Package leaflet: Information for the patient

Brupro Cold & Flu 200 mg/30 mg film-coated tablets
ibuprofen/pseudoephedrine hydrochloride

For adults and adolescents from 12 years and older

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 symptoms worsen, or if this medicine is required for more than 4 days (adults) or 3 days (adolescents), respectively.

What is in this leaflet:

1. What Brupro Cold & Flu is and what it is used for

Brupro Cold & Flu contains two active substances: ibuprofen and pseudoephedrine hydrochloride.

Ibuprofen belongs to a group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs provide relief by reducing pain and high temperature.
Pseudoephedrine hydrochloride belongs to a group of active substances called vasoconstrictors which act on the blood vessels in the nose to relieve nasal congestion.

Brupro Cold & Flu is used for the symptomatic relief of nasal/sinus congestion with headache, fever and pain associated with the common cold and flu, in adults and adolescents aged 12 years and older.

You should only take this combination product if you have a blocked nose with headache or fever. If you have only one of these symptoms you should talk to your pharmacist or doctor about using either ibuprofen or pseudoephedrine by itself.

You must talk to a doctor if symptoms worsen, or if this medicine is required for more than 4 days (adults) or 3 days (adolescents), respectively.

2. What you need to know before you take Brupro Cold & Flu

Do not take Brupro Cold & Flu if you:
- are allergic to ibuprofen or pseudoephedrine hydrochloride or to any of the other ingredients of this medicine (listed in section 6)
- are younger than 12 years
- are in the third trimester of pregnancy (7 months or more pregnant)

- are breast-feeding
- have had an allergic reaction or shortness of breath, asthma, skin rash, itchy runny nose or facial swelling when previously taking acetylsalicylic acid or other NSAIDs
- have an active or history of recurrent stomach/duodenal ulcers (peptic ulcers) or bleeding (at least two different episodes of confirmed ulcers or bleeding)
- have a history of gastro-intestinal bleeding or perforation related to previous NSAID treatment
- have severe liver or kidney failure
- have severe heart failure
- have severe heart or circulation problems (heart disease, high blood pressure, angina, fast heart rate), an overactive thyroid gland, diabetes, pheochromocytoma (a tumour of the adrenal gland)
- have a history of heart attack (myocardial infarction)
- have had a stroke or have previously been told you are at risk of having a stroke
- have a history of seizures (fits)
- have unexplained disorders in the formation of blood components
- have increased pressure in the eye (closed-angle glaucoma)
- have difficulty in urinating related to prostate problems
- have been diagnosed with Systemic Lupus Erythematosus (SLE), an illness affecting the immune system causing joint pain, skin changes and other problems
- are taking:
    - other nasal decongestants (vasoconstrictor drugs) administered orally or nasally (e.g. phenylpropanolamine, phenylephrine, ephedrine, xylometazoline or oxymetazoline)
    - methylphenidate, a medicine for ADHD (attention deficit hyperactivity disorder)
    - medicines for depression like non-selective Monoamine Oxidase Inhibitors (known as MAOIs e.g. iproniazid) or have taken them in the last 14 days

Warnings and precautions
Talk to your doctor or pharmacist before taking Brupro Cold & Flu if you:
- have asthma; use of this medicinal product can cause an asthma attack
- have a history of gastro-intestinal disorders (such as hiatus hernia, gastro-intestinal bleeding, peptic or duodenal ulcer)
- have or have ever had gastro-intestinal disease (ulcerative colitis or Crohn's disease)
- have high blood pressure
- have liver or kidney problems
- have diabetes because of potential diabetic nephropathy
- have overactive thyroid gland (hyperthyroidism) or psychosis
- have a blood clotting disorder
- you have an infection – please see heading "Infections" below.

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

The use with concomitant NSAIDs, including cyclo-oxygenase (COX)-2 specific inhibitors, increases risk of adverse reactions (see section "Other medicines and Brupro Cold & Flu" below) and should be avoided

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 Cold & Flu 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.
Please note that the following conditions are contraindicated due to the pseudoephedrine component (see section "Do not take Brupro Cold & Flu if you" above): severe heart or circulation problems (heart disease, high blood pressure, angina, fast heart rate), an overactive thyroid gland, diabetes, pheochromocytoma (a tumour of the adrenal gland), history of heart attack (myocardial infarction), history of stroke or presence of risk factors for stroke.
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 medications.

Serious skin reactions, some of them fatal, including exfoliative dermatitis, Stevens-Johnson syndrome and toxic epidermal necrolysis, have been reported very rarely in association with the use of NSAIDs. You should stop taking Brupro Cold and Flu 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 treatment: the onset of the reaction occurring in the majority of cases within the first month of treatment.
If you develop a feverish generalized erythema associated with pustules, stop taking Brupro Cold & Flu and contact your doctor or seek medical attention immediately. See section 4.

