

Package leaflet: Information for the user

Brupro Rx 600 mg Film-coated tablets

ibuprofen

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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.

What is in this leaflet

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

Brupro Rx 600 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 lower fever.

This medicine is used to manage pain and inflammation in conditions such as osteoarthritis, rheumatoid arthritis (including juvenile rheumatoid arthritis or Still's disease), fibrositis, arthritis of the spine (ankylosing spondylitis) and other muscular conditions such as lower back pain, soft tissue trauma, inflammation of tendons, joints and ligaments. This medicine can also be used to relieve mild to moderate pain.

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

Do not take Brupro Rx:

- 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.

Warnings and precautions - Take special care with Brupro Rx

Talk to your doctor or pharmacist before taking Brupro Rx 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)
- 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 Rx 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 Rx 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 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 Brupro Rx and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

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

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.

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 Brupro Rx and contact immediately your doctor or medical emergencies if you notice any of these signs.

Other medicines and Brupro Rx

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

Brupro Rx 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 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)
- a herbal extract ginkgo biloba.

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

Pregnancy, breast-feeding and fertility

Pregnancy

Do not take Brupro Rx 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 Rx 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 Rx 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. If you are affected do not drive, operate tools or machines. Do not work without a secure foothold.

Brupro Rx 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 Rx

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).

Always take this medicine exactly as your doctor 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

The recommended dose is 600 – 1800mg daily in divided doses. Your doctor may choose to increase this depending on what you are being treated for, but no more than 2400mg should be taken in one day.

Children

The recommended dose is 20-30mg/kg of bodyweight given in divided doses. In severe cases, the doctor may increase the dosage up to 40mg/kg. In children weighing less than 30kg, no more than 500mg should be given each day.

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 Rx than you should

If you have taken more Brupro Rx 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 Rx

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.
- chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome
- **severe skin reactions** such as rashes covering the whole body, peeling, blistering or flaking skin.
- 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).

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 Rx 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
- weakness, tiredness
- impaired kidney function, inflammatory kidney disorder (interstitial nephritis), nephrotic syndrome (pronounced protein excretion and swelling) and kidney failure.

Frequency “not known”:

- skin becomes sensitive to light - frequency unknown.

Stop using Brupro Rx 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 Rx

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 Rx contains**

- The active substance is ibuprofen. Each film-coated tablet contains 600 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 Rx looks like and contents of the pack

Brupro Rx 600 mg Film-coated tablets are white oblong, biconvex film-coated tablets with a score notch on both sides.

Brupro Rx is available in packs containing 12, 24 or 60 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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