Package leaflet: Information for the user

Brupro 200 mg 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 is and what it is used for
2. What you need to know before you take Brupro
3. How to take Brupro
4. Possible side effects
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1. What Brupro is and what it is used for

Brupro 200 mg Film-coated tablets contain the active substance ibuprofen. Ibuprofen belongs to a group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs) that relieve pain and lowers fever.

This medicine is used for the management of mild to moderate pain such as headache, dental pain, period pain, muscular strain and backache and to treat fever and colds and flu symptoms.

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)
- 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 you have 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 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 certain autoimmune disease (system lupus erythematosus, connective tissue disease)
- you have an infection – please see heading "Infections" below.

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

The use of Brupro 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 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 have been reported in association with Brupro treatment. You should stop taking Brupro and seek medical attention immediately, if you develop any skin rash, lesions of the mucous membranes, blisters or other signs of allergy since this can be the first signs of a very serious skin reaction. See section 4.
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.
During chicken pox (varicella) it is advisable to avoid the use of ibuprofen.

Infections

Brupro may hide signs of infection such as fever and pain. It is therefore possible that Brupro 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 infection 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.

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

Brupro 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 clotting) 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. You should therefore always seek the advice of your doctor or pharmacist before you use Brupro with other medicines.

Pregnancy, breast-feeding and fertility

Pregnancy

Do not take Brupro 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 Brupro 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, Brupro 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

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.

Brupro contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium free'.

3. How to take Brupro

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 or pain) persist or worsen (see section 2).
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.

Adults and children over 12 years:
Take two tablets, then if necessary 1 – 2 tablets every 4 hours. Do not exceed 6 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 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
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 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.

Frequency not known:

- a red, scaly widespread rash with bumps under the skin and blisters mainly localized on the skin folds, trunk, and upper extremities accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis)
- skin becomes sensitive to light - frequency unknown.

Stop using Brupro if you develop these symptoms and seek medical attention immediately. See also section 2.

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 HPRA Pharmacovigilance; website: www.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 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 contains

- The active substance is ibuprofen. Each film-coated tablet contains 200 mg 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 looks like and contents of the pack

Brupro 200 mg Film-coated tablets are white round, biconvex film-coated tablets.

Brupro is available in packs containing 12, 24, 48 or 50 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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