a different way to ibuprofen, but both active substances work together to reduce pain.

[Product name] is used for the short-term symptomatic treatment of mild to moderate pain. [Product name] is especially suitable for pain which has not been relieved by ibuprofen or paracetamol alone.

[Product name] is used in adults aged 18 years and older.

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)
- regularly drink large quantities of alcohol
- have a history of allergic reactions (e.g. bronchospasm, angioedema, asthma, rhinitis or urticaria) associated with acetylsalicylic acid or other NSAIDs
- have an active or recurrent peptic ulcer (i.e. stomach or duodenal ulcer) or bleeding (two or more distinct episodes of proven ulceration or bleeding).
- have a history of gastrointestinal bleeding or perforation related to previous NSAID therapy
- have cerebrovascular or other active bleeding
- have unclarified blood-formation disturbances
- suffer from severe heart, liver or kidney failure
- suffer from severe dehydration (caused by e.g. vomiting, diarrhoea or insufficient fluid intake)

- are in the last 3 months of pregnancy
- if you are under the age of 18 years.

Warnings and precautions
Talk to your doctor or pharmacist before taking [Product name] if you:
- are elderly
- have asthma or have suffered from asthma
- have kidney, heart, liver or bowel problems, hepatitis or difficulty urinating
- are concomitantly treated with medicines affecting liver function
- have glucose-6-phosphate dehydrogenase deficiency
- have haemolytic anaemia
- have Gilbert's syndrome (familial non-haemolytic bilirubinaemia)
- have underweight or chronic malnutrition (low reserves of hepatic glutathione)
- have an infection (see heading "Infections" below)
- are dehydrated
- have recently had a major surgery
- are allergic to other substances
- 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 mixed connective tissue disease
- have heartburn, indigestion or any other stomach problems
- have gastrointestinal disorders or chronic inflammatory bowel disease (e.g. ulcerative colitis, Crohn's disease)
- have a tendency to bleed
- have swelling of ankles or feet
- have inherited genetic or acquired disorder of certain enzymes that manifest with either neurological complications or skin problems or occasionally both i.e. porphyria
- have hayfever, nasal polyps or chronic obstructive respiratory disorders since there may be an increased risk of allergic reactions
- are in the first 6 months of pregnancy or are breast-feeding
- are planning to become pregnant
- 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.

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).

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.

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 [Product name] and contact immediately your doctor or medical emergencies if you notice any of these signs.

In order to avoid the risk of overdose,
- check that other medicines do not contain paracetamol,
- observe the maximum recommended doses (see section 3).

Side effects may be minimised by using the minimum effective dose for the shortest duration necessary to control symptoms. Do not take [Product name] for more than 3 days.

The concomitant use with NSAIDs, including cyclo-oxygenase-2 specific inhibitors, increases the risk of adverse reactions (see section below "Other medicines and [Product name]") and should be avoided.

Gastrointestinal symptoms
Serious gastrointestinal side effects (affecting the stomach and intestines) have been reported with the use of NSAIDs, including ibuprofen. These can occur with or without warning symptoms. The risk of these side effects is higher in patients with a history of stomach or intestine ulcer, particularly if bleeding or perforation was also involved. Elderly patients are at greater risk of gastrointestinal side effects. You should discuss any history of gastrointestinal problems with your doctor, and remain alert for any unusual abdominal symptoms, including nausea, vomiting, diarrhoea, constipation, indigestion, abdominal pain, tar-like stools, or vomiting blood.

Infections
[Product name] 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.

Prolonged use of painkillers
The prolonged use of analgesics for headaches can result in worsening them. If this situation is experienced or suspected, you should tell your doctor and discontinue the treatment.
The regular use of painkillers, particularly in combination with several pain-relieving medicines, may lead to permanent kidney damage with the risk of renal failure, a condition called analgesic nephropathy. This risk may be increased under physical strain associated with loss of salt and dehydration. Therefore, it should be avoided.

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

During chicken pox infection (varicella infection), it is advisable to avoid use of ibuprofen.

Vision problems
If you notice any problems with your vision after using [Product name], stop using the medicine and see a doctor.

Potential laboratory test interferences
The intake of paracetamol can influence the uric acid determination as well as the blood sugar determination.

