

1.3 PRODUCT INFORMATION.

1.3.1 SPC, LABELLING AND PACKAGE LEAFLET.

PACKAGE LEAFLET: INFORMATION FOR THE USER IBUPROFEN GALPHARM MAX 400MG FILM-COATED TABLETS

For adults and adolescents weighing from 40kg body weight (12 years and above)

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.
- You must contact a doctor if you do not feel better or if you feel worse after 3 days with fever and 4 days with pain.

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.

What is in this leaflet

1. What Ibuprofen Galpharm Max 400mg Film-coated Tablets is and what it is used for.
2. What you need to know before you take Ibuprofen Galpharm Max 400mg Film-coated Tablets.
3. How to take Ibuprofen Galpharm Max 400mg Film-coated Tablets.
4. Possible side effects.
5. How to store Ibuprofen Galpharm Max 400mg Film-coated Tablets.
6. Contents of the pack and other information.

1. WHAT IBUPROFEN GALPHARM MAX 400MG FILM-COATED TABLETS IS AND WHAT IT IS USED FOR.

Ibuprofen Galpharm Max 400mg Film-coated Tablets contain ibuprofen, which belongs to a group of medicines called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) which work to reduce pain and fever.

This medicine is used for the short term relief of mild to moderate pain such as headache, period pain, dental pain, and fever and pain associated with the common cold.

You must talk to a doctor if you do not feel better or if you feel worse after 3 days with fever and 4 days with pain.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE IBUPROFEN GALPHARM MAX 400MG FILM-COATED TABLETS.

Do not take Ibuprofen Galpharm Max 400mg Film-coated Tablets if you:

- are allergic to ibuprofen or any of the other ingredients of this medicine (listed in section 6)

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- have ever suffered from shortness of breath, asthma, a runny nose, swelling or hives after using acetylsalicylic acid (known as aspirin) or other similar painkillers (NSAIDs)
- have (or have had two or more episodes of) a stomach ulcer, or bleeding of the stomach
- have a history of gastro-intestinal bleeding or perforation related to previous NSAID therapy
- have severe kidney or severe heart failure or severe liver failure
- are bleeding, including any bleeding within the brain (cerebrovascular bleeding)
- are suffering from blood clotting disorders
- suffer from a currently undiagnosed problem with your body's ability to form blood
- are severely dehydrated (caused by vomiting, diarrhoea or insufficient fluid intake)
- are in the last 3 months of pregnancy.

Warnings and precautions

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 Ibuprofen Galpharm Max 400mg Film-coated Tablets:

- if you suffer from serious skin reactions such as exfoliative dermatitis, Stevens-Johnson syndrome and toxic epidermal necrolysis. The use of Ibuprofen Galpharm Max 400mg Film-coated Tablets should be stopped immediately at the first appearance of skin rash, mucosal lesions, or any other signs of allergic reactions
- if you have hereditary blood formation disorder (acute intermittent porphyria)
- if you are elderly because you may be at more risk of having serious side effects, particularly stomach problems.
- if you have or have suffered from asthma or have allergies as shortness of breath may occur
- if you suffer from hayfever, nasal polyps or chronic obstructive respiratory disorders an increased risk of allergic reactions exists. The allergic reactions may present as asthma attacks (so-called analgesic asthma), Quincke's oedema or urticaria
- during chickenpox (varicella) it is advisable to avoid use of Ibuprofen Galpharm Max 400mg Film-coated Tablets
- if you have reduced liver or kidney function
- directly after major surgery
- if you have stomach or bowel disorders including Crohn's disease or a condition known as ulcerative colitis.
- If you have Systemic Lupus Erythematosus (SLE) or mixed connective tissue disease –illnesses which affect your immune system. They cause joint pains, skin changes and problems with other parts of your body.
- 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 of feet due to narrow or blocked arteries), or any kind of stroke (including 'mini-stroke' or transient ischaemic attack "TIA")>
- if you have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker.
- In prolonged administration of Ibuprofen Galpharm Max 400mg Film-coated Tablets regular checking of your liver values, the kidney function, as well as of the blood count, is required
- The use with concomitant NSAIDs, including cyclo-oxygenase-2 specific inhibitors, increases risk of adverse reactions (see section "If you are taking other medicines" below) and should be avoided.

