PATIENT INFORMATION LEAFLET

IBUPROFEN 400MG TABLETS

Read all of this leaflet carefully before you start taking this medicine. Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist or nurse 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 or nurse. This includes any possible side effects not listed in this leaflet.
• You must talk to a doctor if you do not feel better or if you feel worse.

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

1. What is Ibuprofen and what is it used for

• Ibuprofen belongs to the group of drugs termed Non-Steroidal Anti-Inflammatory Drugs (NSAIDs).
• Ibuprofen Tablets can be used to treat painful conditions such as rheumatic or muscular pain, pain of non-serious arthritis, backache, neuralgia, migraine, headache, dental pain, dysmenorrhoea, feverishness, symptoms of cold and flu.

2. What you need to know before you take Ibuprofen

DO NOT TAKE Ibuprofen if you:
• are allergic to Ibuprofen or any other ingredients of the product (these are listed in Section 6), aspirin or other related painkillers
• have or have had stomach ulcer, perforation or bleeding
• are taking more than 75mg of aspirin a day
• suffer from severe liver, kidney or heart failure
• are in the last 3 months of pregnancy

Warnings and precautions
Talk to your doctor or pharmacist before taking these tablets if you are:
• asthmatic or suffer from kidney, liver or bowel problems
• taking a low dose aspirin (up to 75mg daily)
• suffering from systemic lupus erythematous (SLE), a condition of the immune system affecting connective tissue resulting in joint pain, skin changes and disorders of other organs
• trying to become pregnant- Ibuprofen belongs to a group of medicines which may impair fertility in women. This effect is reversible upon stopping the medicine. It is unlikely that Ibuprofen, used occasionally will affect your chances of becoming pregnant, however tell your doctor before taking this medicine, if you have problems in becoming pregnant in the first 6 months of pregnancy
• told by your doctor that you have an intolerance to some sugars

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 (10 days) without consulting your doctor or pharmacist.

If you have heart problems, previous stroke or think that you may 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.

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

Other medicines and Ibuprofen
Tell your doctor or pharmacist if you are taking:
• anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, ticlodipine)
• medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol, or angiotensin -B receptor antagonists such as losartan)
• diuretics (water tablets)
• cardiac glycosides, such as digoxin, used to treat heart conditions
• zidovudine (an anti-viral drug)
• steroids (used in the treatment of inflammatory conditions)
• methotrexate (used to treat certain cancers)
• 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, lithium
• any other Ibuprofen preparations, 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 (types of anti-fungal drugs)
• gingko biloba herbal medicine (there is a chance you may bleed more easily if you are taking this with Ibuprofen)

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

Pregnancy and breast-feeding
Ibuprofen belongs to a group of medicine which may impair fertility in women. This effect is reversible upon stopping the medicine. The use of Ibuprofen whilst pregnant or breast feeding should be avoided. Ibuprofen should not be used in the last three months of pregnancy and should only be taken in the first six months of pregnancy on the advice of your doctor.

Ibuprofen Tablets contains sucrose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine as it contains sucrose.
3. How to take Ibuprofen

Always take Ibuprofen Tablets exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist or nurse if you are not sure.

- Adults, the elderly and children 12 years and over: 1 tablet to be taken up to 3 times daily with or after food. Do not take more than 3 tablets in 24 hours. Leave at least 4 hours between each dose.

Do not give to children under the age of 12 years.

This product is intended for short term use only. You should take the lowest dose for the shortest time necessary to relieve your symptoms. You should not take these tablets for longer than 10 days unless your doctor tells you. If symptoms persist or worsen consult your doctor. If in adolescents this medicinal product is required for more than 3 days, or if symptoms worsen a doctor should be consulted.

- If you take more tablets than you should
  If you take too many tablets, contact your doctor or hospital immediately. Bring any remaining tablets with you to show the doctor.

