

Package leaflet: Information for the patient

Buplex 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 Buplex Rx is and what it is used for
2. What you need to know before you take Buplex Rx
3. How to take Buplex Rx
4. Possible side effects
5. How to store Buplex Rx
6. Contents of the pack and other information

1. What Buplex Rx is and what it is used for

Buplex Rx belongs to a group of medicines called NSAID (non-steroidal anti-inflammatory drugs) which work by reducing pain, inflammation and fever.

Buplex Rx is used for the treatment of rheumatoid arthritis, osteoarthritis or other inflammatory or painful joint conditions, as well as for inflammatory and painful conditions of soft tissues such as muscles.

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

Do not take Buplex Rx:

- if you are allergic to ibuprofen or any of the other ingredients of this medicine (listed in section 6).
- if you have had allergic reactions such as asthma, runny nose, itchy skin rash or swelling of the lips, face, tongue, or throat after you have taken medicines containing acetylsalicylic acid or other drugs for pain and inflammation (NSAIDs).
- if you have suffered from an ulcer or bleeding in the stomach or small intestine (duodenum) related to previous use of drugs for pain and inflammation (NSAIDs)
- if you are suffering from an ulcer or bleeding in the stomach or small intestine (duodenum) or if you have had two or more of these episodes in the past
- if you suffer from severe liver, kidney or heart problems (including coronary heart disease)
- if you are in the last 3 months of pregnancy
- if you are suffering from significant dehydration (caused by vomiting, diarrhoea or insufficient fluid intake)
- if you have any active bleeding (including in the brain)
- if you suffer from a condition of unknown origin resulting in abnormal formation of blood cells

Warnings and precautions

Talk to your doctor before taking Buplex Rx

- if you have Systemic Lupus erythematosus (SLE) or other autoimmune diseases
- if you have inherited a disorder of the red blood pigment haemoglobin (porphyria)
- if you have chronic inflammatory intestinal diseases such as inflammation of the colon with ulcers (ulcerative colitis), inflammation affecting the digestive tract (Crohn's disease), or other stomach or intestinal diseases
- if you have disturbances in the formation of blood cells
- if you have problems with normal blood clotting mechanism
- if you suffer from allergies, hay fever, asthma, chronic swelling of nasal mucosa, nasal polyps or chronic obstructive disorders of the respiratory tract because ibuprofen can cause narrowing of the airways with difficulty in breathing (bronchospasm)
- if you have impaired liver or kidney function
- if you have heart problems including heart failure, angina (chest pain) or high blood pressure or if you have had a heart attack, bypass surgery or any kind of stroke or transient ischaemic attack ("TIA") or if you suffer from circulation problems in the arteries of your arms or legs (peripheral arterial disease). See section "Effects on the heart and brain".
- if you have just had major surgery
- if you are in the first six months of pregnancy
- if you are breast-feeding
- if you have an infection (see section "Infections").

Undesirable effects may be minimised by using the lowest effective dose for the shortest period of time.

Gastrointestinal effects

The use of Buplex Rx with concomitant NSAIDs including cyclooxygenase-2 selective inhibitors should be avoided.

Elderly

If you are elderly you will be more prone to side effects, especially bleeding and perforation in the digestive tract, which may be fatal.

Ulcers, perforation and bleeding in the stomach or intestines

If you have earlier had an ulcer in the stomach or intestines, especially if this has been complicated by perforation or accompanied by bleeding, you should look out for any unusual symptoms in the abdomen, and report them at once to your doctor, especially if these symptoms occur at the beginning of treatment. This is because the risk for bleeding or ulceration of the digestive tract is higher in this case, especially in elderly patients.

If bleeding or ulceration of the digestive tract occurs, the treatment has to be stopped.

Bleeding, ulceration or perforation in the stomach or intestines may occur without any warning signs even in patients who have never had such problems before. It may also be fatal.