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The lowest effective dose and the shortest possible treatment period should always be used to minimize the risk for adverse effects. Using a higher dose than recommended may increase the risk for adverse effects. Do not use simultaneously other pain killers without a doctors prescription.

In general the habitual use of (several sorts of) analgesics can lead to lasting severe kidney problems. This risk may be increased under physical strain associated with loss of salt and dehydration. Therefore it should be avoided.

There is a risk of renal impairment in dehydrated adolescents.

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.

Consult a doctor before using Ibuprofen Galpharm Max 400mg Film-coated Tablets if any of the above mentioned conditions concern you.

Other medicines and Ibuprofen Galpharm Max 400mg Film-coated Tablets

What should you avoid when you are taking other medicines?

Ibuprofen Galpharm Max 400mg Film-coated Tablets may affect or be affected by some medicines. For example: 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 receptors antagonists such as losartan.

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines, including medicines obtained without a prescription. In particular, tell them if you are taking:

aspirin/acetylsalicylic acid, or other NSAIDs (anti-inflammatories and analgesics)	since this may increase the risk of gastrointestinal ulcers or bleeding
digoxin (for heart insufficiency)	since the effect of digoxin may be enhanced
glucocorticoids (medicinal products containing cortisone or cortisone-like substances)	since this may increase the risk of gastrointestinal ulcers or bleeding
anti-platelet agents (ticlopidine)	since this may increase the risk of bleeding
aspirin/acetylsalicylic acid (low dose)	since the blood-thinning effect may be impaired
medicines for thinning the blood (such as warfarin)	since ibuprofen may enhance the effects of these medicines
phenytoin (for epilepsy)	since the effect of phenytoin may be enhanced
selective serotonin reuptake inhibitors (medicines used for depression)	as these may increase the risk of gastrointestinal bleeding
lithium (a medicine for manic depressive illness and depression)	since the effect of lithium may be enhanced

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probenecid and sulfinpyrazones (medicines for gout)	since the excretion of ibuprofen may be delayed
medicines for high blood pressure and water tablets	since ibuprofens may diminish the effects of these medicines and there could be a possible increased risk for the kidney
potassium sparing diuretics	since this may lead to hyperkalaemia
methotrexate (a medicine for cancer or rheumatism)	since the effect of methotrexate may be enhanced
tacrolimus and cyclosporine (immunosuppressive medicines)	since kidney damage may occur
zidovudine: (a medicine for treating Aids)	since the use of Ibuprofen Tablets may result in an increased risk of bleeding into a joint or a bleeding that leads to swelling in HIV (+) haemophiliacs
sulfonylureas (antidiabetic medicines)	interactions may be possible
quinolone antibiotics	since the risk for convulsions may be increased
Voriconazole, fluconazole (antifungal medicines)	since the effect of ibuprofen may be enhanced

Some other medicines may also affect or be affected by the treatment of Ibuprofen Galpharm Max 400mg Film-coated Tablets. You should therefore always seek the advice of your doctor or pharmacist before you use Ibuprofen Galpharm Max 400mg Film-coated Tablets with other medicines.

Ibuprofen Galpharm Max 400mg Film-coated Tablets with food, drink and alcohol

It is recommended that patients with sensitive stomachs take Ibuprofen Galpharm Max 400mg Film-coated Tablets with food. Some side effects, such as those affecting the gastrointestinal system can be more likely when alcohol is taken at the same time as Ibuprofen Galpharm Max 400mg Film-coated Tablets.

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

Do not take Ibuprofen Galpharm Max 400mg Film-coated Tablets in the last three months of pregnancy. Intake of ibuprofen should be avoided by women who plan pregnancy or are pregnant. Treatment during any part of pregnancy should take place only on doctors advice.

