

## Package Leaflet : Information for the user

### Ibuprofen 400mg Tablets

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

This medicine is available without prescription for you to treat a mild condition without a doctor's help. However, you still need to use it carefully to get the best results from it.

- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### What is in this leaflet

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

#### 1. What Ibuprofen 400mg tablet is and what it is used for

This medicine contains Ibuprofen, which belongs to a group of medicines called non-steroidal anti-inflammatory medicines, which act to relieve pain and reduce swelling. It can be used to relieve headaches, rheumatic and muscular pain, pain from non-serious arthritic conditions, backache, migraine, period pain, dental pain and neuralgia. It can also be used to reduce fever and relieve the symptoms of colds and flu.

#### 2. What you need to know before you take Ibuprofen 400mg tablet

These tablets can be taken by adults and children from the age of 12 years. However, some people should not take this medicine or should talk to their pharmacist or doctor first.

##### Skin reactions

Serious skin reactions have been reported in association with ibuprofen treatment. You should stop taking ibuprofen 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.

##### Do not take if

- **You have a stomach ulcer, perforation or bleeding,** or have had one twice or more in the past
- **You have had a perforation or a bleeding stomach** after taking a non-steroidal anti-inflammatory medicine (you may have been sick and it contained blood or dark particles that look like coffee grounds, passed blood in your stools or passed black, tarry stools)
- **You are allergic** to ibuprofen or any other ingredients in the product, aspirin or other non-steroidal anti-inflammatory medicines (you have ever had asthma, runny nose, itchy skin or swelling of the lips, face or throat after taking these medicines)
- **You are taking aspirin with a daily dose above 75mg,** or other non-steroidal anti-inflammatory medicines
- **You have severe heart, kidney or liver failure**
- **You are pregnant** and in the last three months of pregnancy

##### Talk to your pharmacist or doctor if

- You have asthma, a history of asthma or other allergic disease, bowel problems, ulcerative colitis, Crohn's disease,
- You have other kidney, heart or liver problems, (see above)
- You have a connective tissue disorder such as SLE, (Systemic Lupus Erythematosus)
- You are elderly – you may get more side effects, (see back of leaflet)
- You are taking any other pain killers or receiving regular treatment from your doctor.
- You have had a stroke, or have heart problems, high blood pressure, diabetes, high cholesterol, or you smoke – see **'Risk of heart attack or stroke'** below.
- You are pregnant and in the first 6 months of pregnancy.
- You are breastfeeding. You are an adolescent between the age of 12-18 years and have been taking the medicinal product for more than 3 days or if your symptoms worsen.

##### Other important information

**Risk of heart attack or stroke:** Ibuprofen may increase the risk if you take large amounts for a long time. The risk is small. Take the lowest amount for the shortest possible time to reduce the risk.

**Women of childbearing age:** If you take this medicine, it may reduce your ability to become pregnant. This effect will be reversed when you

stop taking the medicine.

There is a risk of renal impairment in dehydrated children and adolescents.

### 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 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").
- have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker.

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 Ibuprofen 400mg tablets and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

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 Ibuprofen 400mg tablets and contact immediately your doctor or medical emergencies if you notice any of these signs.

If you are taking Ibuprofen 400mg Tablets for longer than the recommended time or at higher than recommended doses you are at risk of serious harms. These include serious harms to the stomach/gut and kidneys, as well as very low levels of potassium in your blood. These can be fatal (see section 4).

### Talk to your pharmacist or doctor if:

- you have an infection - please see heading 'Infections' below.

### 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.

### Other medicines and Ibuprofen 400mg tablet

Before you take these tablets, please tell your pharmacist about ANY other medicines that you are taking or might be taking at the same time, in particular the following:

- Other painkillers
- Aspirin 75mg, (to prevent heart attacks and strokes) – the protection may be reduced when you take ibuprofen
- Tablets that thin your blood, (e.g. warfarin)
- Mifepristone, (for termination of pregnancy) – do not take ibuprofen if you have taken mifepristone in the last 12 days
- Water tablets, (diuretics), medicines to treat high blood pressure, (antihypertensives), medicines for heart problems
- Corticosteroids, lithium, methotrexate, zidovudine
- Quinolone antibiotics, (for infections)
- Medicines for depression
- Ciclosporin or tacrolimus, (given after transplant surgery, or for psoriasis or rheumatism)
- medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/ acetyl salicylic 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)

If you are unsure about interactions with other medicines that you may be taking, talk to your pharmacist. This includes medicines prescribed by your doctor and medicines you have bought for yourself, including herbal and homeopathic remedies.

### 3. How to take Ibuprofen 400mg tablet

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. If the foil is broken, do not take that tablet.

