Package leaflet: Information for the user

Brupro 200 mg Soft capsules
Brupro Max 400 mg Soft capsules

Ibuprofen

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, or in adults treating pain after 4 days.

What is in this leaflet

1. What Brupro is and what it is used for

Brupro contains the active substance ibuprofen. It belongs to a group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs provide relief by changing the body's response to pain and high temperature.

Brupro 200 mg is used for the short-term symptomatic treatment of mild to moderate pain, such as headache, dental pain, period pain and fever and pain in the common cold.

Brupro Max 400 mg is used for the short-term symptomatic treatment of mild to moderate pain, such as headache, acute migraine headache with or without aura, dental pain, period pain and fever and pain in the common cold.

2. What you need to know before you take Brupro

Do not take Brupro if you
- are allergic to ibuprofen or any of the other ingredients of this medicine (listed in section 6)
- have had an allergic reaction such as asthma, difficulty in breathing, swelling of the face, tongue or throat, nettle rash, itchy runny nose to acetylsalicylic acid (ASA) or other NSAIDs
- have (or have had two or more episodes of) a stomach or duodenal ulcer or bleeding
- have had gastrointestinal perforation or bleeding when taking NSAIDs
- are suffering from cerebrovascular or other active bleeding
- are suffering from unclarified blood-formation disturbances
- have severe dehydration (caused by vomiting, diarrhoea or insufficient fluid intake)
- have severe liver, kidney or heart failure
- are in the last 3 months of pregnancy.

Do not use Brupro 200 mg Soft capsules in children under 6 years (less than 20 kg body weight).

Do not use Brupro Max 400 mg Soft capsules in adolescents under 40 kg body weight or children under 12 years.

Warnings and precautions
Talk to your doctor or pharmacist before taking Brupro if you
- have recently had major surgery
- have or have had asthma or allergic disease as shortness of breath may occur
- suffer from hay fever, nasal polyps or chronic obstructive respiratory disorders as an increased risk of allergic reactions exists. The allergic reactions may present as asthma attacks (so-called analgesic asthma), Quincke's oedema or urticaria.
- ever had gastrointestinal ulcers (see also section "Do not take Brupro")
- have a history of gastrointestinal disease (such as ulcerative colitis, Crohn's disease)
- have systemic lupus erythematosus or mixed connective tissue disease (a disease affecting the skin, joints and kidneys)
- have certain hereditary blood formation disorders (e.g. acute intermittent porphyria)
- have a blood clotting disorder
- are taking other NSAIDs. The use with concomitant NSAIDs, including cyclo-oxygenase-2 specific inhibitors, increases the risk of adverse reactions (see section "Other medicines and Brupro" below) and should be avoided.
- have chicken pox (varicella) it is advisable to avoid use of Brupro
- are elderly.

Start treatment with the lowest available dose if you ever had gastrointestinal ulcers, are elderly or require concomitant low-dose acetylsalicylic acid or other medicines likely to increase gastrointestinal risk (see "Other medicines and Brupro" below). Your doctor may also add therapy with gastric mucosal protective medicines (e.g. misoprostol or proton pump inhibitors). Tell your doctor if any unusual symptoms in the stomach occur, especially signs of bleeding such as vomiting blood or black tar-like stools (see also section 4. "Possible side effects").

Patients with kidney or liver problems should first consult a doctor before taking ibuprofen.

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 (see section 3).

You should discuss your treatment with your doctor or pharmacist before taking Brupro 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.

Very rare reports of potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported with the use of ibuprofen. Patients are at higher risk of such reactions during the first month of therapy. **Stop taking** Brupro and talk to your doctor or pharmacist if you notice a skin rash, mucosal lesions, or any other signs of allergic reactions (see section 4).

Undesirable effects may be minimised by using the minimum effective dose for the shortest period of time. Elderly people are at increased risk of side effects.

In general, the habitual use of (several sorts of) analgesics can lead to lasting severe kidney problems. This risk may be increased under physical strain associated with loss of salt and dehydration. Therefore, it should be avoided.