Breast-feeding

This medicine may be used during breast feeding for a maximum of 3 days (when you are treating a fever) or 4 days (for the treatment of pain), as only small amounts of this medicine passes into breast milk.

Fertility

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These tablets belong to a group of medicines (NSAIDs), which may impair fertility in women. This is reversible on stopping the medicine.

Ibuprofen Galpharm Max 400mg Film-coated Tablets contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE IBUPROFEN GALPHARM MAX 400MG FILM-COATED TABLETS

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.

Body weight (Age)	Dose and how often to take
Adults, and adolescents weighing from 40 kg (12 years old and above)	Take 1 tablet with water, up to 3 times a day, as required. Do not take more often than every 6 hours. Do not take more than 3 tablets in any 24 hour period.
These tablets are intended for short-term use only. Use them for the shortest time needed to relieve symptoms. Always use the lowest dose that relieves your symptoms. In adults: If this medicinal product is required for more than 3 days for fever or more than 4 days for pain, or if symptoms worsen a doctor should be consulted. In adolescents: If this medicinal product is required for more than 3 days, or if symptoms worsen a doctor should be consulted.	
Do not give to adolescents weighing under 40 kg or children under 12 years.	

For oral use.

Please speak to the doctor or pharmacist if you feel that the effect of this medicine is greater or less than you expected.

If you take more Ibuprofen Galpharm Max 400mg Film-coated Tablets than you should:

Talk to a doctor straight away, or go to your nearest hospital casualty department. Take the carton and this leaflet with you. The following signs may occur: nausea, vomiting, stomach pain, diarrhoea, ringing in the ear, headache, gastrointestinal bleeding, dizziness, drowsiness, confusion, disorientation. Rarely: loss of consciousness.

If you forget to take Ibuprofen Galpharm Max 400mg Film-coated Tablets

If you forget to take a tablet, take one as soon as you remember unless it is nearly time to take the next one, in which case skip the missed dose.

Do not take a double dose to make up for a forgotten dose.

If you stop taking Ibuprofen Galpharm Max 400mg Film-coated Tablets

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Ibuprofen Galpharm Max 400mg Film-coated Tablets can cause side effects, although not everybody gets them.

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Side effects may be minimised by taking the lowest dose for the shortest time necessary to relieve the symptoms. You may suffer one of the known side effects of NSAIDs (see below). If you do, or if you have concerns, stop taking this medicine and talk to your doctor as soon as possible. Elderly people using this product are at increased risk of developing problems associated with side effects.

The following frequencies are taken as a basis when evaluating side effects:

very common	affects more than 1 user in 10
common	affects 1 to 10 users in 100
uncommon	affects 1 to 10 users in 1,000
rare	affects 1 to 10 users in 10,000
very rare	affects less than 1 user in 10,000
not know	frequency cannot be estimated from the available data.

STOP TAKING this medicine and seek immediate medical help if you develop:

- **signs of intestinal bleeding** such as: severe pain in the abdomen, black tarry stools, vomiting blood or dark particles that look like coffee grounds.
- **signs of very rare but serious allergic reaction** such as worsening of asthma or shortness of breath, swelling of the face, 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.

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

Common

- Headache, dizziness
- gastrointestinal complaints, such as indigestion, heart burn, abdominal pain, feeling sick and indigestion, vomiting, nausea, wind (flatulence), diarrhoea, constipation, black stools and slight blood losses in stomach and/or bowel that may cause anaemia in exceptional cases.
- rash
- tiredness.

Uncommon

- rhinitis
- problems in the blood cell production - first signs are: fever, sore throat, superficial mouth ulcers, flu-like symptoms, severe exhaustion, nose and skin bleeding. In these cases you must stop the therapy immediately and consult a doctor. Any self-treatment with pain killers or medicinal products that reduce fever (antipyretic medicinal products) mustn't be done.
- worsening of asthma, bronchospasm, dyspnoea
- stomach or intestinal ulcers, sometimes with bleeding and perforation, inflammation of the lining of the mouth with ulceration (ulcerative stomatitis), inflammation of the stomach (gastritis)
- hepatitis, jaundice, abnormal liver function
- sleeplessness, agitation, irritability
- insomnia, anxiety
- tingling sensation, drowsiness
- visual disturbances
- photosensitivity
- allergic reactions, such as hives, skin rashes, itching and asthma attacks. You must stop taking Ibuprofen Tablets and inform your doctor at once.
- Cloudy urine (nephrotic syndrome), inflammatory kidney disease (interstitial nephritis), kidney failure.