AGE	HOW MANY	HOW OFTEN
Adults and children over 12 years.	One tablet.	Every 4 hours, if required. Up to 3 times a day.
<b>Do not</b> take more than 3 tablets in 24 hours. <b>Do not</b> take more often than every 4 hours. Take the lowest amount for the shortest possible time to relieve your symptoms.		

Swallow the tablets with water.

Do not give to children under 12 years.

Do not take more than recommended in the table above. If your symptoms worsen at any time, talk to your doctor. If your symptoms do not go away within 10 days, talk to your doctor.

#### If you take too many tablets

If you have taken more ibuprofen tablets than you should, or if children have taken this medicine by accidental ways contact a doctor or nearest hospital straightaway to get an opinion of the risk and advice on action to be taken. Take your medicine and this leaflet with you. 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.

#### 4. Possible side effects

Like all medicines, Ibuprofen 400mg tablet can cause side-effects, although not everybody gets them. Tell your doctor or pharmacist if you notice any of the following:

- Ared, scaly wide spread 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)
- 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). Stop using ibuprofen if you develop these symptoms and seek medical attention immediately. If you are elderly, you may be more likely to get some of these side effects

- You are sick (vomiting) and it contains blood or dark particles that look like coffee grounds

- Pass blood in your stools or pass black, tarry stools
- Stomach problems including pain, indigestion or heart burn
- Allergic reactions such as skin rash (which can sometimes be severe and include peeling and blistering of the skin), swelling of the face, neck or throat, worsening of asthma, difficulty in breathing
- Meningitis (e.g. stiff neck, fever, disorientation)
- Liver, kidney problems or difficulty urinating
- Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome

**Ibuprofen 400mg Tablets, especially when taken at higher than recommended doses or for a prolonged period of time, can cause damage to your kidneys and affect them removing acids properly from your blood into the urine (renal tubular acidosis). It can also cause very low levels of potassium in your blood (see section 2). This is a very serious condition and will require immediate treatment. Signs and symptoms include muscle weakness and light-headedness**

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

- 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 serious allergic reaction such as difficulties in breathing and unexplained wheezing, dizziness or faster heartbeat, severe forms of skin reactions such as itchiness, skin rash with redness, peeling, flaking or blistering (e.g. Stevens-Johnson syndrome), swelling of your face, tongue or throat, drop in blood pressure leading to shock
- 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].
- signs of kidney problems such as: passing less or more urine, cloudy urine or blood in urine, pain in the back and/or swelling (particularly in the legs)

- signs of aseptic meningitis with neck stiffness, headache, feeling sick, being sick, fever or consciousness. Patients with autoimmune disorders (lupus, mixed connective tissue disease) may be more likely to be affected
- 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 localised on the skin folds, trunk, and upper extremities accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis) (frequency not known). See also section 2.

STOP taking this medicine and tell your doctor if you experience the following uncommon side effects, which may affect up to 1 in 100 people:

- indigestion, heartburn or feeling sick
- pains in your stomach (abdomen) or other abnormal stomach problems

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

Uncommon: may affect up to 1 in 100 people

- allergic reactions, such as skin rashes (urticaria), itching, peeling
- headaches

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

- flatulence (wind), diarrhoea, constipation and vomiting

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

- blood disorders resulting in unexplained or unusual bruising or bleeding, fever, sore throat, mouth ulcers, flu-like symptoms and severe exhaustion

- drop in blood pressure
- 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)

- liver problems

Not known: frequency cannot be estimated from the data

- worsening of asthma or bronchospasm
- swelling (oedema), high blood pressure, heart failure or attack
- worsening of colitis and Crohn's disease
- skin becomes sensitive to light

Any anti-inflammatory / pain-killer medicines such as this medicine may be associated with a small increased risk of heart attack or stroke,

particularly when used at high doses. Do not exceed recommended dose or duration of treatment.

You should discuss your treatment with your doctor or pharmacist before taking this medicine 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.

**If any side effects becomes severe, or you notice other side effects not stated here, talk to your pharmacist or doctor.**

**Reporting of side effects:**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at:

[www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

**5. How to store Ibuprofen 400mg tablet**

This medicinal product does not require any special storage conditions.

Keep this medicine out of the sight and reach of children. Do not use after the Use By date on the end flap of the carton (marked 'EXP').

**6. Contents of the pack and other information**

**What Ibuprofen 400mg tablet contains**

Each tablet contains: ibuprofen 400mg. This is the active ingredient.

These tablets also contain pregelatinised starch, maize starch, anhydrous silicon dioxide, magnesium stearate, hypromellose, polyethylene glycol 400, water and titanium dioxide (E171).

**What Ibuprofen 400mg tablet looks like and contents of the pack**

The pack contains 12, 16, 24, 32, 48, 84 or 96 white, filmcoated tablets marked with the letter 'I' on one face.

**Marketing Authorisation Holder and Manufacturer**

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