

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 more 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.

DAFEN 400 mg film-coated tablets
DAFEN 600 mg film-coated tablets
ibuprofen

What this leaflet contains:

1. What **DAFEN** is and what it is used for?
2. What should you know before taking **DAFEN**?
3. How should you take **DAFEN**?
4. Possible side effects of **DAFEN**.
5. How should you store **DAFEN**?
6. Further information about **DAFEN**

1. What DAFEN is and what it is used for?

DAFEN belongs to a group of medicines called anti-inflammatory pain killers. 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.

DAFEN can also be used to treat other painful conditions such as toothache, pain after operations, period pain and headache, including migraine.

The active ingredient in **DAFEN** is ibuprofen and each tablet contains either 400 or 600 mg.

2. What should you know before taking DAFEN?

If the answer to any of the following questions is 'YES' please tell your doctor or pharmacist

BEFORE taking any DAFEN:

Are you pregnant or planning to become pregnant, or are you breast-feeding? **DAFEN** 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 tablets? These are listed in Section 6. Do you have, or have you previously had, a stomach ulcer or other gastric complaint?

Do not take DAFEN 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 **DAFEN** 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 **DAFEN** if you:

- have heart problems including heart failure, angina (chest pain) or you have had a heart attack, bypass 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?

Have you been told by your doctor that you have an intolerance to some sugars?

Is your child dehydrated? As there is a risk of kidney damage in dehydrated children and adolescents.

Can you take **DAFEN** 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)

gingko biloba herbal medicine (there is a chance you may bleed more easily if you are taking this with ibuprofen).

Pregnancy and breast-feeding: The use of **DAFEN** whilst pregnant or breast feeding should be avoided. **DAFEN** should not be used in late (the last three months of) pregnancy and should only be taken in the first six months of pregnancy on the advice of your doctor.

Driving and Using Machines: **DAFEN** 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.

3. How should you take DAFEN?

ALWAYS take **DAFEN** exactly as your doctor has told you.

If you are not sure refer to the label on the carton or check with your doctor or pharmacist.

Take your **DAFEN** with or after food, with a glass of water.

DAFEN should be swallowed whole and not chewed, broken, crushed or sucked to help prevent discomfort in the mouth or irritation in the throat.

DOSEAGE:

Adults and children over 12 years - The usual dosage is 600 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 bodyweight each day, given in divided doses.

DAFEN should NOT be taken by children weighing less than 7 kg. The 600 mg tablets should not be given to children under the age of 12 years.

In cases of severe juvenile arthritis your doctor may increase the dosage up to 40 mg/kg 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.

If you take more **DAFEN** than you should

If you have taken more **DAFEN** than you should, or if children have taken this 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 YOUR DAFEN 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. Never double up on a dose to make up for the one you have missed.

4. Possible side effects of DAFEN

As with all medicines, **DAFEN** may cause side effects, although they are usually mild and not everyone will suffer from them. If any side effects become serious or if you notice any side effects that are not listed in this leaflet, please tell your doctor or pharmacist. You can minimise the risk of side effects by taking the least amount of tablets for the shortest amount of time necessary to control your symptoms.

STOP TAKING DAFEN 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)

Passing black tarry stools

Vomiting any blood or dark particles that look like coffee grounds

TELL YOUR DOCTOR AND STOP TAKING DAFEN IF YOU EXPERIENCE:

Unexplained stomach pain (abdominal pain) or other abnormal stomach symptoms, indigestion, heartburn, feeling sick and/or vomiting.

Unexplained wheezing, shortness of breath, skin rash, itching or bruising (these may be symptoms of an allergic reaction).

Loss of vision, blurred or disturbed vision (visual impairment) or seeing/hearing strange things (hallucinations).

Severe spreading skin rash ('Stevens-Johnson Syndrome', 'toxic epidermal necrolysis' and 'erythema multiforme', symptoms include severe skin rash, blistering of skin, including inside mouth, nose, and genitals, as well as skin peeling which may be accompanied with symptoms such as aching, headaches, and feverishness)

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 **DAFEN** have been associated with a small increased risk of high blood pressure, heart attack (myocardial infarction), stroke or heart failure.

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

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.

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

Other side effects

Common (affects 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 (affects up to 1 in a 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 (affects up to 1 in a 1000 people):

feeling depressed or confused

Very rare (affects up to 1 in 10,000 people):

inflammation of the pancreas

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.

5. How should you store DAFEN?

Keep this medicine out of the sight and reach of children. Do not store above 30°C.

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. Further information about DAFEN

The active substance in **DAFEN** is ibuprofen.

Other ingredients: microcrystalline cellulose, colloidal silicon dioxide, copovidone, croscarmellose sodium, talc, magnesium stearate.

Film: Opadry II pink, purified water

Marketing Authorization Holder and Manufacturer:

ZADA Pharmaceuticals Ltd.
Donji Bistarac without number
75 300 Lukavac
Bosnia and Herzegovina

Date and number of marketing authorization:

Dafen, film-coated tablet, 30 x 400 mg:

Number: 04-07.3-2-2412/16

Date: 06.03.2017.

Dafen, film-coated tablet, 30 x 600 mg:

Number: 04-07.3-1-1811/14

Date: 17.12.2015.

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