Package leaflet: Information for the user

Ibuprofen (als lysine) HTP 200 mg, filmomhulde tabletten
Ibuprofen (als lysine) HTP 400 mg, filmomhulde tabletten

Ibuprofen (as ibuprofen lysine)

For use in adults and adolescents from 40 kg (12 years and above).

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 contact a doctor if your symptoms worsen or do not improve
  - after 3 days in adolescents.
  - after 3 days if you have fever and 4 days for the treatment of pain in adults .

What is in this leaflet

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

[Product name] contains the active substance ibuprofen. Ibuprofen belongs to a group of medicines called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs). These medicines provide relief by changing the body's response to pain and high temperature.

[Product name] is indicated in short-term symptomatic treatment of mild to moderate pain, such as headache, toothache and period pain and/or fever.

[Product name] is used in adults and adolescents from 40 kg body weight (12 years of age and above).

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

DO NOT take [Product name]
- If you are allergic to ibuprofen or any of the other ingredients of this medicine (listed in section 6).
- If you have a history of gastrointestinal bleeding or perforation related to previous treatment with other NSAIDs.

- If you have an active, or history of recurrent stomach or duodenal ulcer (peptic ulcers) or bleeding (at least two different episodes of proven ulceration or bleeding).
- If you have a history of allergic reactions (such as asthma, bronchospasm, rhinitis, angioedema or urticaria) associated with the use of acetylsalicylic acid or other NSAIDs.
- If you suffer from severe liver, kidney or heart failure.
- If you have bleeding in the brain (cerebrovascular bleeding) or other active bleeding;
- If you have severe dehydration (e.g. caused by vomiting, diarrhoea or insufficient fluid intake).
- If you are in the last three months of pregnancy (see also 'Pregnancy, breast-feeding and fertility').

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

If you have an infection - please see heading "Infections" below.

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 the treatment with the 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 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.
- have or have ever had gastrointestinal disorders (ulcerative colitis, Crohn's disease), as your condition may get worse.
- have Systemic Lupus Erythematosus (SLE, an autoimmune disease) or mixed connective tissue disease.
- have certain hereditary blood formation disorders (e.g. acute intermittent porphyria).
- suffer from mild to moderate liver or kidney impairment.
- have just had major surgery.
- are allergic to other substances.
- suffer from hay fever, nasal polyps, or chronic obstructive respiratory disorders, because you are at higher risk of allergic reactions. The allergic reactions may present as asthma attacks (so-called analgesic asthma), rapid swelling (Quincke's oedema) or a nettle rash.

<u>Effects on the gastrointestinal tract</u>
Combined use of [Product name] with other non-steroidal anti-inflammatory drugs (NSAIDs), including so-called COX-2 inhibitors (cyclooxygenase-2 inhibitors), should be avoided.

Bleeding of the gastrointestinal tract, ulcers and perforation:
Bleeding of the gastrointestinal tract, ulcers and perforation, sometimes with fatal outcome, have been reported with all NSAIDs. These have occurred at any time during therapy, with or without previous warning symptoms or a history of serious gastrointestinal events.

The risk of experiencing gastrointestinal bleeding, ulcers and perforation is higher with

increasing NSAID dose and is higher in patients with a history of ulcers, especially with complications of bleeding or perforation (see section 2 “Do not take [Product name]”) and in elderly patients. These patients should start treatment at the lowest available dose. For these patients, as well as patients requiring additional treatment with low dose acetylsalicylic acid or other medicines that may increase the risk of gastrointestinal disorders, combination treatment with protective medicines (e.g. misoprostol, proton pump inhibitors) should be considered.

If you have a history of side effects affecting the gastrointestinal tract - especially if you are elderly - you should contact a doctor in the event of unusual abdominal symptoms (especially gastrointestinal bleeding), particularly at the start of therapy.

Caution is advised if you are taking other medicines that may increase the risk of ulcer or bleeding, such as corticosteroids, anticoagulants (such as warfarin), selective serotonin reuptake inhibitors (antidepressants), or antiplatelet medicines such as acetylsalicylic acid.

In case of gastrointestinal bleeding or ulceration, you should stop taking ibuprofen.

Bronchospasm may occur in patients with bronchial asthma or allergic disease.