5. How to store Ibuprofen

- If you forget to take a dose
  If you forget to take a dose, take 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. Never double up on a dose to make up for the one you have missed.

4. Possible side effects

Like all medicines, your medicine can cause side effects, although not everybody gets them. The following side effects are very rare (less than 1 in 10,000 people) but if you experience any of the effects then STOP TAKING this medicine immediately and contact your doctor or pharmacist.

- Severe allergic reactions: symptoms could include faster heart rate, swelling of the face, tongue and throat.
- Severe skin reactions (Steven’s Johnson-Syndrome, toxic epidermal necrolysis): symptoms could include blistering of the skin, mouth, eyes and genitals. Skin rash, easy bruising or bleeding from the skin or nose.
- Peptic ulceration or perforation: symptoms could include severe abdominal pain, indigestion, heartburn, feeling sick, vomiting blood (or liquid with what looks like coffee grounds), blood in the faeces (stools/motions) or passing black tarry stools.
- Inflammation of the brain lining: symptoms could include stiff neck, severe headache, feeling or being sick, fever or feeling disorientated.
- Worsening of asthma and wheezing or difficulty in breathing.
- Fluid retention (e.g. swollen ankles), yellowing of the eyes and/or skin.
- Blurred or disturbed vision or seeing/hearing strange things.

If you experience any of the above mentioned side effects then STOP TAKING this medicine immediately and contact your doctor or pharmacist.

- Rare side effects (less than 1 in 1000):
  - blood disorders, kidney problems, liver problems may occur.

- Other side effects:
  - headache, hallucinations, dizziness
  - tingling of hands and feet, ringing in the ears
  - depression, confusion, difficulty sleeping
  - anxiety, impaired hearing
  - diarrhoea, constipation, flatulence (wind)
  - unexpected sensitivity of the skin to the sun
  - tiredness, malaise, mood swings
  - swelling and irritation inside the nose

Ibuprofen has also been shown to sometimes worsen the symptoms of Crohn’s disease or colitis. Medicines such as Ibuprofen have been associated with a small increased risk of heart attack (myocardial infarction) or stroke.

If any of the side effects mentioned get serious or if you notice any side effects not listed in this leaflet, contact your doctor or pharmacist.

Also you can help to make sure that medicines remain as safe as possible by reporting any unwanted side effects via the internet at www.mhra.gov.uk/yellowcard. Alternatively you can call Freephone 0808 100 3352 (available from 10 a.m. to 2 p.m. Mondays to Fridays) or fill in a paper form available from your local pharmacy.

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

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

- What Ibuprofen 400mg tablets contain
  - The active substance (the ingredient that makes the tablet work) is Ibuprofen. Each tablet contains 400mg of Ibuprofen BP.

- The other ingredients are pregelatinised starch, maize starch, povidone, sodium lauryl sulphate, silicon dioxide, magnesium stearate, sucrose, purified talc, titanium dioxide and erythrose aluminium lake (E127), bees wax (white), carnauba wax.

- What Ibuprofen tablets look like and contents of the pack
  - Ibuprofen 400mg are pink sugar coated tablets.
  - The pack sizes are “25, 50, 100 tablets in plastic containers and 12, 16, 24, 48, 84 and 96 tablets in blister packs”. Not all pack sizes may be marketed.

The Marketing Authorization Holder and company responsible for manufacture: Pharmvit Ltd, 177 Bilton Road, Perivale, Greenford, Middlesex, UB6 7HQ.

Telephone: 0208 997 5444
Fax: 0208 997 5433

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Read all of this leaflet carefully before you start taking this medicine.

• Keep this leaflet. You may need to read it again.
• If you have any further questions, ask your doctor, pharmacist or nurse.
• 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 or nurse. This includes any possible side effects not listed in this leaflet.