The risk of ulcers, perforation or bleeding in the stomach or intestines generally increases with higher doses of ibuprofen. The risk also increases if certain other medicines are taken at the same time as ibuprofen (see "Other medicines and Buplex Rx", below).

NSAIDs should be given with care to patients with a history of gastrointestinal disease (ulcerative colitis, Crohn's disease) as their condition may be exacerbated.

Effects on the heart and brain

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 Buplex 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, or have a family history of heart disease or stroke, or if you are a smoker.

Effects on the kidneys

Ibuprofen may cause kidney problems in children, adolescents and the elderly who are dehydrated.

Ibuprofen may cause problems with kidney function even in patients who have not had kidney problems before. This may result in swelling of the legs and may even lead to heart failure or high blood pressure in predisposed individuals.

Ibuprofen may cause kidney damage especially in patients who already have kidney, heart or liver problems, or are taking diuretics or ACE inhibitors, as well as in the elderly. Stopping Ibuprofen however generally leads to recovery.

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 Buplex Rx and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Allergic reactions

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

Infections

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

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

Aseptic meningitis (inflammation of the brain membrane without bacterial infection)

During treatment with ibuprofen, some cases of meningitis (presenting as stiff neck, headache, nausea, vomiting, fever or disorientation) have been seen. Although it is probably more likely to occur in patients with existing autoimmune disorders such as systemic lupus erythematosus or mixed connective tissue diseases, it has been reported in patients who do not have an existing long-term disease.

Other precautions

During long-term, high-dose use of pain killers headache may occur which should not be treated with high doses of this medicine.

The habitual use of painkillers may cause permanent damage to the kidneys and a risk of kidney failure.

Ibuprofen may temporarily prolong bleeding time.

In prolonged administration of Buplex Rx, regular checking of your liver values, the kidney function, as well as the blood count is required.

Buplex Rx may decrease your chance of becoming pregnant. You should inform your doctor if you are planning to become pregnant or if you have problems becoming pregnant. See section “Pregnancy, breast-feeding and fertility”.

Children and adolescents

Do not use in children younger than 12 years.

Other medicines and Buplex Rx

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

The side effects of Buplex Rx may be increased if certain medicines are taken at the same time. On the other hand, Buplex Rx may increase or decrease the effect of other medicines or increase their side effects when taken at the same time.

In particular you should tell your doctor or pharmacist if you are taking any of the following medicines:

- other NSAIDs
- anticoagulants (medicines, which thin blood/prevent clotting e.g. acetylsalicylic acid, warfarin, heparin)
- platelet aggregation inhibitors (against clotting) such as clopidogrel, ticlopidine
- SSRIs (medicines against depression) such as paroxetine, sertraline, citalopram
- corticosteroids (used against inflammations)
- methotrexate (used to treat cancer and auto-immune diseases)
- digoxin (for treatment of various heart conditions)
- phenytoin (used in prevention of the occurrence of epileptic seizures)
- lithium (used to treat depression and mania)
- diuretics (water tablets), including potassium-sparing diuretics
- medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol, angiotensin-II receptor antagonists such as losartan)
- cholestyramine (used in the treatment of high cholesterol)
- aminoglycosides (medicines against certain types of bacteria)
- ciclosporin, tacrolimus (for immuno-suppression after organ transplant)
- zidovudine (used to treat patients with HIV)
- mifepristone
- probenecid or sulfinpyrazone (for treating gout)
- quinolone antibiotics
- sulphonylureas (to treat type 2 diabetes)
- fluconazole or voriconazole (used to treat fungal infections)

Buplex Rx with food and drink

You should swallow Buplex Rx with a glass of water during or after a meal.

Avoid alcohol since it may enhance the side effects of Buplex Rx, especially those affecting the stomach, intestines or brain.

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.

Do not take ibuprofen if you are 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 ibuprofen 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, ibuprofen 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.

Ibuprofen appears in breast milk in a very small amount and breastfeeding will usually not need to be stopped during short-term treatments. If, however, longer treatment is prescribed, early weaning should be considered.

