

Artwork For Submission - SPUK



Package leaflet: Information for the user

Ibuprofen 400 mg Soft Capsules 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.
- You must contact a doctor if your symptoms worsen or do not improve after 3 days for children and adolescents between 12 and 18 years and after 10 days for adults.
- 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 Ibuprofen capsule is and what it is used for
2. What you need to know before you take Ibuprofen capsules
3. How to take Ibuprofen capsules
4. Possible side effects
5. How to store Ibuprofen capsules
6. Contents of the pack and other information

1. What Ibuprofen capsule is and what it is used for

The name of your medicine is Ibuprofen 400 mg Soft Capsules and mentioned as Ibuprofen capsule(s) throughout the package leaflet. Ibuprofen capsules contain the active ingredient as "ibuprofen", which belongs to a family of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs such as ibuprofen provide relief by changing the body's response to pain, swelling, and high temperature.

Ibuprofen capsules are used to relieve:

- Headaches and migraine pain
- Dental pain and neuralgia
- Period pain
- Rheumatic, muscular and back pain
- Feverishness and symptoms of cold and flue
- The pain of non-serious arthritis

2. What you need to know before you take Ibuprofen capsules

Do not take Ibuprofen capsules if:

- you are allergic to ibuprofen or any of the other ingredients of this medicine (listed in section 6)
- you are allergic to acetylsalicylic acid or other painkillers (your allergy may cause you to have difficulty breathing, asthma, a runny nose, a skin rash or swelling to your face)
- if you previously had bleedings or perforations in your gastrointestinal system caused by NSAIDs
- you have (or have had two or more episodes of) a stomach ulcer, perforation or bleeding
- you are taking other NSAID painkillers or more than 75mg of aspirin a day
- you have severe liver or kidney problems
- you have heart problems, high blood pressure or blood coagulation disorder
- you have breathing difficulties
- you are under 12 years old
- you are in the last three months of pregnancy (see also Section 2 "Pregnancy, breast-feeding and fertility").

Warnings and precautions

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

Talk to your doctor or pharmacist before taking Ibuprofen capsules.

Other medical problems may affect how you should use ibuprofen. Before you take this medicine, make sure your doctor knows if:

- you have or have had asthma
- you have kidney, heart, liver or bowel problems
- you have high cholesterol or previously have had a heart attack or stroke
- you have a history of gastrointestinal disease (such as ulcerative colitis, Crohn's disease)
- you have Systemic Lupus Erythematosus (a condition of the immune system causing joint pain, skin changes and other organ disorders)
- you are a smoker
- you are in the first 6 months of pregnancy (see Section 2 "Pregnancy, breast-feeding and fertility").
- **have an infection.** Ibuprofen capsules may hide signs of infections such as fever and pain. It is therefore possible that ibuprofen capsules 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 ibuprofen capsules while you have an infection and your symptoms of the infection persist or worsen, consult a doctor without delay.

If you have heart problems, previous stroke or think that you might be at risk of these conditions (for example if you have high blood pressure, diabetes or high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist.

If you are taking ibuprofen capsules 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).

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 capsules treatment. Stop using Ibuprofen capsules and seek medical attention immediately, if you notice any of the symptoms related to 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.

Children and adolescents

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

Other warnings

- Anti-inflammatory/pain-killer medicines such as 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 capsules 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.

Other medicines and Ibuprofen capsules

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

To reduce the risk of side effects, do not take this product with other NSAID containing products (e.g. aspirin, ibuprofen).

Ibuprofen capsules may affect or be affected by some other medicines. For example:

Avoid taking this product with corticosteroid tablets, quinolone antibiotics, or drugs that are prescribed:

- medicines that are anti-coagulants (i.e. thin blood/ prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, ticlopidine)
- to stimulate your heart (e.g. glycosides)
- medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan)
- to help you passing water (diuretics)
- for the temporary suppression of your immune system (e.g. methotrexate, ciclosporin, tacrolimus)
- for mania or depression (e.g. Lithium or SSRIs)
- for pregnancy termination (e.g. mifepristone)
- for HIV treatment (e.g. zidovudine)

Ibuprofen capsules with food, drink and alcohol

You may take Ibuprofen capsules without food, but it is better to take it with a meal as this may help to avoid stomach problems, particularly if you take it for long term use.

You should limit or avoid drinking alcohol when you are taking Ibuprofen capsules as this may increase gastrointestinal side effects.

Pregnancy, breastfeeding and fertility

Do not take ibuprofen capsules 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 capsules 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 capsules 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.

Pregnancy

You must not take Ibuprofen capsules during the last three months of pregnancy, as this may seriously harm your unborn baby, even at very low doses.

In the first six months of pregnancy you should only use Ibuprofen capsules after consulting your doctor.

Breastfeeding

In limited studies, ibuprofen appears in the breast milk in very low concentration and is unlikely to affect the breast-fed infant adversely.

Fertility

Ibuprofen capsules belongs to a group of medicines which may impair fertility in women. This is reversible on stopping the medicine. It is unlikely that Ibuprofen capsules, used occasionally will affect your chances of becoming pregnant. However, tell your doctor before taking this medicine if you have problems becoming pregnant.

Driving and using machines

If you have side effects like feeling dizzy, drowsy, tired, or if you have a blurred vision after taking Ibuprofen capsules, you should avoid driving or using any dangerous machines (see section 4 Possible side effects).