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2. What you need to know before you take Ibuprofen
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5. How to store Ibuprofen Tablets
6. Contents of the pack and other information

1. What is Ibuprofen and what is it used for

• Ibuprofen belongs to the group of drugs termed Non-Steroidal Anti-Inflammatory Drugs (NSAIDs).
• Ibuprofen tablets can be used to relieve pain and inflammatory effects such as rheumatoid arthritis (including juvenile rheumatoid arthritis or Still’s disease), ankylosing spondylitis, osteoarthritis and other non-rheumatoid arthropathies.
• Other conditions such as arthritis of the spine, swollen joints, frozen shoulder, bursitis, tendonitis, tenosynovitis, lower back pain, sprains and strains.
• Ibuprofen Tablets can also be used to treat other painful conditions such as dysmenorrhoea, toothache, pain after operations, period pain and headache, including migraine and neuralgia, feverishness and the symptoms of cold and flu.

2. What you need to know before you take Ibuprofen

◆ DO NOT TAKE Ibuprofen if you:
• are allergic to Ibuprofen or any other ingredients of the product (these are listed in Section 6), aspirin or other related painkillers
• have or have had stomach ulcer, perforation or bleeding
• are taking more than 75mg of aspirin a day
• suffer from severe liver, kidney or heart failure
• are in the last 3 months of pregnancy

◆ Warnings and precautions

Talk to your doctor or pharmacist before taking these tablets if you are:
• asthmatic or suffer from kidney, liver or bowel problems
• suffering from systemic lupus erythematosus (SLE), a condition of the immune system affecting connective tissue resulting in joint pain, skin changes and disorders of other organs
• trying to become pregnant- Ibuprofen belongs to group of medicines which may impair fertility in women. This effect is reversible upon stopping the medicine. It is unlikely that Ibuprofen, used occasionally will affect your chances of becoming pregnant, however tell your doctor before taking this medicine, if you have problems in becoming pregnant
• in the first 6 months of pregnancy
• told by your doctor that you have an intolerance to some sugars

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.
If you have heart problems, previous stroke or think that you may 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.

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

◆ Other medicines and Ibuprofen

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, especially:
• 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, or angiotensin -I receptor antagonists such as losartan)
• diuretics (water tablets)
• cardiac glycosides, such as digoxin, used to treat heart conditions
• zidovudine (an anti-viral drug)
• steroids (used in the treatment of inflammatory conditions)
• methotrexate (used to treat certain cancers)
• 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, lithium
• any other Ibuprofen preparations, such as those you can buy without a prescription
• any other anti-inflammatory pain killer, including aspirin
• cholesterol (a drug used to lower cholesterol)
• medicines known as sulphonylureas such as glibenclamide (used to treat diabetes)
• voriconazole or fluconazole (types of anti-fungal drugs)
• gingko biloba herbal medicine (there is a chance you may bleed more easily if you are taking this with Ibuprofen)

◆ Driving and Using Machines

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

◆ Pregnancy and breast-feeding

Ibuprofen belongs to a group of medicine which may impair fertility in women. This effect is reversible upon stopping the medicine. The use of Ibuprofen whilst pregnant or breast feeding should be avoided. Ibuprofen should not be used in the last three months of pregnancy and should only be taken in the first six months of pregnancy on the advice of your doctor.

◆ Ibuprofen Tablets contains sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine as it contains sucrose.
3. How to take Ibuprofen

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

Take your Ibuprofen Tablets with or after food. Leave at least 4 hours between each dose.

◆ Adults - The usual dosage is 1200 to 1800 mg spread throughout the day. Your doctor may choose to increase this depending on what you are being treated for, but not more than 2400 mg should be taken in one day in divided doses.

◆ Children - The usual daily dosage is 20 mg per kg of bodyweight, given in divided doses, except that in children weighing less than 30 kg, the total of Ibuprofen given in 24 hours should not exceed 500mg. Ibuprofen Tablets should NOT be taken by children weighing less than 7 kg. In cases of severe juvenile arthritis your doctor may increase the dosage up to 40 mg/kg of bodyweight daily in divided doses.

