

Package leaflet: Information for the user

Brupro Max 400mg Film-coated tablets

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

What is in this leaflet

1. What Brupro Max is and what it is used for
2. What you need to know before you take Brupro Max
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1. What Brupro Max is and what it is used for

Brupro Max 400mg Film-coated tablets contain the active substance ibuprofen. Ibuprofen belongs to a group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs) that relieves pain and lowers fever.

This medicine is used to manage muscle pain, backache, dental pain and period pain.

2. What you need to know before you take Brupro Max

Do not take Brupro Max:

- 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 shortness of breath, asthma attacks or skin reactions (swelling or hives) after taking acetylsalicylic acid (aspirin) or other non-steroidal anti-inflammatory drugs (NSAIDs).
- if you have an active or history of recurrent stomach/duodenal ulcers (peptic ulcers) or bleeding (two or more distinct episodes of proven ulceration or bleeding)
- if a history of gastro-intestinal bleeding or perforation, related to previous NSAIDs therapy
- if you have severe heart failure, liver failure or kidney failure
- if you have a condition which increases your tendency to bleeding
- if you are in the last 3 months of pregnancy
- if you are under 12 years of age

Warnings and precautions

Talk to your doctor or pharmacist before taking Brupro Max if:

- you have, or previously suffered from asthma
- you suffer from impaired kidney, liver or heart function
- you suffer from heart failure and/or high blood pressure (hypertension)
- you are elderly - the elderly have an increased frequency of adverse reactions to NSAIDs especially gastrointestinal bleeding and perforation which may be fatal
- you have a history of gastrointestinal disease (ulcerative colitis, Crohn's disease) as your condition may get worse (see section 4)
- you are dehydrated
- you have a condition which increases your tendency to bleeding or have bleeding in the skull
- you have a certain autoimmune disease (system lupus erythematosus and connective tissue disease)

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

The use of Brupro Max at the same time as NSAIDs, including so-called COX-2 inhibitors should be avoided.

Bleeding of the gastrointestinal tract, ulcers and perforation

The risk of developing gastrointestinal bleeding, ulcers and perforation is higher with the increasing NSAID doses and is higher in patients with a history of ulcers, especially with complications of bleeding or perforation and in elderly patients. These patients should start treatment at the lowest available dose. For these patients, as well as patients who require additional therapy with low-dose acetylsalicylic acid or other medicines likely to increase gastrointestinal risk, combination treatment with protective agents (e.g. misoprostol or proton pump inhibitors) should be considered.

If you experience bleeding or ulcers in the stomach or intestine during treatment, stop taking this medicine.

Effects on the cardiovascular and cerebrovascular system

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 your treatment with your doctor or pharmacist before taking Brupro Max

if you:

- have heart problems including heart failure, angina (chest pain), or if you have had a heart attack, bypass surgery, peripheral artery disease (poor circulation in the legs 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.

Skin reactions

Serious skin reactions with reddening and blistering, some of them fatal (exfoliative dermatitis, Stevens-Johnson syndrome and toxic epidermal necrolysis) have been reported very rarely in association with the use of NSAIDs.

Patients appear to be at highest risk of these reactions early in the course of therapy: the onset of the reaction occurring in the majority of cases within the first month of treatment.

This medicine should be discontinued and a doctor consulted at once at the first appearance of skin rash, mucous-membrane lesions, or any other signs of hypersensitivity.

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

Other information

NSAIDs such as ibuprofen may mask the symptoms of infection and fever.

Adequate hydration should be ensured, as dehydration can lead to renal insufficiency when ibuprofen is given.

Other medicines and Brupro Max

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

Brupro Max may affect or be affected by some other medicines. For example:

- lithium (medicine for treating psychiatric disorders)
- methotrexate (medicine for treating cancer or certain rheumatic disorders)
- medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/ acetylsalicylic acid, warfarin, ticlopidine)
- aminoglycosides (a certain group of antibiotics)
- sulfonylureas (medicines for lowering blood sugar)
- diuretics (medicines for increasing fluid excretion)
- mifepristone
- medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan)
- cholestyramine (used to treat high cholesterol)
- voriconazole and fluconazole (anti-fungal medicines)

Increase in side effects:

- cardiac glycosides (medicine for strengthening the output of the heart)
- corticosteroids (used to treat inflammatory conditions)
- other anti-inflammatory painkillers and analgesic
- anti-platelet agents (to prevent blood clots) and selective serotonin reuptake inhibitors (medicines for treating depressive mood)
- quinolone antibiotics
- probenecid (for treating gout)
- sulphonylureas (medicines for lowering blood sugar)
- ciclosporin or tacrolimus (medicines for suppressing the immune response, after a transplant for example)
- zidovudine (medicine for treating HIV infection)
- herbal extract: ginkgo biloba

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

Pregnancy, breast-feeding and fertility

Pregnancy
Do not take this medicine in the last 3 months of pregnancy. Avoid the use of this medicine in the

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Datum: 14-06-13	Formgeving: 150x26,25
Chesapeake	Kleur: Zwart
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first 6 months of pregnancy unless your doctor advises otherwise.