Side effects may be minimised by taking the lowest effective dose for the shortest possible duration necessary to control the symptoms.

Serious 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 generalised 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 chickenpox infection (varicella infection), it is advisable to avoid the use of [Product name].

<u>Infections</u>
[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.

<u>Other warnings</u>
Severe acute hypersensitivity reactions (e.g. anaphylactic shock) have been very rarely observed. At the first signs of a hypersensitivity reaction after taking [Product name], treatment must be stopped and a doctor should be consulted. Medically required measures, in line with the symptoms, must be initiated by healthcare professional.

Ibuprofen can temporarily inhibit blood platelet function (blood platelet aggregation). Patients with blood clotting disorders should therefore be carefully monitored.

During prolonged use of [Product name], regular monitoring of liver function tests, kidney function and blood counts is required.

If you use painkillers for a prolonged time, this can cause headaches, which should not be treated with more painkillers. If you think this applies to you, talk to your doctor.

In general, habitual intake of painkillers, especially when several pain-killing medicines are combined, may lead to permanent kidney damage, with a risk of renal failure (analgesic nephropathy). This risk may be increased under physical strain associated with loss of salt and dehydration. Therefore it should be avoided.

The risk of renal failure is increased in dehydrated patients, the elderly and those taking diuretics and ACE inhibitors

In case you experience sight problems please contact your doctor.

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

Elderly patients

Elderly patients should be aware of their increased risk of adverse events, especially bleeding and perforation in the gastrointestinal tract, which may be fatal.

Adolescents

There is a risk of renal impairment in dehydrated adolescents.

Other medicines and [Product name]

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

[Product name] may affect or be affected by some other medicines. For example:

- Digoxin, phenytoin and lithium: Combined use of [Product name] and digoxin (used to strengthen the heart), phenytoin (used to treat seizures/epilepsy) or lithium (used to treat for example depression) can increase the concentration of these medicines in the blood. Monitoring of serum lithium levels, serum digoxin levels and serum phenytoin levels is not generally required when used as directed (over 3 or 4 days maximum).
- Anticoagulants (i.e. thin blood/prevent clotting, e.g. acetylsalicylic acid, warfarin, ticlopidine): NSAIDs may enhance the effects of anticoagulants such as warfarin.
- Diuretics (water tablets) and high blood pressure medicines:
  [Product name] can reduce the effect of medicines used to increase urine output (diuretics) and lower blood pressure (antihypertensive medicines, e.g. ACE inhibitors, beta-blockers and angiotensin II receptor antagonists). Combined administration of [Product name] and potassium-sparing diuretics (certain types of water tablet) can lead to an increase in blood potassium levels.
- Medicines that reduce high blood pressure (ACE inhibitors such as captopril, beta-blockers such as atenolol, angiotensin-II receptor antagonists such as losartan): [Product name] can reduce the effect of ACE inhibitors (used to treat heart failure and high blood pressure). Furthermore, during combined use, there is an increased risk that kidney dysfunction may occur.
- Cholestyramine (a medicine used to lower cholesterol) used in combination with [Product name] may reduce the absorption of [Product name] in the gastro-intestinal tract. However, the clinical significance is unknown.

