

Package leaflet: Information for the user

Mybufen Max Rapid 400 mg soft capsules 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 after 3 days.

What is in this leaflet

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

Mybufen Max Rapid 400 mg soft capsules contain ibuprofen which belongs to a group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs provide relief by changing the body's response to pain, swelling and high temperature.

Mybufen Max Rapid 400 mg soft capsules are for the relief of headaches, migraine, backache, period pain, dental pain, neuralgia, muscular pain, rheumatic pain, cold and flu symptoms and fever.

2. What you need to know before you take Mybufen Max Rapid

Do not take Mybufen Max Rapid if you:

- are allergic (hypersensitive) to ibuprofen, aspirin, or any of the ingredients listed in Section 6.
- have experienced shortness of breath, worsening of asthma, allergic rash or an itchy, runny nose when taking ibuprofen, aspirin or other similar medicines
- have ever had stomach bleeding or perforation after taking ibuprofen, aspirin or other similar medicines
- have or have ever had a stomach ulcer, perforation or bleeding
- suffer from severe kidney or liver problems
- have severe heart failure
- are in the last 3 months of pregnancy
- are under 12 years of age

Warnings and precautions

What you need to know before you take Mybufen Max Rapid:

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 Mybufen Max Rapid and contact immediately your doctor or medical emergencies if you notice any of these signs.

Take special care with Mybufen Max Rapid:

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

Talk to your doctor or pharmacist before taking Mybufen Max Rapid if you:

- have an infection – please see heading ‘Infections’ below
- have asthma or have suffered from asthma
- have kidney or liver problems
- 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")
- are already taking non-steroidal anti-inflammatory medication (NSAIDs)
- have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker
- suffer from a connective tissue disease such as Systemic Lupus Erythematosus (SLE) (Lupus)
- have problems with bleeding or blood clotting
- have been told by your doctor that you have an intolerance to some sugars
- are elderly
- have a history of inflammatory bowel disease such as ulcerative colitis or Crohn’s disease.
- are receiving regular treatment from your doctor (see section “Taking other medicines” below)
- have chicken pox as it is advisable to avoid the use of Mybufen Max Rapid

Adolescents

There is a risk of renal impairment in dehydrated adolescents.

Other warnings

Mybufen Max Rapid may make it more difficult to become pregnant. You should inform your doctor if you are planning to become pregnant or if you have problems becoming pregnant.

Tell your doctor if you notice any unusual symptoms - especially dark bowel motions, vomiting blood or stomach pains – particularly soon after you have taken this medicine.

Shortness of breath can occur if you suffer from or have a history of allergic diseases.

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 chicken pox. If you take this medicine while you have an infection and the symptoms of the infection persist or worsen, consult a doctor without delay.

There is increased risk of GI bleeding, ulceration or perforation with increasing NSAID doses, in patients with a history of ulcers, and the elderly. It is recommended to commence treatment at the lowest dose. The option of adding a protective agent should also be discussed with your doctor.

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 (3 days).

Do not exceed the recommended dose or duration of treatment [3 days].

Prolonged use of any type of painkiller for headaches can make them worse. If your headache or other symptoms persist or if your pain or fever worsens, or if new symptoms occur talk to your doctor or pharmacist.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. In particular discuss with your doctor or pharmacist if you are taking any of the following:

- other pain relievers or anti-inflammatory medicines such as aspirin, ibuprofen or other NSAIDs
- corticosteroids (such as prednisolone) since these may increase the risk of gastrointestinal ulceration or bleeding
- water tablets (diuretics) since NSAIDs may diminish the effect of this drug
- selective serotonin-reuptake inhibitors (SSRIs, medicine for depression) since these may increase the risk of gastrointestinal side effects
- Cardiac glycosides such as digoxin since the effect of these may be enhanced
- lithium (a medicine for depression) since the effect of lithium may be enhanced
- methotrexate (a medicine for cancer or rheumatism) since the effect of methotrexate may be enhanced
- cyclosporin (a medicine to suppress the immune reaction) since there is evidence of an increased risk of kidney toxicity
- Aminoglycosides (a type of antibiotic) since there is evidence of an increased risk of kidney toxicity
- Probenecid (a medicine for gout) since it may enhance the effect of the Mybufen Max Rapid 400 mg soft capsules
- Oral hypoglycemic agents (tablets for diabetes) since the effects of these may be enhanced
- Zidovudine (a medicine for HIV) since there is evidence of an increased risk of bleeding in HIV+ hamophilliacs who take zidovudine and ibuprofen together
- Mifepristone (used in pregnancy terminations)
- medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, ticlopidine)
- medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan)

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

Pregnancy and breastfeeding.

