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Please refer to this leaflet

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Package leaflet: Information for the patient

## Ibuprofen 400mg 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.
- 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. See section 4.

### What is in this leaflet

1. What Ibuprofen soft capsules are and what they are used for
2. What you need to know before you take Ibuprofen soft capsules
3. How to take Ibuprofen soft capsules
4. Possible side effects
5. How to store Ibuprofen soft capsules
6. Contents of the pack and other information

### 1. What Ibuprofen soft capsules are and what they are used for

Ibuprofen soft capsules belong to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs).

They can be used to:

- **relieve pain and inflammation** in conditions such as osteoarthritis, rheumatoid arthritis (including juvenile rheumatoid arthritis or Still's disease), arthritis of the spine, ankylosing spondylitis, swollen joints, frozen shoulder, bursitis, tendinitis, tenosynovitis, lower back pain, sprains and strains.
- treat **other painful conditions** such as toothache, pain after operations, period pain and headache (including migraine).

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

- **If the answer to any of the following questions is 'YES' please tell your doctor or pharmacist BEFORE taking any Ibuprofen soft capsules:**
- Are you pregnant or planning to become pregnant, or are you breast-feeding? Ibuprofen 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.
- Are you sensitive (allergic) to any of the ingredients in the capsules? These are listed in Section 6.
- Do you have, or have you previously had, a stomach ulcer or other gastric complaint?
- Do not take ibuprofen if you currently have a peptic ulcer (ulcer in your stomach or duodenum) or bleeding in your stomach, or have had two or more episodes of peptic ulcers, stomach bleeding or perforation in the past.
- Do you have a condition which increases your tendency to bleeding?
- Do you suffer from asthma or have you ever had an allergic reaction or suffered from wheezing after taking ibuprofen, aspirin or other anti-inflammatory pain killers?
- Do you suffer from swelling and irritation inside the nose?
- Do you suffer from liver or kidney disease?
- Do you suffer from heart disease?

Medicines such as ibuprofen 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.

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 you have had a heart attack, by-pass surgery or peripheral artery disease (poor circulation in the legs or feet due to narrow or blocked arteries).
- have any kind of stroke or think that you might be at risk of these conditions (e.g. if you have a family history of heart disease or stroke, high blood pressure, diabetes, high cholesterol or are a smoker).
- Do you have systemic lupus erythematosus (SLE, sometimes known as lupus) or a connective tissue disease (autoimmune diseases affecting connective tissue)?
- Do you have chicken pox or shingles?
- Are you or your child dehydrated? As there is a risk of kidney damage in dehydrated children adolescents and the elderly.

If you are taking Ibuprofen soft capsules for longer than the recommended time or at higher than recommended doses you are at risk of serious harm. These include serious harm to the stomach/gut and kidneys, as well as very low levels of potassium in your blood. These can be fatal (see 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 soft capsules and contact immediately your doctor or medical emergencies if you notice any of these signs.

#### 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 treatment. You should stop taking the capsules and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

#### Can you take ibuprofen with other medicines?

Some medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, ticlodipine), some medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol, or angiotensin-II receptor antagonists such as losartan) and other medicines may affect or be affected by treatment with ibuprofen.

You should therefore always seek the advice of your doctor or pharmacist before you use ibuprofen with other medicines. In particular you should tell your doctor or pharmacist if you are taking any of the following medicines in addition to those mentioned above:

- diuretics (water tablets)
- cardiac glycosides such as digoxin, used to treat heart conditions
- lithium
- zidovudine (an anti-viral drug)
- steroids (used in the treatment of inflammatory conditions)
- methotrexate (used to treat certain cancers and rheumatoid arthritis)
- medicines known as immunosuppressants such as ciclosporin and tacrolimus (used to dampen down your immune response)
- medicines known as selective serotonin reuptake inhibitors (SSRIs), used for the treatment of depression
- antibiotics called quinolones such as ciprofloxacin
- aminoglycosides (a type of antibiotic)
- mifepristone
- any other ibuprofen, such as those you can buy without a prescription
- any other anti-inflammatory pain killer, including aspirin
- cholestyramine (a drug used to lower cholesterol)
- medicines known as sulphonylureas such as glibenclamide (used to treat diabetes)
- voriconazole or fluconazole (type of anti-fungal drugs)
- ginkgo biloba herbal medicine (there is a chance you may bleed more easily if you are taking this with ibuprofen).

#### Alcohol

Ibuprofen may cause some side effects including dizziness, drowsiness and stomach problems such as bleeding in the stomach. Drinking excessive alcohol with Ibuprofen might make these side effects worse.

#### Pregnancy and breast-feeding

- The use of ibuprofen whilst pregnant or breast feeding should be avoided.
- Ibuprofen should not be used in the last three 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 in the first six months of pregnancy unless absolutely necessary and on the advice of 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 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.

#### Driving and using machines

Ibuprofen may make you feel dizzy or drowsy. If the capsules affect you in this way do not drive, operate machinery or do anything that requires you to be alert.

#### Ibuprofen soft capsules contain potassium and sorbitol

This medicine contains 31mg potassium per capsule. This should be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.

This medicine contains 59mg sorbitol in each 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 this medicine.

### 3. How to take Ibuprofen soft 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.

#### How to take the capsules

Take your capsules with or after food, swallow the capsules whole with a glass of water. Do not chew, suck or burst the capsules.