Prolonged use of any type of painkiller for headaches can make them worse. If this situation is experienced or suspected, medical advice should be obtained, and treatment should be discontinued. The diagnosis of medication overuse headache (MOH) should be suspected in patients who have frequent or daily headaches despite (or because of) the regular use of headache medicines.

NSAIDs may mask symptoms of infection and fever.

In prolonged administration of Brupro regular checking of your liver values, the kidney function, as well as the blood count, is required. Your doctor may ask you to have blood tests during treatment.

Children and adolescents
There is a risk of renal impairment in dehydrated children and adolescents.

Do not use Brupro 200 mg Soft capsules in children under 6 years (less than 20 kg body weight).

Do not use Brupro Max 400 mg Soft capsules in adolescents under 40 kg body weight or in children under 12 years.

Other medicines and Brupro
Brupro may affect or be affected by some other medicines. For example:
- 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).

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

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. In particular, tell them if you are taking:
- Acetylsalicylic acid, or other NSAIDs (anti-inflammatories and analgesics): Since this may increase the risk of gastrointestinal ulcers or bleeding
- Digoxin (for heart insufficiency): Since the effect of digoxin may be enhanced
- Glucocorticoids (medicines containing cortisone or cortisone-like substances): Since this may increase the risk of gastrointestinal ulcers or bleeding
- Phenytoin (for epilepsy): Since the effect of phenytoin may be enhanced
- Selective serotonin reuptake inhibitors (medicines used for depression): As these may increase the risk of gastrointestinal bleeding
- Lithium (a medicine for manic depressive illness and depression): Since the effect of lithium may be enhanced
- Probenecid and sulfinpyrazones (medicines for treating gout): Since the excretion of ibuprofen may be delayed
- Potassium sparing diuretics: Since this may lead to hyperkalaemia (high potassium levels in the blood)
- Methotrexate (a medicine for cancer or rheumatism): Since the effect of methotrexate may be enhanced
- Tacrolimus and cyclosporin (immunosuppressive medicines): Since kidney damage may occur
- Zidovudine (a medicine for treating HIV infections/AIDS): Since the use of ibuprofen may result in an increased risk of bleeding into a joint or a bleed that leads to swelling in HIV (+) haemophiliacs
- Sulfonylureas (antidiabetic medicines): Interactions may be possible
- Quinolone antibiotics: Since the risk for convulsions may be increased
- Mifepristone (medicine prescribed for pregnancy termination): Since ibuprofen may reduce the effect of this medicine
- Bisphosphonates (medicines prescribed to treat osteoporosis): Since these may increase the risk of gastrointestinal ulcers or bleeding

- Oxpentifylline (pentoxyfilline) (medicine prescribed to increase the blood flow to arms and legs): Since this may increase the risk of gastrointestinal bleeding
- Baclofen, a muscle relaxant: Since the toxicity of baclofen may be enhanced.

Brupro with alcohol
Consumption of alcohol should be avoided while taking Brupro as it may intensify possible side effects.

Pregnancy, breast-feeding and fertility
Do not take Brupro in the last 3 months of pregnancy.
If you are in the first 6 months of pregnancy, are 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.

Ibuprofen can pass in very small concentrations into breastmilk but can be used during breast-feeding when used at the recommended dose and for the shortest possible time. Safety of long-term use has not been established.

Brupro capsules belong to a group of medicines which may impair fertility in women. This effect is reversible on stopping the medicine. It is unlikely that Brupro, used occasionally, will affect your chances of becoming pregnant, however tell your doctor before taking this medicine if you have problems becoming pregnant.

Driving and using machines
For short-term use and at normal dose this medicine has no or negligible influence on the ability to drive and use machines. If side-effects such as tiredness, dizziness, drowsiness and visual disturbances occur, do not drive or operate machines. Alcohol consumption increases the risk of these side effects.

Brupro contains sorbitol
Brupro 200 mg Soft capsules
This medicine contains 38,9 mg sorbitol in each capsule.

Brupro Max 400 mg Soft capsules
This medicine contains 50 mg sorbitol in each capsule.