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

Infections

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

Sudden abdominal pain or rectal bleeding may occur with Brupro Cold & Flu, due to inflammation of the colon (ischemic colitis). If you develop these gastro-intestinal symptoms, stop taking Brupro Cold & Flu and contact your doctor or seek medical attention immediately. See section 4.

Interference with blood test result
Pseudoephedrine has the potential to interfere with some diagnostic blood tests. You should tell your doctor that you are taking this medicine if you have a blood test.

Children and adolescents
Brupro Cold & Flu must not be given to children below 12 years.
There is a risk of renal impairment in dehydrated adolescents.

Athletes
Pseudoephedrine hydrochloride can lead to positive results in doping tests.

Other medicines and Brupro Cold & Flu
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Brupro Cold & Flu may affect or be affected by some other medicines. For example:
- 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 Cold & Flu. Always seek the advice of a doctor before you use Brupro Cold & Flu with other medicines.

Brupro Cold & Flu must not be used in combination with:

- other vasoconstrictor agents used as nasal decongestants, whether administered orally or nasally (e.g. phenylpropanolamine, phenylephrine and ephedrine)
- a medicine for ADHD (attention deficit hyperactivity disorder) called methylphenidate
- medicines for depression like non-selective Monoamine Oxidase Inhibitors (MAOIs, such as iproniazid). Also do not take this medicine if you have taken them within the last 14 days.

In particular tell your doctor or pharmacist if you are taking:

- other nonsteroidal anti-inflammatory drugs (NSAIDs) including high dose acetylsalicylic acid and COX-2 selective inhibitors
- medicines to treat heart arrhythmias (cardiac glycosides, e.g. digoxin)
- medicine to treat epilepsy (e.g. phenytoin)
- glucocorticoids, which are used for many conditions such as pain, swelling, allergy, asthma, rheumatism and skin problems
- injectable heparin
- some medicines for depression (e.g. lithium, selective serotonin reuptake inhibitors (SSRIs), monoamine oxidase A inhibitors (MAOIs)),
- medicines for the temporary suppression of your immune system e.g. methotrexate (for arthritis, psoriasis and some cancers), ciclosporin or tacrolimus (given after transplant surgery)
- antidiabetic medicines (sulphonylureas)
- medicines used to treat infections (e.g. quinolone antibiotics, trimethoprim)
- medicines to help you pass water (water tablets e.g. potassium sparing diuretics)
- medicines for gout (e.g. probenecid and sulfinpyrazones)
- any anti migraine medicinal products (including ergot alkaloid derivatives medicinal products)
- medicine for treating HIV/AIDS (zidovudine)
- preparations containing Ginkgo biloba

Being given pseudoephedrine may cause a sudden increase in blood pressure around the time of your surgery. Discontinue treatment with Brupro Cold & Flu several days before surgery and inform your anaesthetist.

Brupro Cold & Flu with alcohol
You should avoid alcohol intake during the treatment.

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
Avoid the use of this medicine in the first 6 months of pregnancy unless your doctor advises otherwise. Do not take Brupro Cold & Flu during the third trimester of pregnancy.

Breast-feeding

Do not take this medicine if you are breastfeeding, as it may harm your baby.

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

Driving and using machines
Brupro Cold & Flu could cause dizziness, hallucinations, unusual headache and visual or hearing disturbances and therefore might temporarily affect your ability to drive and use machines. If you experience any of these symptoms you should avoid driving or using machines.

Brupro Cold & Flu 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 Cold & Flu

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.

Duration of Use
This medicine is for short term use only. The lowest effective dose shoud 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).
You must talk to a doctor if symptoms worsen, or if this medicine is required for more than 4 days (adults) or 3 days (adolescents), respectively.

Dosage
The recommended dose is for adults and adolescents aged 12 years and older:
1 tablet every 6 hours, if necessary. For more severe symptoms, take 2 tablets every 6 hours, if necessary.

Never exceed the maximum daily dose of 6 tablets per day (equivalent to 1200 mg ibuprofen and 180 mg pseudoephedrine hydrochloride).

Method of administration:
The tablets are for oral use. They should be swallowed whole and without chewing with a large glass of water, preferably during meals.

Use in children and adolescents
Brupro Cold & Flu must not be given to children and adolescents below 12 years.

If you take more Brupro Cold & Flu than you should
Stop treatment and consult your doctor immediately, even if you feel well.

