

### 1.3 PRODUCT INFORMATION.

#### 1.3.1 SPC, LABELLING AND PACKAGE LEAFLET.

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##### **PACKAGE LEAFLET: INFORMATION FOR THE USER Ibuprofen Max 400mg 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.

#### **What is in this leaflet**

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

#### **1. WHAT Ibuprofen Max 400mg Coated Tablets IS AND WHAT IT IS USED FOR.**

Ibuprofen Max 400mg 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 Max 400mg Coated Tablets.**

##### **Do not take Ibuprofen Max 400mg Coated Tablets if you:**

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

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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.

#### **Skin reactions**

Serious skin reactions have been reported in association with Ibuprofen Max 400mg Coated Tablets treatment. You should stop taking this medicine 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.

#### **You should discuss your treatment with your doctor or pharmacist before taking Ibuprofen Max 400mg Coated Tablets:**

- 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 Max 400mg 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 Max 400mg 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.
- if you have an infection - please see heading "Infections" below.

#### Infections

This medicine may hide signs of infections such as fever and pain. It is therefore possible that this medicine 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.

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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 Max 400mg Coated Tablets if any of the above mentioned conditions concern you.

#### **Other medicines and Ibuprofen Max 400mg Coated Tablets**

##### **What should you avoid when you are taking other medicines?**

Ibuprofen Max 400mg 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 Max 400mg Coated Tablets. You should therefore always seek the advice of your doctor or pharmacist before you use Ibuprofen Max 400mg Coated Tablets with other medicines.

#### **Ibuprofen Max 400mg Coated Tablets with food, drink and alcohol**

It is recommended that patients with sensitive stomachs take Ibuprofen Max 400mg 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 Max 400mg 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 [product name] 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**

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

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#### **Ibuprofen Max 400mg Coated Tablets contain lactose and sucrose**

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

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

### 3. HOW TO TAKE Ibuprofen Max 400mg 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.

<b>Body weight (Age)</b>	<b>Dose and how often to take</b>
<b>Adults, and adolescents weighing from 40 kg (12 years old and above)</b>	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. Take the lowest effective dose for the shortest duration necessary to relieve symptoms. <b>In adults:</b> 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. <b>In adolescents:</b> If this medicinal product is required for more than 3 days, or if symptoms worsen a doctor should be consulted.	
<b>Do not give to adolescents weighing under 40 kg or children under 12 years.</b>	

If you have an infection, consult a doctor without delay if symptoms (such as fever and pain) persist or worsen (see section 2).

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 Max 400mg Coated Tablets than you should:**

If you have taken more Ibuprofen Max 400mg Coated Tablets than you should, or if children have been 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 Ibuprofen Max 400mg 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 Max 400mg Coated Tablets**

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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 Max 400mg Coated Tablets can cause side effects, although not everybody gets them.

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.
  - 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).
  - 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 **Ibuprofen Max 400mg Coated Tablets** if you develop these symptoms and seek medical attention immediately. See also section 2.
- skin becomes sensitive to light - frequency unknown.
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**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**

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- 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.

#### 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

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- Colitis and Crohn's disease.
- 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).

Medicines such as Ibuprofen Max 400mg 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.

You can also report side effects directly via HPRA Pharmacovigilance Website: [www.hpra.ie](http://www.hpra.ie).

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

## 5. HOW TO STORE Ibuprofen Max 400mg 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 Max 400mg Coated Tablets contain:**

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

**The other ingredients are:** Croscarmellose Sodium, Lactose Monohydrate, Magnesium Stearate, Maize Starch, Povidone, Silica, Colloidal Anhydrous, Talc, Sucrose, Carnauba Wax and Titanium Dioxide.

**What Ibuprofen Max 400mg Coated Tablets looks like and contents of the pack**

Ibuprofen Max 400mg Coated Tablets are white, capsule-shaped, 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:** [to be completed nationally]

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

Omega Pharma International NV, Venecoweg 26, Nazareth, 9810, Belgium

[To be completed nationally]

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