◆ Elderly – The elderly are at increased risk of the serious consequences of adverse reactions. If an NSAID is considered necessary, the lowest dose should be used and for the shortest possible duration. The patient should be monitored regularly for GI bleeding during NSAID therapy.

◆ If you take more tablets than you should If you take too many tablets, contact your doctor or hospital immediately. Bring any remaining tablets with you to show the doctor.

Symptoms of overdose: Include headache, drowsiness, low blood pressure and sickness.

◆ If you forget to take a dose If you forget to take a dose, take 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. Never double up on a dose to make up for the one you have missed.

4. Possible side effects

Like all medicines, your medicine can cause side effects, although not everybody gets them. The following side effects are very rare (less than 1 in 10,000 people) but if you experience any of the effects then STOP TAKING this medicine immediately and contact your doctor or pharmacist.

• Severe allergic reactions: symptoms could include faster heart rate, swelling of the face, tongue and throat.

• Severe skin reactions (Steven’s Johnson-Syndrome, toxic epidermal necrolysis): symptoms could include blistering of the skin, mouth, eyes and genitals. Skin rash, easy bruising or bleeding from the skin or nose.

• Peptic ulceration or perforation: symptoms could include severe abdominal pain, indigestion, heartburn, feeling sick, vomiting blood (or liquid with what looks like coffee grounds), blood in the faeces (stools/motions) or passing black tarry stools.

• Inflammation of the brain lining: symptoms could include stiff neck, headache, feeling or being sick, fever or feeling disoriented.

• Worsening of asthma and wheezing or difficulty in breathing.

• Fluid retention (e.g. swollen ankles), yellowing of the eyes and/or skin.

• Blurred or disturbed vision or seeing/hearing strange things.

If you experience any of the above mentioned side effects then STOP TAKING this medicine immediately and contact your doctor or pharmacist.

◆ Rare side effects (less than 1 in 1000):

• blood disorders, kidney problems, liver problems may occur

◆ Other side effects:

• headache, hallucinations, dizziness

• tingling of hands and feet, ringing in the ears

• depression, confusion, difficulty sleeping

• anxiety, impaired hearing

• diarrhoea, constipation, flatulence (wind)

• unexpected sensitivity of the skin to the sun

• tiredness, malaise, mood swings

• swelling and irritation inside the nose

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

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

If any of the side effects mentioned get serious or if you notice any side effects not listed in this leaflet, contact your doctor or pharmacist.

Also you can help to make sure that medicines remain as safe as possible by reporting any unwanted side effects via the internet at www.mhra.gov.uk/yellowcard. Alternatively you can call Freephone 0808 100 3352 (available from 10 a.m. to 2 p.m. Mondays to Fridays) or fill in a paper form available from your local pharmacy.

5. How to store Ibuprofen

• This medicine should not be used after the "expiry date" printed on the pack.

• Store in a cool and dry place protected from light.

• Do not store above 30°C. Do not freeze.

• They should be kept in their original packaging.

Keep all medicines out of the sight and reach 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 400mg tablets contain

• The active substance (the ingredient that makes the tablet work) is Ibuprofen. Each tablet contains 400mg of the active ingredient Ibuprofen BP.

• The other ingredients are pregelatinised starch, maize starch, povidone, sodium lauryl sulphate, silicon dioxide, magnesium stearate, sucrose, purified talc, titanium dioxide and erythrosine aluminium lake (E127), bees wax (white), carnauba wax.

◆ What Ibuprofen tablets look like and contents of the pack

• Ibuprofen 400mg are pink sugar coated tablets.

• The dispensing pack size is 250 tablets in plastic containers.

The Marketing Authorization Holder and company responsible for manufacture:

Pharmvit Ltd, 177 Bilton Road, Perivale, Greenford, Middlesex, UB6 7HQ.

Telephone: 0208 997 5444

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