Do not take 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 child. 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 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, it 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 can pass in very small concentration into breast milk with no harmful effects to the infant. It is not necessary to interrupt breast feeding for short term treatment at the recommended dose.

Mybufen Max Rapid 400 mg soft capsules belong to a group of medicines which may impair fertility in women. This is reversible on stopping the medicine. Patients should be aware that this product may make it more difficult to become pregnant and should inform their doctor if planning to become pregnant or having problems becoming pregnant.

Driving and using machines

Ibuprofen does not have any effect on the ability to drive and use machines.

This medicine contains sorbitol (E-420)

This medicine contains 58.25 mg of sorbitol (E-420) per capsule. Patients with hereditary fructose intolerance (HFI) should not take this medicine.

3. How to take Mybufen Max Rapid

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.

Adults and children over 12 years: 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). Take 1 capsule with water and subsequently, if necessary, one capsule every 4 hours. Do not take more than 3 capsules in any 24 hour period. Do not chew the capsules. If in adolescents this medicinal product is required for more than 3 days, or if symptoms worsen a doctor should be consulted.

Elderly:

NSAIDs should be used with particular caution in elderly patients who are more prone to side-effects. This product is intended for short term use only.

You should take the lowest dose for the shortest time necessary to relieve your symptoms. You should not take Mybufen Max Rapid for longer than 3 days unless your doctor tells you to do so.

If you take more Mybufen Max Rapid than you should

If you accidentally take or administer more medicine than you should, or if a child has accidentally ingested the medicine always contact a doctor or nearest hospital to get an opinion of the risk and advise on action to be taken. The symptoms of overdose can include nausea, stomach pain, vomiting (may be blood streaked), headache, ringing in the ears, confusion and shaky eye movement. Also agitation, somnolence, disorientation or coma may occur. Occasionally patients develop convulsions. At high doses, drowsiness, chest pain, palpitations, loss of consciousness, convulsions (mainly in children), weakness and dizziness, blood in urine, low levels of potassium in your blood, cold body feeling, and breathing problems have been reported. Further, the prothrombin time/INR may be prolonged, probably due to interference with the actions of circulating clotting factors. Acute renal failure and liver damage may occur. Exacerbation of asthma is possible in asthmatics. Furthermore, there may be low blood pressure and reduced breathing.

If you forget to take Mybufen Max Rapid

Take your tablets as usual. Do not take a double dose to make up for forgotten tablets. If you have any further questions on the use of this product ask your doctor or pharmacist:

4. Possible side effects

Like all medicines, this medicine can cause side effects although not everybody gets them.

If you experience any of the following or any other unusual symptoms, stop taking the capsules and tell your doctor or pharmacist:

- stomach problems such as unexplained stomach pain, indigestion, feeling sick and/or vomiting, diarrhoea or constipation, flatulence.
- worsening of colitis or Crohn's disease
- Stomach ulcers or any sign of bleeding from the stomach or bowels (vomiting blood and/or passing black stools). These symptoms may not necessarily be preceded by warning signals, may occur in people who have not experienced stomach problems before and in rare cases can be fatal. When bleeding occurs, the treatment should be stopped immediately.
- liver or kidney problems
- severe sore throat with a high fever and flu-like symptoms, severe exhaustion, nose or skin bleeding, mouth ulcers
- severe skin reactions such as skin peeling
- a severe headache, stiff neck, nausea, vomiting, fever or confusion.
- allergic reactions such as unexplained wheezing, shortness of breath, swelling of the face, tongue or throat, palpitations, skin rash or itching ('nettle rash').
- asthma, aggravation of asthma or wheezing
- swelling, increased blood pressure or heart failure
- Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome
- severe skin infections and soft tissue complications during chicken pox (varicella) infection
- Skin becomes sensitive to light.
- 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). **Stop using Mybufen Max Rapid if you develop these symptoms and seek medical attention immediately. See also section 2**

Medicines such as Mybufen Max Rapid 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 Mybufen Max Rapid

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 and blister foil after "EXP". The expiry date refers to the last day of that month.

Store below 30 °C.

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 Mybufen Max Rapid contains

Each soft capsule contains 400 mg of ibuprofen as the active substance.

The other ingredients are:

Core: macrogol, potassium hydroxide and purified water.

Capsule: gelatin, sorbitol liquid non-crystallising (E-420) and purified water.

What Mybufen Max Rapid looks like and contents of the pack

Mybufen Max Rapid are oval-shaped transparent soft capsules containing a clear, light-yellow solution. Capsule dimensions: 16.5 x 9.7mm

It is presented in packs containing 24 soft capsules packed in Al/PVC/PVdC blister.

Not all pack sizes may be marketed.

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