Ibuprofen capsules contains potassium

This medicine contains 28 mg potassium per capsule. To be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.

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Product Name: Ibuprofen 400 mg Soft Capsules

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Ibuprofen capsules contains sorbitol

This medicine contains 71.3 mg Sorbitol (E420) per capsule.

Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

Ibuprofen capsules contains soya oil (soya lecithin). If you are allergic to peanut or soya, do not use this medicinal product.

3. How to take Ibuprofen capsules

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

This product is intended for short term use only. You should take the lowest dose for the shortest time necessary to relieve your symptoms.

Method of administration

Ibuprofen capsule is for oral use. Take Ibuprofen capsules with a glass of water or some other liquid.

Do not take more than 400 mg for a **single dose**,

e.g. one 400 mg capsule up to three times a day.

Do not take more than 1200 mg **a day**, do not take more than three 400 mg capsules in 24 hours.

Leave at least 4 hours between doses.

Children

As there is not enough experience in children Ibuprofen capsules should not be used below the age of 12.

Children and adolescents between 12 and 18 years

If in children and adolescents this medicinal product is required for more than 3 days, or if symptoms worsen a doctor should be consulted.

Adults and elderly

Do not take for longer than 10 days unless your doctor tells you to. If symptoms persist or the pain or fever worsen, or if any new symptoms occur, consult your doctor or pharmacist.

If you take more Ibuprofen capsules than you should

If you have taken more capsules, than you should, or if children have taken this medicine by accident always contact your doctor straight away or 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, vomiting (may be blood streaked), gastrointestinal bleeding (see also part 4 below), diarrhoea, 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 Ibuprofen capsules

Do not take a double dose to make up for a capsule you have forgotten to take. Take the next capsule as usual.

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

4. Possible side effects

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

- Liver, kidney problems or difficulty urinating

Ibuprofen capsules, 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.

- Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome.

If you suffer from any of the following at any time during your treatment

- **STOP TAKING the medicine and seek immediate medical help:** pass blood in your faeces (stools/motions); pass black tarry stools; vomit any blood or dark articles that look like coffee grounds.
- Signs of serious allergic reaction such as: difficulties in breathing or unexplained wheezing, dizziness or faster heartbeat, severe skin reaction (rashes, itchiness, peeling, flaking or blistering), swelling of your face or throat
- a severe skin reaction known as DRESS syndrome. Symptoms of DRESS include skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cells).
- 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 TAKING the medicine and tell your doctor if you experience:

indigestion or heartburn; abdominal pain (pains in your stomach) or other abnormal stomach symptoms.

Other side effects that might occur

Uncommon may affect up to 1 in 100 people

- Urticaria and pruritus
- Anxiety
- Headache
- Abdominal pain, nausea, dyspepsia
- Various skin rashes

Rare may affect up to 1 in 1,000 people

- Psychotic reaction, depression, irritability
- Diarrhoea, flatulence, constipation and vomiting

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

- Haematopoietic disorders (anaemia, leucopenia, thrombocytopenia, pancytopenia, agranulocytosis)
- Severe hypersensitivity reactions. Symptoms could be facial, tongue and laryngeal swelling, dyspnoea, tachycardia, hypotension (anaphylaxis, angioedema or severe shock)
- Aseptic meningitis
- Peptic ulcer, perforation or gastrointestinal haemorrhage, melaena, haematemesis, sometimes fatal, particularly in the elderly. Ulcerative stomatitis, gastritis
- Severe forms of skin reactions such as bullous reactions including Stevens-Johnson Syndrome, erythema multiforme and toxic epidermal necrolysis can occur
- Acute renal failure, papillary necrosis, especially in long-term use, associated with increased serum urea and oedema
- Decreased haemoglobin levels
- Liver disorders

Not known cannot be estimated from the available data

- Respiratory tract reactivity comprising asthma, aggravated asthma, bronchospasm or dyspnoea.
- Cardiac failure and oedema
- Hypertension
- Exacerbation of colitis and Crohn's disease
- Acute generalised exanthematous pustulosis (AGEP), Drug reaction with eosinophilia and systemic symptoms (DRESS syndrome)
- Renal insufficiency

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

Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment.

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 the Yellow Card Scheme at: 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 capsules

Keep this medicine out of the sight and reach of children.

This medicine does not require any special storage conditions.

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 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 Ibuprofen capsules contains

- The active substance is ibuprofen.
- The other ingredients are: Macrogol (E 1521), Gelatin, Purified water, Sorbitol, liquid, partially dehydrated (E 420), Potassium hydroxide (E 525), Gelatin hydrolysed, FD & C Red #3 (E127), Triglycerides, medium chain, Lecithin (Soyalecithin)

What Ibuprofen capsules looks like and contents of the pack

Ibuprofen capsules 400 mg Soft Capsules
Reddish pink colored transparent, oval shaped soft gelatin capsules containing clear to pink colored viscous liquid. The packs are available in 10, 12, 16, 18, 20, 24, 28, 30, 32, 36, 48, 96 PVC/PVDC/Aluminium blister packs.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Strides Pharma UK Ltd.
Unit 4, The Metro Centre,
Dwight Road, Watford,
WD18 9SS
United Kingdom

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