- Other painkillers: Combined use of [Product name] with other anti-inflammatories and painkillers of the NSAID group, including COX-2 inhibitors (e.g. celecoxib), may increase the risk of gastrointestinal ulcers and bleeding.
- Platelet aggregation inhibitors and certain antidepressants (selective serotonin reuptake inhibitors/SSRIs) can increase the risk of gastrointestinal bleeding.
- Methotrexate: Administration of [Product name] within 24 hours before or after administration of methotrexate (used to treat certain types of cancers or rheumatism) can lead to increased methotrexate concentrations and an increase in its side effects.
- Ciclosporin and tacrolimus: There is a greater risk that medicines known as immunosuppressant like ciclosporin and tacrolimus may damage the kidneys.
- Probenecid or sulfinpyrazone: Medicines containing probenecid or sulfinpyrazone (used to treat gout) may delay the excretion of ibuprofen. This can cause [Product name] to accumulate in the body, with an increase in its side effects.
- Sulfonylureas: During combined use of [Product name] and sulfonylureas (medicines used to treat diabetes), monitoring of blood sugar levels is recommended as a precaution.
- Zidovudine: There is evidence to suggest a higher risk of haemarthrosis (blood accumulation in joints) and bruises (haematoma) in HIV-positive haemophilic patients using zidovudine (an anti-viral drug used to treat HIV infections) together with ibuprofen.
- Antibiotics of the quinolone group: The risk of seizures (fits) may be increased when antibiotics called quinolone, such as ciprofloxacin, and ibuprofen are taken at the same time.
- Aminoglycosides: Combined use of [Product name] with aminoglycosides (a type of antibiotics) may decrease the excretion of aminoglycosides.
- Voriconazole and fluconazole (CYP2C9 inhibitors) used for fungal infections, since the effect of ibuprofen may increase. Reduction of the ibuprofen dose should be considered, particularly when high dose ibuprofen is administered with either voriconazole or fluconazole.
- Ginkgo biloba (an herbal medicine) can increase the risk of bleeding with NSAIDs.
- Mifepristone: Combined use of mifepristone with other anti-inflammatories and painkillers of the NSAID group (i.e. ibuprofen) can decrease the effect of mifepristone.
- Ritonavir: A combined use with ritonavir (an anti-viral medicine used to treat HIV infections) may increase the plasma concentrations of painkillers of the NSAID group.
- Alcohol, bisphosphonates and oxpentifylline (pentoxifylline): The combined use of ibuprofen with alcohol, bisphosphonates (used in osteoporosis) or pentoxifylline (used in peripheral arterial circulatory problems) may increase gastrointestinal side effects and the risk of bleeding and ulcers.
- Baclofen (a muscle relaxant) because of elevated baclofen toxicity.
- Medicines to treat inflammation (corticosteroids) because of increased risk of gastrointestinal ulcers or bleeding.

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

[Product name] with alcohol
Alcohol may enhance side effects of [Product name], especially those affecting the central nervous system and the gastrointestinal tract. Do not drink alcohol while using [Product name].

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.

Pregnancy
Do not use this medicine 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 use of 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, <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 pass into breast milk. <Product name> may be used during breast-feeding, if it used at the recommended dose and for the shortest possible time.

Fertility
The product belongs to a group of medicines (NSAIDs) which may impair the fertility in women. This effect is reversible on stopping the medicine.

Driving and using machines
When used at the recommended dose for a short time [Product name] has no or negligible influence on the ability to drive and use machines. However, since at higher dose central nervous side effects such as tiredness and dizziness may occur, the ability to react and the ability to take part actively in road traffic and to operate machines may be impaired in individual cases. This is especially important when combined with alcohol.

3. How to take [Product name]

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.

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).

The recommended dose is

<Product name> 200 mg
Adults and adolescents from 40 kg body weight (12 years of age and above)
The initial dose is 1 to 2 tablets (200 to 400 mg), and then, if necessary, the dose may be repeated every 6 hours.
Do not exceed 6 tablets (1 200 mg) in any 24 hours.
<Product name> 400 mg

Adults and adolescents from 40 kg body weight (12 years of age and above)
The initial dose is 1 tablet (400 mg), and then, if necessary, the dose may be repeated every 6 hours.
Do not exceed 3 tablets (1 200 mg) in any 24 hours.

[Product name] is not intended for use in children under 12 years of age or in adolescents weighing less than 40 kg.

This medicine is intended for short term use only.

If in adults this medicine is required for more than 3 days for fever or for more than 4 days for pain, or if symptoms worsen, a doctor should be consulted.

If in adolescents (12 years of age and above) this medicine is required for more than 3 days, or if symptoms worsen, a doctor should be consulted.

If you have mild to moderate liver or kidney impairment or are elderly your doctor will tell you the correct dose to take which will be the lowest dose possible.

Method of administration
[Product name] is for oral use.
Take the tablets with a glass of water.
It is recommended that patients with a sensitive stomach take [Product name] with food.

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 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, agitation, disorientation, loss of consciousness, coma, raised blood potassium levels, increased prothrombin time/INR, acute renal failure, liver damage, respiratory depression, cyanosis, 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.

If you forget to take [Product name]
Do not take a double dose to make up for a forgotten dose.

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.