Urine tests
Taking this medicine 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

this medicine or other paracetamol containing products for several hours before or during the collection of the urine specimen.

Children and adolescents
This medicine is not for use in children and adolescents under 18 years.

Other medicines and [Product name]
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

This medicine should be avoided with other medicines containing paracetamol (for example some medicines for cold and flu or pain), ibuprofen, acetylsalicylic acid, salicylates or with any other anti-inflammatory drugs (NSAIDs), including COX-2 inhibitors such as celecoxib or etoricoxib, unless under a doctor's instruction.

[Product name] may affect or be affected by some other medicines. For example:
- corticosteroids, such as prednisone, cortisone
- some antibiotics (e.g. chloramphenicol, co-trimoxazole, aminoglycosides or quinolones)
- anti-sickness medicines (e.g. metoclopramide, domperidone)
- cardiac glycosides (digoxin), medicines to strengthen the heart
- medicines for high cholesterol (cholestyramine)
- diuretics (to help you pass water)
- medicines to suppress the immune system (e.g. methotrexate, ciclosporin, tacrolimus)
- medicines for mania or depression (lithium or SSRIs)
- mifepristone, a medicine used for medical termination of pregnancy
- zidovudine, a medicine to treat HIV (the virus that causes acquired immunodeficiency disease)
- other potentially hepatotoxic medicines or medicines that induce liver microsomal enzymes such as alcohol and antiepileptic medicines (e.g. carbamazepine, phenobarbital, diazepam, lorazepam)
- medicines used to treat tuberculosis (e.g. isoniazid)
- medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. acetylsalicylic acid, warfarin, ticlopidine)
- medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol, angiotensin-II receptor antagonists such as losartan)
- medicines that decrease gastric emptying
- phenytoin medicine to prevent seizures in epilepsy
- medicines used to treat gout (probenecid and sulfinpyrazone)
- medicines used to treat diabetes (sulphonylureas)
- antifungal medicines that inhibit CYP2C9 (voriconazole, fluconazole)
- ginkgo biloba (an herbal medicine) can increase the risk of bleeding with NSAIDs
- 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.

[Product name] with alcohol
Do not drink alcohol during treatment with this medicine. Alcohol may increase paracetamol toxicity in the liver.

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.

<u>Pregnancy</u>

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.

Breast-feeding
Only small amounts of ibuprofen and its metabolites pass into breast-milk. It is not necessary to interrupt breastfeeding during short-term treatment with the recommended dose of this medicine.

Fertility
The use of ibuprofen may impair female fertility and is not recommended in women attempting to conceive. In women who have difficulties conceiving or who are undergoing investigation of fertility, withdrawal of ibuprofen should be considered.

Driving and using machines
[Product name] has minor influence on the ability to drive and use machines. Undesirable effects such as dizziness, drowsiness, fatigue and visual disturbances are possible after taking NSAIDs.
If you are affected, do not drive and do not use machines.

3. How to take [Product name]

[For medicines available without a prescription:]
Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure. **Do not take for more than 3 days.**

Adults
The recommended dose is 1 tablet with a glass of water, up to 3 times a day.
Leave at least 6 hours between doses.
Do not take more than six tablets in any 24 hour period (equivalent to 1 200 mg ibuprofen and 3 000 mg paracetamol a day).
To reduce the risk of gastrointestinal side effects, it is recommended to take [Product name] with food.

Use in elderly
No special dose modifications are required. There is an increased risk of serious consequence of adverse reactions. The lowest possible dose should be used for the shortest possible duration.

Use in children and adolescents
[Product name] is not for use in children and adolescents under 18 years.

Your dose may need to be reduced to a maximum of 4 tablets per day if you:
- have kidney problems
- have liver problems
- weigh less than 50 kg
- suffer from chronic malnutrition
- are regularly drinking alcohol (chronic alcoholism)
- are not hydrated sufficiently

If anything of the above applies to you, talk to your doctor before taking [Product name] (see also section 2 "Warnings and precautions").

For oral use and for short term use only.
Do not take this medicine for more than 3 days.
If your symptoms worsen or persist, consult your doctor.

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).

