

Nashat® Ibuprofen

TJ PHARMA
Total Quality
شركة التقدم للصناعات الدوائية
Al-Taqaddom Pharmaceutical Industries

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 or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What **Nashat®** is and what it is used for.
2. Before you take **Nashat®**
3. How to take **Nashat®**
4. Possible side effects.
5. How to store **Nashat®**
6. Further information.

1. What **Nashat®** is and what it is used for:

Pharmacotherapeutic group:
Nashat® belong to a group of medicines called anti-inflammatory pain killers.

Therapeutic indications:

- Temporary relief of mild to moderate migraine headaches including associated symptoms of nausea, and sensitivity to light and sound.
- Fast and effective relief of muscles aches and pain, joint and body pain, backache, muscle sprains and strains, pain of inflammation associated with conditions including arthritis and physical or athletic overexertion (e.g. sprains or strains), headache including tension headache, dental pain, menstrual pain, aches and pain due to the common cold and flu and for reduction of fever.

2. Before you take **Nashat®**:

a. Do not take **Nashat®**:

- If you are sensitive (allergic) to ibuprofen or any of the ingredients.
- Previously experienced stomach bleeding or perforation after taking ibuprofen or other non-steroidal anti-inflammatory drugs (NSAIDs)
- 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.
- have a history of inflammatory bowel disease (ulcerative colitis, Crohn's disease).
- suffer from severe heart failure, liver failure or kidney failure.
- have a condition which increases your tendency to bleeding.
- are sensitive (allergic) or previously had an allergic reaction or suffered from Wheezing after taking ibuprofen, aspirin or other anti-inflammatory pain killers.
- are in the third trimester (last 3 months) of pregnancy.

Do not take **Nashat®** if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist.

b. Take special care with **Nashat®**:

- If you have, or previously suffered from bronchial asthma, chronic rhinitis or allergic disease.
- If you suffer from liver, kidney or heart disease.
- If you suffer from high blood pressure (hypertension).
- If you are elderly – elderly people are more prone to side effects to NSAIDs, particularly stomach bleeding and perforation which can be fatal.
- If you have been told by your doctor that you have an intolerance to some sugars.
- If you have, or you previously had a stomach ulcer, stomach bleeding or other gastric complaint.
- If you are dehydrated - there is a risk of renal impairment in dehydrated children, adolescents and the elderly.
- If you have a condition which increases your tendency to bleeding or have bleeding in the skull.
- If you have lupus or a connective tissue disease (autoimmune diseases affecting Connective tissue).

Heart attack and stroke

Anti-inflammatory / pain-killer medicines like **Nashat®** 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 **Nashat®** capsules 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), 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.

C. Taking other medicines, herbal, or dietary supplements:

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines that you can buy without a prescription, including herbal medicines.

Nashat® may affect or be affected by some medicines. For example:

- medicines that are 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-II receptor antagonists such as losartan).

- Some other medicines may affect or be affected by treatment with **Nashat®**. You should therefore always seek the advice of your doctor or pharmacist before you use **Nashat®** 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
- a medicine called zidovudine (an anti-viral drug)
- steroids (used in the treatment of inflammatory conditions)
- a medicine called methotrexate (used to treat some forms of cancer and rheumatoid arthritis)
- medicines called immunosuppressants such as ciclosporin and tacrolimus (used to dampen down your immune response)
- medicines known as selective serotonin reuptake inhibitors (SSRIs) (used to treat depression)
- antibiotics called quinolones such as ciprofloxacin
- aminoglycosides (atype of antibiotic)
- mifepristone
- any other ibuprofen, such as those you can buy without a prescription
- any other anti-inflammatory pain killer, including aspirin
- cholestyramine (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).

Please tell your doctor, health care provider or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

d. Taking **Nashat®** with food and drink:

Take **Nashat®** capsules with or after food, with a glass of water. **Nashat®** capsules should be Swallowed whole and not chewed, broken, or sucked to help prevent discomfort in the mouth or irritation in the throat.

e. Pregnancy and breast-feeding:

the use of **Nashat®** whilst pregnancy or breast feeding should be avoided. **Nashat®** 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.

f. Driving and using machines:

Nashat® 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.