The listing of side effects below compromises all side effects reported during treatment with ibuprofen, including those reported during high-dose long-term therapy in patients with rheumatic disorders. Reported frequencies other than very rare reports refer to short-term use

of daily doses of up to 1 200 mg ibuprofen for oral formulations and a maximum of 1,800 mg for suppositories.

Regarding the following side effects, it must be remembered that these are mainly dose-dependent and vary between individuals.

The most commonly observed side effects affect the digestive tract. Stomach/duodenal ulcers (peptic ulcers), perforation or bleeding, sometimes fatal, may occur, especially in elderly patients (see section 2 “Warnings and precautions”). Nausea, vomiting, diarrhoea, flatulence, constipation, digestive complaints, abdominal pain, tarry stools, vomiting of blood, wounds (ulceration) in the mouth and throat region (ulcerative stomatitis), worsening of colitis and Crohn’s disease (see section 2 “Warnings and precautions”) have been reported after use. Less commonly, inflammation of the stomach lining (gastritis) has been observed. In particular, the risk of developing gastrointestinal bleeding depends on the dose level and duration of treatment.

Tissue fluid accumulation (oedema), high blood pressure and heart failure have been reported in association with treatment with NSAIDs.

Particular serious side effects

- **Stop taking [Product name] and contact a doctor immediately** if you develop severe general allergic (hypersensitivity) reactions, a very rare side effect (may affect up to 1 in 10 000 people): These may manifest as:
    - swelling of the face (face oedema), tongue or throat (laryngeal swelling with constriction of the airways)
    - difficulty breathing
    - rapid heartbeat
    - drop in blood pressure up to life threatening shock
- You should see your doctor immediately if you experience an infection with symptoms such as fever and serious deterioration of your general condition, or fever with local infection symptoms such as sore throat/pharynx/mouth or urinary problems. [Product name] may cause a reduction in the number of white blood cells [agranulocytosis, a very rare side effect (may affect up to 1 in 10 000 people)] with decreased resistance to infection. It is important to inform your doctor about your medicine.
- 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).
- Stop taking [Product name] if you experience relatively severe pain in the upper abdomen, vomiting blood, bloody stools and/or black bowel movements and tell your doctor immediately.
- Tissue fluid accumulation (oedemas), particularly in patients with high blood pressure (hypertension) or kidney problems, nephrotic syndrome, interstitial nephritis that may be accompanied by acute renal insufficiency (kidney failure) [a very rare side effect (may affect up to 1 in 10 000 people)]. Reduced urine output, fluid accumulation within

the body (oedema) and malaise (generally feeling ill) can be signs of kidney disease and even kidney failure.
- Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome.

If any of the symptoms listed should appear or get worse, you must stop [Product name] and contact your doctor immediately.

Other side effects

Common (may affect up to 1 in 10 people)
- Gastrointestinal complaints, e.g. heartburn, abdominal pain, nausea, vomiting, flatulence, diarrhoea, constipation, digestive problems and minor gastrointestinal blood loss, which may cause anaemia in exceptional cases.

Uncommon (may affect up to 1 in 100 people)
- central nervous disorders, such as headache, dizziness, sleeplessness, agitation, irritability or tiredness
- Visual disturbances. In this case, you must stop using [product name] and tell your doctor.
- Stomach/gut ulcers (peptic ulcers), sometimes with bleeding and perforation (hole in the wall of the digestive tract), sometimes fatal, may occur, especially in elderly patients, ulcerative stomatitis (inflammation of the mouth lining with ulceration), worsening of colitis (inflammation of the colon) or Crohn's disease
- inflammation of the stomach lining (gastritis)
- Hypersensitivity reactions such as skin rash and itchy skin, as well as asthma attacks (with a possible drop in blood pressure).

In such cases you must tell a doctor immediately and stop taking [Product name].