If you take more [Product name] than you should
If you have taken more [Product name] 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 of ibuprofen overdose can include nausea, stomach pain, vomiting (may be blood streaked), gastrointestinal bleeding, headache, ringing in the ears, confusion and shaky eye movement (nystagmus), or more rarely diarrhoea. In addition, at high doses, vertigo, blurred vision, low blood pressure, excitation, disorientation, coma, hyperkalaemia (raised blood potassium level), increased prothrombin time/INR, acute renal failure, liver damage, respiratory depression, cyanosis and exacerbation of asthma in asthmatics, 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.

The hazard of paracetamol overdose is greater in patients with non-cirrhotic alcoholic liver disease. Symptoms of paracetamol overdose in the first 24 hours include nausea, vomiting, anorexia, pallor and abdominal pain. Liver damage may become apparent 12 to 48 hours after ingestion as liver function tests become abnormal.

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, which may be fatal. Even if there are no signs of discomfort or poisoning, you may need urgent medical attention. In order to avoid liver damage, it is essential to get medical treatment as early as possible.

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.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

With regard to the following side effects, it must be considered that they are largely dependent on the dose and vary from patient to patient.
The most commonly observed side effects are gastrointestinal in nature. Peptic ulcers, perforation or gastrointestinal bleeding, sometimes fatal, particularly in the elderly, may occur. Nausea, vomiting, diarrhoea, flatulence, constipation, indigestion, abdominal pain, tarry stool, vomiting of blood, ulcerative stomatitis, exacerbation of colitis and Crohn's disease have been reported following administration. Less frequently, gastritis has been observed. Particularly the risk of gastrointestinal bleeding occurring is dependent on the dose range and the duration of use.
Oedema, high blood pressure and heart failure have been reported in association with NSAID treatment.

STOP TAKING the medicine and seek medical attention immediately if you notice any of the following symptoms:

Uncommon (may affect up to 1 in 100 people)
- 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)

Very rare (may affect up to 1 in 10 000 people)
- symptoms of aseptic meningitis, inflammation of the brain lining such as: stiff neck, headache, feeling or being sick, fever or clouding of consciousness
- severe allergic reactions. Symptoms can include: swelling of the face, tongue or larynx, difficult breathing, fast heartbeats, low blood pressure (anaphylaxis, angioedema or severe shock)
- respiratory reactivity including asthma, worsening of asthma, wheezing, difficulty in breathing
- 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 and toxic epidermal necrolysis]
- worsening of existing severe skin infections (you may notice a rash, blistering and discolouration of the skin, fever, drowsiness, diarrhoea and sickness), or worsening of other infections including chicken pox or shingles or severe infection with destruction (necrosis) of subcutaneous tissue and muscle, blistering and peeling of the skin

Not known (frequency cannot be estimated from the available data)
- chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome.
- widespread rash, high body temperature, enlarged lymph nodes and an increase of eosinophils (a type of white blood cells) (DRESS syndrome).
- 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. The symptoms usually appear at the initiation of treatment (acute generalized exanthematous pustulosis).

Other possible side effects

Common (may affect up to 1 in 10 people)
- gastrointestinal complaints such as stomach pain, heartburn, indigestion, feeling sick, being sick, wind and constipation, diarrhoea, slight gastrointestinal blood loss that may cause anaemia in exceptional cases
- alanine aminotransferase increased, gamma-glutamyltransferase increased and liver function tests abnormal with paracetamol
- swelling and fluid retention, swelling of ankles or legs (oedema); fluid retention generally responds promptly to discontinuation of the combination
- increased levels of creatinine and urea in blood
- increase in sweating

Uncommon (may affect up to 1 in 100 people)
- central nervous disturbances such as headache, dizziness, sleeplessness, agitation, irritability or tiredness
- hives, itching
- inability to completely empty the bladder (urinary retention)
- thickened respiratory tract mucus
- various skin rashes
- gastrointestinal ulcers, potentially with bleeding and perforation or gastrointestinal bleeding, worsening of inflammation of the colon (colitis) and digestive tract (Crohn's disease), ulcerative stomatitis, gastritis
- decrease in haemoglobin and haematocrit, aspartate aminotransferase increased, blood alkaline phosphatase increased, blood creatine phosphokinease increased, increase in platelets (blood clotting cells) number