#### Adults and children over 12 years

The daily dose is 600 mg to 1800 mg spread throughout the day.

Your doctor may choose to increase this depending on what you are being treated for; but no more than 2400 mg should be taken in one day.

#### Children

The usual daily dose is 20 mg per kg of their bodyweight each day, given in divided doses. The capsules should NOT be taken by children weighing less than 7 kg.

In cases of severe juvenile rheumatoid arthritis, your doctor may increase the dose up to 40 mg per kg of bodyweight in divided doses.

**You should avoid excessive use of painkillers.** If you usually take painkillers, especially combinations of different painkillers, you may damage your kidneys. **Tell your doctor if you are already taking another painkiller before taking this medicine and your doctor will decide whether you should take this medicine.** This risk may be increased if you are dehydrated.

The use of painkillers for a long period of time has in some patients been linked to headaches, a condition called 'medication overuse headache'. Patients who have frequent or daily headaches despite (or because of) the regular use of pain killers should not be treated with increased doses of ibuprofen. Tell your doctor if you have been having headaches while taking this medicine.

#### If you take more Ibuprofen soft capsules than you should

If you have taken more than you should, or if children have taken this medicine by accident, contact a doctor or nearest hospital.

The symptoms of an overdose 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 soft capsules

Take them as soon as you remember, unless it is almost time for your next dose. If it is, do not take the missed dose at all. Do not take a double dose to make up for the one you have missed.

## 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. You can minimise the risk of side effects by taking the least amount of capsules for the shortest amount of time necessary to control your symptoms.

Medicines such as ibuprofen have in exceptional cases been associated with severe skin problems for patients with chicken pox or shingles.

#### Tell your doctor or pharmacist if you notice any of the following:

- Liver, kidney problems or difficulty urinating.

Ibuprofen soft 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.

#### Stop taking the capsules and seek immediate medical help if you experience:

- signs of **aseptic meningitis** such as severe headache, high temperature, stiffness of the neck or intolerance to bright light.
- signs of **intestinal bleeding** such as passing blood in your faeces (stools/motions), black tarry stools, vomiting any blood or dark particles that look like coffee grounds.

#### Tell your doctor and stop taking the capsules if you experience:

- unexplained wheezing, shortness of breath, skin rash, itching or bruising (these may be symptoms of an **allergic reaction**).
- 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).
- **unexplained stomach pain** (abdominal pain) or other abnormal stomach symptoms, indigestion, heartburn, feeling sick and/or vomiting.
- loss of vision, blurred or disturbed vision (**visual impairment**) or seeing/hearing strange things (**hallucinations**).

Medicines such as Ibuprofen have been associated with a small increased risk of high blood pressure, heart attack (myocardial infarction), stroke or heart failure.

Blood disorders such as reduction in blood cells and platelet counts – the first signs are high temperature, sore throat, mouth ulcers, flu-like symptoms, bleeding from the mouth, nose, ear and the skin. Kidney problems such as reduced kidney function, fluid retention (oedema), inflammation of the kidney and kidney failure. Liver problems such as inflammation of the liver, reduced liver function and yellowing of the eyes and/or skin (jaundice) or severe skin reactions may occur rarely with ibuprofen.

Ibuprofen has also been shown to sometimes worsen the symptoms of Crohn's disease or colitis.

#### Other side effects

##### Common (may affect up to 1 in 10 people):

- feeling dizzy or tired.
- diarrhoea, wind, constipation.
- headache – if this happens while you are taking this medicine it is important not to take any other medicines for pain to help with this.

##### Uncommon (may affect up to 1 in 100 people):

- feeling drowsy
- feeling anxious
- feeling a tingling sensation or 'pins and needles'
- difficulty sleeping
- hives
- skin becomes sensitive to light
- hearing problems
- sneezing, blocked, itchy or runny nose (rhinitis)
- stomach or gut ulcer, hole in the wall of the digestive tract
- inflammation of your stomach lining
- ringing in ears (tinnitus)
- sensation of spinning (vertigo)
- mouth ulcers

##### Rare (may affect up to 1 in 1,000 people):

- feeling depressed or confused.

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

- inflammation of the pancreas.

##### Not known (frequency cannot be estimated from the available data):

- Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome.
- 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 soft capsules if you develop these symptoms and seek medical attention immediately. See also section 2.

#### 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 the Yellow Card Scheme Website: [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 soft 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 soft capsules contain

The active substance is ibuprofen. Each soft capsule contains 400mg ibuprofen. The other ingredients are macrogol 600, potassium hydroxide and triglycerides, medium chain.

The soft capsule shell contains gelatin and sorbitol liquid. The printing ink contains purified water, black iron oxide, isopropyl alcohol, propylene glycol and hypromellose.

#### What Ibuprofen soft capsules look like and contents of the pack

Ibuprofen soft capsules are oval, transparent, soft capsules (approximately 15.8mm x 9.8mm) containing a clear, colourless liquid imprinted with L 160 in black edible ink.

The capsules are packaged in blister packs containing 10, 20, 60, 84, 100, 250 or 500 capsules.

Not all pack sizes may be marketed.

#### Marketing Authorisation Holder

Resolution Chemicals Ltd., Wedgwood Way, Stevenage, Herts, SG1 4QT, United Kingdom.

#### Manufacturer

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