Breast-feeding

Small amounts of ibuprofen pass into the breast milk. This medicine is not recommended for use in nursing mothers.

Fertility

This medicine belongs to a group of medicines (NSAIDs) which may impair fertility in women.

Driving and using machines

Side effects like dizziness, drowsiness, tiredness and problems with vision may occur with this medicine at higher doses. If you are affected do not drive, operate tools or machines. Do not work without a secure foothold.

3. How to take Brupro Max

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.

Take your tablets with a glass of water, preferably with or after food. You should swallow the tablets without chewing or crushing them. The tablets can be divided into equal doses.

Adults and children over 12 years:

Take one tablet, then if necessary one tablet every 4 – 6 hours. Do not exceed 3 tablets in 24 hours.

Children under 12 years:

Not recommended.

Elderly

Refer to adult dosing. If you have liver or kidney problems however, your dose may need to be adjusted in which case you should contact your doctor for advice.

If you take more Brupro Max than you should

If you have taken more Brupro Max 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 Max

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.

Stop taking this medicine and seek immediate medical help if you develop:

- **signs of intestinal bleeding** such as relatively severe pain in the abdomen, black tarry stools, vomiting blood or dark particles that look like coffee grounds
- **signs of a serious allergic reaction** such as worsening of asthma, unexplained wheezing or shortness of breath, swelling of the face, lips, tongue or throat, difficulty breathing, racing heart, drop in blood pressure leading to shock. These can happen even on first use of this medicine.
- **severe skin reactions** such as rashes covering the whole body, peeling, blistering or flaking skin.

The most commonly observed side effects are gastro-intestinal in nature. Stomach/duodenal ulcers (peptic ulcers), perforation or gastro-intestinal bleeding, sometimes fatal, particularly in the elderly, may occur. Nausea, vomiting, diarrhoea, flatulence, constipation, digestive complaints, abdominal pain, tarry stool, vomiting blood, ulcerative stomatitis (inflammation of the lining of the mouth), worsening of the intestinal disorders ulcerative colitis and Crohn's disease have been reported following use.

Less frequently, inflammation of the mucous membrane of the stomach (gastritis) has been observed.

Oedema, high blood pressure and heart failure have been reported in association with NSAID treatment.

Medicines such as Brupro Max may be associated with a small increased risk of heart attack or stroke, particularly with high doses and prolonged treatment.

Symptoms of an inflammation of the brain lining (aseptic meningitis), like severe headache, nausea, vomiting, fever, neck stiffness or consciousness clouding have been observed rarely. An increased risk appears to exist for patients who are already suffering from certain auto-immune disorders (systemic lupus erythematosus, mixed connective-tissue disease).

Other possible side effects include:

- inflammation of the pancreas (pancreatitis)
- disturbances to blood formation (anaemia, leukopenia, thrombocytopenia, neutropenia, agranulocytosis). The first signs may be fever,

sore throat, superficial wounds in the mouth, influenza-like complaints, severe fatigue, nosebleeds and skin bleeding

- difficulty sleeping, anxiety, depression, confusion, hallucinations
- headache, numbness or tingling of hands or feet, dizziness, drowsiness
- visual disturbances, inflammation of the optic nerve, damage to the optic nerve tissue
- hearing problems, vertigo, ear noises (tinnitus)
- liver function disturbances, liver failure, acute inflammation of the liver (hepatitis), jaundice (yellowing of the skin or eyes)
- sensitivity of skin to light, severe skin reactions like skin rash with reddening and blistering (e.g. Stevens-Johnson syndrome and toxic epidermal necrolysis)
- 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).
- weakness, tiredness
- impaired kidney function, inflammatory kidney disorder (interstitial nephritis), nephrotic syndrome (pronounced protein excretion and swelling) and kidney failure

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRC 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 Max

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 blister and carton after Exp. The expiry date refers to the last day of that month.

This medicinal product 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 Brupro Max contains

- The active substance is ibuprofen. Each film-coated tablet contains 400mg ibuprofen
- The other ingredients are colloidal anhydrous silica, croscarmellose sodium, microcrystalline cellulose, magnesium stearate, stearic acid, maize starch, hypromellose, talc, macrogol 400 and titanium dioxide (E171).

What Brupro Max looks like and contents of the pack

Brupro Max 400mg Film-coated tablets are white oblong, biconvex film-coated tablets with a score notch on both sides.

Brupro Max is available in packs containing 12 or 24 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Rowa Pharmaceuticals Ltd., Bantry, Co. Cork, Ireland.

Manufacturers:

Rowa Pharmaceuticals Ltd., Bantry, Co. Cork, Ireland.

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