Rare side effects (may affect up to 1 in 1 000 people)
- ringing in the ears (tinnitus)
- hearing losses
- damage of kidney tissue (papillary necrosis), increased uric acid concentration in the blood, elevated urea concentration in the blood

Very rare side effects (may affect up to 1 in 10 000 people)
- Disorders of blood cell formation, such as decrease in the amount of red blood cells or haemoglobin (anaemia), white blood cells (leukopenia) or in the platelets level (thrombocytopenia); and other disorders of the blood (pancytopenia, agranulocytosis, eosinophilia, coagulopathy, neutropenia, aplastic anaemia or haemolytic anaemia). The first symptoms may be fever, sore throat, superficial wounds in the mouth, flu-like symptoms, severe fatigue, nasal and skin bleeding.
- Worsening of infection-related inflammation (e.g. development of necrotising fasciitis) has been described in temporal association with the use of certain anti-inflammatory agents (non-steroidal anti-inflammatory drugs; to which [Product name] also belongs). If signs of infection appear or get worse whilst using [Product name] (e.g. redness, swelling, overheating, pain, fever), a doctor should therefore be consulted immediately. Your doctor will study if you need an antibiotic therapy.
- Symptoms of aseptic meningitis (inflammation of the brain lining not caused by infection) have been observed during use of ibuprofen, such as severe headache,

nausea, vomiting, fever, stiff neck or clouding of consciousness. There seems to be an increased risk for patients already suffering from certain autoimmune diseases (systemic lupus erythematosus, mixed connective tissue disease).
- low level of blood sugar (hypoglycaemia)
- low level of sodium in blood (hyponatraemia)
- palpitations, heart muscle weakness (heart failure), heart attack
- high blood pressure (hypertension)
- vascular inflammation (vasculitis)
- inflammation of gullet (oesophagus) or pancreas (pancreatitis), narrowing of the bowel (intestinal diaphragm-like strictures)
- psychotic reactions, hallucinations, confusion, depression and anxiety
- asthma, difficulty in breathing (dyspnoea), bronchospasm
- Yellowing of the eyes and/or skin (jaundice,) liver dysfunction, liver damage, especially during long-term therapy, liver failure, acute liver inflammation (hepatitis).
- Hair loss (alopecia), red or purple discoloured spots on the skin (purpura) or photosensitivity reactions (triggered by sunlight).
- In exceptional cases severe skin infections and soft-tissue complications may occur during chickenpox (varicella infection).

Frequency not known (frequency cannot be estimated from the available data)
- inflammation of nasal mucus (rhinitis)
- pins and needles (paraesthesia) and inflammation of the optic nerve (optic neuritis)
- malfunction of the kidney
- Skin becomes sensitive to light.

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 label and carton after 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 [Product name] contains

- The active substance is ibuprofen. Each film-coated tablet contains ibuprofen 200 mg (as ibuprofen lysine).
- The other ingredients are: *Tablet core*: microcrystalline cellulose, crospovidone (type A), copovidone, purified talc, magnesium stearate. *Coating*: polyvinyl alcohol, part hydrolysed; titanium dioxide (E171); macrogol 4000; purified talc, iron oxide red (E172).
- The active substance is ibuprofen. Each film-coated tablet contains ibuprofen 400 mg (as ibuprofen lysine).
- The other ingredients are: *Tablet core*: microcrystalline cellulose, crospovidone (type A), copovidone, purified talc, magnesium stearate. *Coating*: polyvinyl alcohol, part hydrolysed; titanium dioxide (E171); macrogol 4000; purified talc.

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

Product name> 200 mg
Pale red, round, biconvex, film-coated tablets, plain on both sides with diameter of nucleus 11 mm.
Opaque PVC/PVDC//Au blisters in boxes of 2, 4, 6, 8, 10, 12, 15, 16, 20, 24 or 30 tablets.

Product name> 400 mg
White to almost white, capsule shape, biconvex film-coated tablets, plain on both sides, with dimensions of nucleus 19x10 mm.
Opaque PVC/PVDC//Al blisters in boxes of 10, 12, 20, 24, 30 or 50 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
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Marketing Authorisation Numbers

RVG 127748
RVG 127750

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

following names:

Germany	Ibu-LYSIN STADA 200 mg Filmtabletten Ibu-LYSIN STADA 400 mg Filmtabletten
Portugal	Ibuprofeno lysine STADA
The Netherlands	Ibuprofen (als lysine) HTP 400 mg, filmomhulde tabletten Ibuprofen (als lysine) HTP 200 mg, filmomhulde tabletten

Deze bijsluiter is voor het laatst goedgekeurd in februari 2025