If you have taken more Brupro Cold & Flu 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 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 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 Brupro Cold & Flu and consult a doctor immediately if you experience:

- **signs of intestinal bleeding** such as: bright red faeces (stools/motions), black tarry stools, vomiting blood or dark particles that look like coffee grounds
- **signs of a serious allergic reaction** such as: severe skin rashes, peeling, flaking or blistering skin, facial swelling, unexplained wheeziness, shortness of breath, easy bruising
- 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). Stop using Brupro Cold & Flu if you develop these symptoms and seek medical attention immediately. See also section 2 (frequency not known).

Tell your doctor if you have any of the following side effects, they become worse or you notice any effects not listed.

Common (may affect up to 1 in 10 people)

- indigestion, abdominal discomfort or pain, nausea, vomiting, flatulence, diarrhoea, constipation, minor gastrointestinal blood loss in rare cases leading to anaemia

Uncommon (may affect up to 1 in 100 people)

- hypersensitivity reactions with nettle rash, itching and asthma attacks (with drop in blood pressure)
- central nervous disturbances such as headache, dizziness, difficulty in sleeping, agitation, irritability or tiredness
- visual disturbances
- stomach or intestinal ulcers, sometimes with bleeding and perforation, gastritis, inflammation of the mouth lining with ulceration (ulcerative stomatitis), worsening of colitis and Crohn's disease
- various skin rashes

Rare (may affect up to 1 in 1,000 people)

- tinnitus (ringing in the ears)
- sleeplessness, nervousness, anxiety, restlessness, tremor, hallucinations
- worsening of asthma or hypersensitivity reaction with shortness of breath
- kidney-tissue damage (papillary necrosis), increased uric acid concentrations in the blood

Very rare (may affect up to 1 in 10,000 people)

- worsening of infectious inflammations (e.g. necrotizing fasciitis), aseptic meningitis (stiffness of the neck, headache, nausea, vomiting, fever or disorientation) in patients with preexisting autoimmune diseases (Systemic Lupus Erythematosus (SLE), mixed connective tissue disease)
- problems in blood cell production (anaemia, leucopenia, thrombocytopenia, pancytopenia, agranulocytosis) that might make you bruise more easily or make you more susceptible to infections
- severe allergic reactions

- psychotic reactions and depression
- high blood pressure, palpitations, heart failure, heart attack
- inflammation of the oesophagus (oesophagitis) and the pancreas (pancreatitis), intestinal diaphragm-like strictures
- liver dysfunction, liver damage, especially in long-term therapy, liver failure, acute liver inflammation (hepatitis)
- severe skin reactions including skin rash with redness and blistering (e.g. Stevens-Johnson syndrome, toxic epidermal necrolysis/Lyell's syndrome), loss of hair (alopecia), severe skin infections and soft-tissue complications in a chicken pox infection (varicella zoster infection)
- increase in serum creatinine, oedemas (especially in patients with arterial hypertension or renal insufficiency), nephrotic syndrome, interstitial nephritis, acute renal insufficiency

Not known (frequency cannot be estimated from the available data)

- abnormal behaviour
- stroke, fits, headache
- palpitations, tachycardia, chest pain, arrhythmia
- high blood pressure
- dry mouth, thirst, nausea, vomiting
- rash, nettle rash, itching, excessive sweating
- difficulty in passing urine
- 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).
- sudden onset of fever, reddening of the skin, or many small pustules (possible symptoms of Acute Generalised Exanthematous Pustulosis-AGEP) may occur within the first 2 days of treatment with Brupro Cold & Flu. See section 2

  Stop using Brupro Cold & Flu if you develop these symptoms and contact your doctor or seek medical attention immediately.
- skin becomes sensitive to light - frequency unknown
- inflammation of the colon due to insufficient blood supply (ischemic colitis)

Medicines such as Brupro Cold & Flu may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke.

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
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 Cold & Flu

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 or the blister after (EXP). The expiry date refers to the last day of the month.

Do not store above 30ºC.

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 to protect the environment.

6. Contents of the pack and other information

What Brupro Cold & Flu contains

- The active substances are ibuprofen and pseudoephedrine hydrochloride.
  Each film-coated tablet contains 200 mg ibuprofen and 30 mg pseudoephedrine hydrochloride

- The other ingredients are:
  Tablet core: microcrystalline cellulose, calcium hydrogen phosphate anhydrous, croscarmellose sodium, maize starch, silica colloidal anhydrous, magnesium stearate.
  Tablet coat: hypromellose, macrogol 400, talc, titanium dioxide (E 171), iron oxide yellow (E 172)

What Brupro Cold & Flu looks like and contents of the pack
Brupro Cold & Flu are round, yellow film-coated tablets.
Pack sizes: 10, 12, 20 or 24 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Rowa Pharmaceuticals Ltd.,
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This leaflet was last revised in January 2022 .