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

- abnormal dreams
- damage of the kidney tissue (particularly in long-term use)
- high level of uric acid in your blood (hyperuricemia)
- abnormal sensation of the skin (tingling, pins and needles)

Very rare (may affect up to 1 in 10 000 people)
- blood formation disorders (agranulocytosis, anaemia, aplastix anaemia, haemolytic anaemia, leucopenia, neutropenia, pancytopenia and thrombocytopenia). First signs are: fever, sore throat, superficial mouth ulcers, flu-like symptoms, severe exhaustion, unexplained bleeding, bruising and nose bleeds
- optic neuritis and somnolence, aseptic meningitis in patients with existing disorders (such as systemic lupus erythematosus and mixed connective tissue disease), symptoms include stiff neck, headache, nausea, vomiting, fever or clouding of consciousness
- visual disturbances; in this case, you must stop using [Product name] and see a doctor
- hearing loss, ringing in the ears, spinning sensation (vertigo), confusion, psychotic reactions, hallucinations, depression
- fatigue, generally feeling unwell
- red spotty rash on the skin (purpura)
- loss of hair
- high blood pressure, vasculitis
- inflammation of the oesophagus, inflammation of the pancreas, formation of intestinal diaphragm-like strictures
- liver problems, dysfunction, liver damage (particularly in long term use), liver failure, acute hepatitis, yellowing of the skin and/or whites of the eyes, also called jaundice; in overdose paracetamol can cause acute liver failure, liver impairment, liver necrosis, and liver injury
- nephrotoxicity in various forms, including interstitial nephritis, nephrotic syndrome and acute and chronic renal failure; adverse renal effects are most often observed after overdose, after chronic abuse (often with multiple analgesics), or in association with paracetamol-related hepatotoxicity; acute tubular necrosis usually occurs in conjunction with liver failure, but has been observed as an isolated finding in rare cases
- fast or irregular heartbeats, also called palpitations, tachycardia, arrhythmia, and other cardiac dysrhythmias, heart failure (causing breathlessness, swelling), myocardial infarction

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.

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

Store in the original package in order to protect from light.

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 substances are ibuprofen and paracetamol. Each film-coated tablet contains 200 mg of ibuprofen and 500 mg of paracetamol.
- The other ingredients are: *Tablet core*: maize starch, crospovidone (E1202), silica, colloidal anhydrous (E551), povidone (E1201), starch, pregelatinised (maize), talc (E553b), stearic acid. *Film-coating*: poly(vinyl alcohol) (E1203), talc (E553b), macrogol 3350 (E1521), titanium dioxide (E171).

What [Product name] looks like and contents of the pack

The film-coated tablets are white to off-white, oval shaped, tablets with dimensions of 19.7 mm x 9.2 mm.

Aluminium-PVC/PVDC blisters and perforated unit dose blisters packed in carton boxes of 10, 20, 20x1 film-coated tablets.

Child resistant aluminium-PVC/PVDC blisters and perforated unit dose blisters packed in carton boxes of 10, 20, 20x1 film-coated tablets.

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant
Houder van de vergunning voor het in de handel brengen
Teva B.V.
Swensweg 5
2031 GA Haarlem
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Rontis Hellas Medical and Pharmaceutical Products S.A.
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41 500, Larissa
Griekenland

In het register ingeschreven onder
RVG 133421

Dit medicijn is geregistreerd in lidstaten van de Europese Economische Ruimte onder de volgende namen:

Oostenrijk	Mexalen Duo 200 mg/500 mg Filmtabletten
Bulgarije	Ибуксин Дуо 200 mg/500 mg филмирани таблетки Ibuxin Duo 200 mg/500 mg film-coated tablets
Duitsland	Paracetamol/Ibuprofen-ratiopharm bei Schmerzen 500 mg/200 mg Filmtabletten

Nederland	Parabufin 500 mg/200 mg, filmomhulde tabletten

Deze bijsluiter is voor het laatst goedgekeurd in december 2025.

Other sources of information

Latest approved information on this medicine is available by scanning the QR code included in the <package leaflet> <outer carton> with a smartphone/device. The same information is also available on the following URL: [URL to be included] and the <NCA> website.>