3. How to take Brupro

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 product is intended for short term use only. You should take the lowest effective dose for the shortest time necessary to relieve your symptoms.

Brupro 200 mg Soft capsules
Adults and adolescents over 40 kg body weight (12 years of age and above)
The recommended dose is 200 mg to 400 mg (1 or 2 capsules), up to three times a day as required. Leave at least four hours between 200 mg (1 capsule) doses and at least six hours between 400 mg (2 capsules) doses. Do not take more than 1200 mg (6 capsules) in 24 hours.

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

Use in children over 6 years (20 kg – 40 kg body weight)
The recommended daily dose is 20 mg to 30 mg of ibuprofen per kg body weight divided into three or four separate doses as shown in the table below. Leave at least six to eight hours between doses.

Body weight	Single dose	Maximum daily dose
20 kg – 29 kg	one 200 mg capsule (equals 200 mg ibuprofen)	three 200 mg capsules (equals 600 mg ibuprofen)
30 kg – 39 kg	one 200 mg capsule (equals 200 mg ibuprofen)	four 200 mg capsules (equals 800 mg ibuprofen)

If in children and in adolescents this medicine is required for more than 3 days, or if symptoms worsen a doctor should be consulted.

Use in children under 6 years (less than 20 kg body weight)
Do not use Brupro 200 mg Soft capsules in children under 6 years (less than 20 kg body weight).

Brupro Max 400 mg Soft capsules
Adults and adolescents from 40 kg body weight (12 years of age and above)
The recommended dose is 400 mg (1 capsule), up to three times a day as required. Leave at least six hours between 400 mg (1 capsule) doses. Do not take more than 1200 mg (3 capsules) in 24 hours.

For treatment of migraine headache, the recommended dose is 1 capsule of 400 mg as a single dose. If necessary, take 400 mg (1 capsule) dose with intervals of 4 to 6 hours. Do not take more than 1200 mg (3 capsules) in any 24 hours.

If in adults, this medicine is required for more than 3 days in the case of migraine headache or fever or for more than 4 days for the treatment of pain or if the 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.

Use in adolescents under 40 kg body weight or in children under 12 years of age
Do not use Brupro Max 400 mg Soft capsules in adolescents under 40 kg body weight or in children under 12 years.

Method of administration
Brupro capsules are swallowed whole with plenty of water. **Do not** chew the capsules.

Patients with a sensitive stomach should take the capsules during a meal. Taking the capsules after a meal may delay the onset of pain or fever relief. Do not exceed the recommended dose or take more frequently than recommended.

If you take more Brupro than you should
If you have taken more Brupro 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.

If you forget to take Brupro
Simply refer to the directions above on how to take the medicine and **do not** take more than is advised. **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.

Side effects may be minimised by taking the lowest dose for the shortest time necessary to relieve the symptoms. Elderly people using this product are at increased risk of developing problems associated with side effects.

Medicines such as Brupro may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke (see section 2 "Warnings and precautions").

Some of the undermentioned undesirable effects are less frequent when the maximum daily dose is 1200 mg compared to high-dose therapy in rheumatic patients.

If you think you have any of the following side effects or symptoms, stop taking this medicine and seek immediate help:

- stomach and intestinal ulcers, sometimes with bleeding and perforation, vomiting blood or have black tar-like stools (common: may affect up to 1 in 10 people)
- kidney disease with blood in the urine which can be associated with renal failure (uncommon: may affect up to 1 in 100 people)
- severe allergic reactions (very rare: may affect up to 1 in 10,000 people) such as:
  - difficulties in breathing or unexplained wheezing
  - dizziness or faster heartbeat
  - drop in blood pressure leading to shock
  - swelling of your face, tongue or throat
- potentially life-threatening skin rashes with severe blisters and bleeding in the lips, eyes, mouth, nose and genitals (Steven-Johnson syndrome) or serious skin reactions which starts with painful red areas, then large blisters and ends with peeling of layers of skin. This is accompanied by fever and chills, aching muscles and generally feeling unwell (toxic epidermal necrolysis) (very rare: may affect up to 1 in 10,000 people).
- a severe skin reaction known as DRESS syndrome can occur. Symptoms of DRESS include: skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cells) (frequency not known: frequency cannot be estimated from the available data).
- severe condition of the skin that may affect the mouth and other parts of the body with symptoms including: red, often itchy spots, similar to the rash of measles, which starts on the limbs and sometimes on the face and the rest of the body. The spots may blister or may progress to form raised, red, pale-centred marks. Those affected may have fever, sore throat, headache and/or diarrhoea (very rare: may affect up to 1 in 10,000 people).
- severe flaking or peeling of the skin (very rare: may affect up to 1 in 10,000 people)
- inflammation of the pancreas with severe upper stomach pain, often with nausea and vomiting (very rare: may affect up to 1 in 10,000 people)
- nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, light coloured bowel motions, dark coloured urine which may be signs of hepatitis or liver failure (very rare: may affect up to 1 in 10,000 people)
- disease of the heart with shortness of breath and swelling of the feet or legs due to fluid build-up (heart failure) (very rare: may affect up to 1 in 10,000 people)
- aseptic meningitis (infection around the brain or spinal cord with symptoms including fever, nausea, vomiting, headache, stiff neck and extreme sensitivity to bright light and clouding of the mental state and thus not being fully in contact with the environment) (very rare: may affect up to 1 in 10,000 people)
- heart attack ("myocardial infarction", very rare: may affect up to 1 in 10,000 people) or stroke (not known: frequency cannot be estimated from the available data)
- severe kidney damage (papillary necrosis), particularly in long term use (rare: may affect up to 1 in 1,000 people)
- worsening of infection-related inflammations (e.g. development of flesh eating bacteria syndrome) particularly if using other NSAIDs (very rare: may affect up to 1 in 10,000 people)
- problems in blood cell production – first signs are: fever, sore throat, superficial mouth ulcers, flu-like symptoms, severe exhaustion, nose and skin bleeding (very rare: may affect up to 1 in 10,000 people).

Stop taking the medicine and tell your doctor if you experience:
Very common (may affect more than 1 in 10 people)
- indigestion or heartburn
- abdominal pain (pains in your stomach) or other abnormal stomach.

Uncommon (may affect up to 1 in 100 people):
- visual disturbances.

Tell your doctor if you experience any of the below side effects:

Very common (may affect more than 1 in 10 people)
- nausea, wind, diarrhoea, constipation, vomiting.

Common (may affect up to 1 in 10 people):
- headache, sleepiness, dizziness, spinning sensation, tiredness, agitation, inability to sleep, irritability
- stomach and intestinal ulcers, sometimes with bleeding and perforation; hidden blood loss which may lead to a condition in which there is a decreased number of red blood cells (symptoms include tiredness, headaches, being short of breath when exercising, dizziness and looking pale), black tar-like stools, vomiting blood, mouth ulcers and cold sores, inflammation of the colon (symptoms include diarrhoea, usually with blood and mucus, stomach pain, fever), worsening of inflammatory bowel disease, inflammation of bowel wall.

Uncommon (may affect up to 1 in 100 people):
- hives, itching, unusual bleeding or bruising under the skin, skin rash, asthma attacks (sometimes with hypotension)
- runny or blocked nose, sneezing, facial pressure or pain, difficulty in breathing
- inflammation of the stomach (symptoms include pain, nausea, vomiting, vomiting blood, blood in the bowel motions)
- increased sensitivity of the skin to sun
- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing, sometime with high blood pressure
- fluid build-up in the body's tissues especially in patients with high blood pressure or kidney problems.

Rare (may affect up to 1 in 1,000 people)
- a disease affecting the skin, joints and kidneys (lupus erythematosus syndrome)
- depression, confusion, hallucinations, mental illness with strange or disturbing thoughts or moods
- buzzing, hissing, whistling, ringing or other persistent noise in the ears
- increase of blood urea nitrogen, serum transaminases and alkaline phosphatase, decrease in haemoglobin and haematocrit values, inhibition of platelet aggregation, prolonged bleeding time, decrease of serum calcium, increase in serum uric acid, all seen on a blood test
- loss of vision.