The product belongs to a group of medicines (NSAIDs) which may impair the fertility in women. This effect is reversible on stopping the medicine.

Driving and using machines

Ibuprofen may impair reaction time in some people, for example due to side effects such as dizziness, drowsiness, vertigo or visual disturbances. The ability to drive a car or operate machinery may be impaired in individual cases. This applies to a greater extent in combination with alcohol.

Buplex Rx contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially 'sodium-free'.

3. How to take Buplex Rx

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

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).

The ibuprofen dose depends on the patient's age and body weight. The maximum single dose for adults should not be greater than 800 mg of ibuprofen. The recommended dose is:

Rheumatic diseases

Adults:

The usual dose is 400 mg-600 mg 3 times a day. Lower doses may be prescribed by your doctor. Due to the nature and severity of your condition, the doctor may increase your medication to a maximum of 2400 mg daily, taken in 3 or 4 divided doses.

Adolescents over 12 years of age (>40 kg):

The recommended dose is 20 mg/kg to a maximum of 40 mg/kg body weight daily in 3 to 4 divided doses. These tablets may not be suitable for this age and body weight group since they may contain a higher level of ibuprofen in 1 tablet than is appropriate. Your doctor will advise you accordingly.

Method of administration

The tablet should be swallowed with a glass of water during or after a meal. For the ease of swallowing or adjusting of doses the tablets can be divided in equal doses.

Use in children

Do not use in children younger than 12 years.

Elderly

If you are elderly you will be more prone to side effects, especially bleeding and perforation in the digestive tract, which may be fatal. Your doctor will advise you accordingly.

Reduced kidney or liver function

If you suffer from reduced kidney or liver function, your doctor will advise you accordingly.

If you take more Buplex Rx than you should

If you have taken more Buplex Rx than you should, or if a child has taken this medicine by accident, always contact a doctor or your nearest hospital to get an opinion of the risk and advice on action to be taken.

The symptoms of overdose can include nausea, stomach pain, diarrhoea, vomiting (may be blood streaked), headache, ringing in the ears, confusion and shaky eye movement. Bleeding from the stomach or intestines may also occur.

At high doses and in more serious cases of overdose, drowsiness, chest pain, palpitations, loss of consciousness, excitation, disorientation, coma, convulsions (mainly in children), weakness, dizziness, cramps (especially in children), blurred vision and eye problems, kidney failure, blood in urine, low levels of potassium in your blood, liver damage, low blood pressure, cold body feeling, breathing problems, bluish discolouration of lips, tongue and fingers, and increased bleeding tendency have been reported. Worsening of asthma in asthmatics can also occur.

If you forget to take Buplex Rx

If you forget to take a dose, take it as soon as you can, except if there is less than four hours remaining until the time for the next dose.

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. Undesirable effects are more likely with higher doses and longer duration of treatment.

The following side effects are serious and will require immediate action if you experience them. **You should stop taking Buplex Rx and see your doctor immediately if the following symptoms occur:**

- Black tarry stools or blood-stained vomit (digestive tract ulcer with bleeding, a common side effect)
- Swelling of the face, tongue or throat (larynx) which can cause difficulty in swallowing or breathing and hives (angioedema, an uncommon side effect)
- Rapid heartbeat, severe fall in blood pressure or life threatening shock (anaphylactic reaction, a rare side effect)
- If you experience an infection with symptoms such as fever and serious deterioration of your general condition, or fever with local infection symptoms such as sore throat/pharynx/mouth or urinary problems you should see your doctor immediately. Ibuprofen may cause a reduction in the number of white blood cells and your resistance to infection may be decreased. A blood test will be taken to check possible reduction of white blood cells (agranulocytosis, a rare side effect). It is important to inform your doctor about your medicine.
- 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, very rare side effects).
- A severe skin-related infection with destruction (necrosis) of skin, subcutaneous tissue and muscle (necrotizing fasciitis, a very rare side effect).

- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome, 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. The symptoms usually appear at the initiation of treatment (acute generalised exanthematous pustulosis (AGEP), frequency not known). See also section 2.

Other possible side effects are:

Common (may affect up to 1 in 10 people):

- Headache, fatigue, dizziness, agitation, insomnia and irritability
- Gastrointestinal side effects, such as heartburn, dyspepsia, stomach pain, feeling sick, vomiting, wind, diarrhoea, constipation
- Digestive tract ulcer, sometimes with bleeding and perforation
- Occult bleeding from the intestine, which may result in anaemia, black, tarry stools and vomiting blood (see serious side effects above)
- Bowel inflammation and worsening of inflammation of the colon (colitis) and digestive tract (Crohn's disease) and complications of diverticula of the large bowel (perforation or fistula)
- Rash

Uncommon (may affect up to 1 in 100 people):

- Runny nose (rhinitis)
- Disorders of blood cell formation (with symptoms like: fever, sore throat, surface mouth ulcers, flu-like symptoms, severe fatigue, nasal and skin bleeding, see also serious side effects above).
- reduction in blood cells (anaemia)
- Hypersensitivity (see serious side effects above)
- Anxiety
- Tingling of the hands and feet (paraesthesia)
- Sleepiness
- Visual disturbances
- Impaired hearing
- Asthma
- Difficulty breathing (bronchospasm)
- Shortness of breath (dyspnoea)
- Inflammation of the stomach lining
- Mouth ulcers and inflammation
- Skin becomes sensitive to light (photosensitivity reactions)
- Urticaria, pruritus, purpura
- Kidney problems including development of oedema, inflammation of the kidneys and kidney failure

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

- Inflammation of the brain membrane without bacterial infection (aseptic meningitis)
- Anaphylactic reaction (see serious side effects above)
- Depression, confusion, hallucinations
- Inflammation of the optic nerve which may cause vision problems, vision loss
- Ringing or buzzing in the ears
- vertigo
- Increase of blood urea nitrogen and other liver enzymes, decrease in haemoglobin and haematocrit values, inhibition of platelet aggregation and prolonged bleeding time, decrease of serum calcium and increase in serum uric acid values

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

- Unpleasant awareness of heart beat, heart failure, heart attack, sudden filling of lungs with water resulting in difficulty to breathe

- High blood pressure
- Inflammation of the oesophagus or pancreas
- Narrowing of the bowel
- Acute inflammation of the liver, yellowish discolouration of the skin or whites of the eyes, liver dysfunction, damage or failure
- Severe skin reactions (see serious side effects above)
- Damage of the kidney tissue
- Hair loss

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

- General feeling of being unwell (malaise)
- Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome
- Fixed drug eruption

Medicines such as Buplex Rx may be associated with a small increased risk of heart attack (myocardial infarction) or stroke.

Water retention (oedema), high blood pressure and heart failure have been reported in association with NSAIDs.

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 Buplex 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 packs 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 Buplex Rx contains

- The active substance is ibuprofen. Each film-coated tablet contains 600 mg ibuprofen.
- The other ingredients are:
Tablet core: cellulose, microcrystalline, silica, colloidal anhydrous, hydroxypropylcellulose, sodium laurylsulfate, croscarmellose sodium, talc
Film coating (Opadry (white) 06B28499): hypromellose, macrogol 400, titanium dioxide (E171).

What Buplex Rx looks like and contents of the pack

Film-coated tablets.

White, oval, biconvex film-coated tablets with a score on one face.

Pack sizes:

Blisters: 6, 10, 12, 20, 24, 30, 50, 60, 90, 100 and 250 film-coated tablets.

Tablet containers: 10, 20, 30, 50, 100 and 250 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Teva B.V.

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Manufacturer

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

Austria: Ibuprofen Actavis 600 mg Filmtabletten;

Denmark: Ifenin;

Iceland: Íbúfen;

Ireland: Buplex Rx 600 mg Film-coated tablets.

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