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Rare

- tinnitus (ringing in the ears)
- Vertigo
- impaired vision
- allergic reaction
- kidney damage (papillary necrosis) and elevated uric acid concentrations in the blood
- liver damage

Very rare

- swelling (oedema), high blood pressure (hypertension) and cardiac failure have been reported in association with NSAID treatment.
- inflammation of the oesophagus or pancreas, formation of membrane-like narrowing in the small and large intestines (intestinal, diaphragm-like strictures)
- inflammation of blood vessels (vasculitis)
- serious infections of the skin and soft-tissue complications have occurred during chicken pox (varicella) infection.
- passing less urine than normal and swelling (especially in patients with high blood pressure or reduced kidney function); psychotic reactions and depression
- exacerbation of infection-related inflammations (e.g. necrotising fasciitis) associated with use of certain painkillers (NSAIDs) has been described. If signs of an infection occur or get worse during use of Ibuprofen Tablets, you must go to a doctor without delay. It is to be investigated whether there is an indication for an anti-infective/antibiotic therapy.
- high blood pressure, palpitations, heart failure, heart attack.
- liver failure
- the symptoms of aseptic meningitis with neck stiffness, headache, feeling sick, being sick, fever or consciousness clouding have been observed when using ibuprofen. Patients with autoimmune disorders (SLE, mixed connective-tissue disease) may be more likely to be affected. Contact a doctor at once, if these occur.
- severe forms of skin reactions such as skin rash with redness and blistering (e.g. Stevens-Johnson syndrome, toxic epidermal necrolysis/Lyell's syndrome), hair loss (alopecia).
- severe general hypersensitivity reactions.

Not known

- Colitis and Crohn's disease.

Medicines such as Ibuprofen Galpharm Max 400mg Film-coated Tablets 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. Reports may be made by following the links to the online reporting option accessible from the IMB homepage, or by completing the downloadable report form also accessible from the IMB website, which may be completed manually and submitted to the IMB via freepost, to the following address:

FREEPOST

Pharmacovigilance Section

Irish Medicines Board

Kevin O'Malley House

Earlsfort Centre

Earlsfort Terrac

Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

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Website: www.imb.ie

E-mail: imbpharmacovigilance@imb.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE IBUPROFEN GALPHARM MAX 400MG FILM-COATED TABLETS

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not store above 25°C. Keep in the original container in order to protect from light and moisture.

Keep all medicines out of the reach and sight of children.

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 Ibuprofen Galpharm Max 400mg Film-coated Tablets contains:

The active ingredient is: Ibuprofen 400mg per film-coated tablet.

The other ingredients are: Croscarmellose Sodium, Lactose Monohydrate, Macrogol 3350, Magnesium Stearate, Maize Starch, Poly(Vinyl-Alcohol), Povidone, Silica, Colloidal Anhydrous, Talc and Titanium Dioxide.

What Ibuprofen Galpharm Max 400mg Film-coated Tablets looks like and contents of the pack

Ibuprofen Galpharm Max 400mg Film-coated Tablets are white, capsule-shaped, film-coated tablets.

This pack contains 6, 8, 10, 12, 16, 20, 24, 30, 48, 50, 96 or 100 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder: Galpharm Healthcare Limited, Hugh House, Upper Cliffe Road, Dodworth Business Park, Dodworth, South Yorkshire S75 3SP, United Kingdom.

Manufacturer: Galpharm International Ltd, Upper Cliffe Road, Dodworth Business Park, Dodworth, South Yorkshire S75 3SP

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