Very rare (may affect up to 1 in 10,000 people):
- fast or irregular heartbeat (palpitations)
- fluid build-up in the body's tissues
- high blood pressure
- inflammation of the food pipe, narrowing of intestines
- liver disease, liver damage (especially in long-term use), liver failure, yellowing of the skin and/or eyes, also called jaundice
- unusual hair loss or thinning
- severe skin infections with soft tissue complications may occur if you have chicken pox
- menstrual period disorders

- build-up of fluid in the lungs, symptoms include breathlessness, which may be very severe and usually worsens on lying down.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Brupro

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 blister after EXP. The expiry date refers to the last day of that month.

Do not store above 30ºC.

Do not throw away any medicines via wastewater. 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 Brupro Soft capsules contain
Brupro 200 mg Soft capsules
- The active substance is ibuprofen.
  Each capsule contains 200 mg of ibuprofen.
- The other ingredients are: macrogol 400 (E1521), sorbitol solution (E420), sorbitan oleate (E494), potassium hydroxide (E525)
  Capsule shell: gelatin (E441), macrogol 400, sorbitol solution (E420) medium-chain triglycerides
  Capsule printing: shellac glaze, ammonia solution, concentrated, iron oxide black and propylene glycol.

What Brupro 200 mg Soft capsules look like and contents of the pack
Clear oval shaped soft gelatin capsules containing colourless to pale yellow coloured, transparent, viscous liquid, printed '200' in black colour on capsule shell.
Dimensions: 15 mm x 8 mm
Available in PVC/Aluminium blister packs of 10, 12, 20, 24, 30, 48 and 50 capsules.

Not all pack sizes may be marketed.

Brupro Max 400 mg Soft capsules
- The active substance is ibuprofen.
  Each capsule contains 400 mg of ibuprofen.
- The other ingredients are: macrogol 400 (E1521), sorbitan oleate (E494), povidone K-30, potassium hydroxide (E525)
  Capsule shell: gelatin (E441), macrogol 400 (E1521), sorbitol solution (E420), medium-chain triglycerides
  Capsule printing: propylene glycol, ammonia solution, concentrated, schellac glaze, iron oxide black (E172).

What Brupro Max 400 mg Soft capsules look like and contents of the pack
Clear oval shaped soft gelatin capsules containing colourless to pale yellow coloured, transparent, viscous liquid, printed '400' in black colour on capsule shell.
Dimensions: 15 mm x 10 mm

Available in PVC/Aluminium blister packs of 10, 12, 20, 24, 30, 48 and 50 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers
Marketing Authorisation Holder
Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers
Pharmachemie B.V., Swensweg 5, 2031 GA, Haarlem, The Netherlands.
Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, Sachsen-Anhalt, 39179 Barleben, Germany.

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

NL:	Ibuprofen Sandoz 200 mg, capsules, zacht, Ibuprofen Sandoz 400 mg, capsules, zacht
BE:	Ibuprofen Sandoz 200mg capsules, zacht Ibuprofen Sandoz 400mg capsules, zacht
BG:	Ibupain 200 mg capsules, soft Ibupain 400 mg capsules, soft
DE:	IbuHEXAL 400 mg Weichkapseln
EL:	FENPAIN
ES:	Ibuprofeno Sandoz 400 mg cápsulas blandas
FI:	Capsibu 200 mg kapseli, pehmeä, Capsibu 400 mg kapseli, pehmeä
HU:	Ibuprofen Sandoz 400 mg lágy kapszula
HR:	Ibutren 200 mg meke kapsule, Ibutren Forte 400 mg meke kapsule
IE:	Brupro 200 mg Soft capsules Brupro Max 400 mg Soft capsules
IT:	Ibuprofene Sandoz GmbH
LU:	Ibuprofen Sandoz 400 mg capsules molles
RO:	Ibuprofen Sandoz 200 mg capsule moi, Ibuprofen Sandoz 400 mg capsule moi
SI:	Diverin zipp 200 mg mehke kapsule , Diverin zipp 400 mg mehke kapsule

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