3. How to take **Nashat®**:

Always take **Nashat®** exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

For migraine headaches: Adults and children over 12:

Take 1 capsule (every 6-8 hours) at the first sign of symptoms as needed. Do not exceed 3 capsules in 24-hours, unless directed by a doctor.

For all other uses: Adults and children over 12:

Take 1 capsule (every 6-8 hours) as

needed. Do not exceed 3 capsules in 24-hours, unless directed by a doctor. Do not use longer than 3 days for a fever or 5 days for pain relief.

Do not give to children under 12.

If you take more **Nashat®** than you should

In case of accidental overdose, discontinue use and seek professional assistance immediately even if there is no symptoms.

If you forget to take **Nashat®**:

• If you forget to take a dose, take it as soon as you remember it. However, if it is almost time for your next dose, skip the missed dose.

• Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

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

4. Possible side effects

Like all medicines, **Nashat®** can cause side effects, although not everybody gets them. Stop taking **Nashat®** 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)
- Passing black tarry stools

Vomiting any blood or dark particles that look like coffee grounds.

Tell your doctor and stop taking **Nashat®** capsules if you experience:

- Unexplained stomach 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).
- Yellowing of the eyes and/or skin (jaundice)
- severe sore throat with high fever (these may be symptoms of a condition known as agranulocytosis).
- blurred or disturbed vision (visual impairment) or seeing / hearing strange things (hallucinations).
- fluid retention e.g. swollen ankles (this may be a sign of kidney problems).

Severe spreading skin rash (stevens-johnson syndrome 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).

Medicines such as **Nashat®** capsules have been associated with small increase risk of heart attack (myocardial infarction) or stroke.

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

blood disorders, kidney problems, liver problems or severe skin reactions may occur rarely with ibuprofen.

Very rarely **Nashat®** capsules may cause aseptic meningitis (inflammation of the protective membrane surrounding the brain).

Nashat® 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):

- Rash
- Feeling dizzy or tired
- Stomach pain, indigestion, diarrhea, feeling sick, being sick, 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.
- Passing black tarry stool.
- Passing blood in the faeces (stool / motion)
- Vomiting any blood

Uncommon (affects up to 1 in 100 people):

- Feeling drowsy
- Feeling anxious
- Feeling a tingling sensation or "pins and needles"
- Difficulty sleeping
- Hives, itching
- Skin becomes sensitive to light
- Visual disturbances, hearing problems
- Hepatitis, yellowing of your skin or eyes, reduced liver function

Reduced kidney function, inflammation of the kidneys, kidney failure

- Sneezing, blocked, itchy or runny nose (rhinitis)

- Stomach or gut ulcer, hole in the wall of the digestive tract

- Inflammation of your stomach lining

- Small bruises on your skin or inside your mouth, nose or ears

- Difficulty breathing, wheezing or coughing, asthma or worsening of asthma

- Ringing in ears (tinnitus)

- Sensation of feeling dizzy or spinning (vertigo)

- Mouth ulcers

- Serious allergic reaction which causes swelling of the face or throat.

Rare (affects up to 1 in 1000 people):

- Feeling depressed or confused

- Fluid retention (edema)

- brain infection called 'non -bacterial meningitis'

- Loss of vision

- Changes in blood count- the first signs are: high temperature, sore throat, mouth ulcers, flu-like syndroms, feeling very tired, bleeding from the nose and skin

- Reduction in blood cells (anemia)

- Serious allergic reaction which causes difficulty in breathing or dizziness

- Severe sore throat with high fever (agranulocytosis)

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

- liver failure

- heart failure

- heart attack

- Inflammation of the pancreas

- skin problems (which can also affect inside your mouth, nose, or ears) such as 'stevens-johnson syndrome' 'toxic epidermal necrolysis' or 'erythema multiforme'.

- high blood pressure

Not known (frequency can't be estimated from available data):

- Worsening of ulcerative colitis or Crohn's Disease (inflammation of the colon)

If any of the side effects gets serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store **Nashat®** capsules

- Keep out of the reach and sight of children.

- Do not store above 30°C.

- Do not use **Nashat®** after the expiry date which is stated on the carton after Exp. The expiry date refers to the last day of that month.

- **Nashat®** does not require any special storage conditions.

- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

a. What **Nashat®** contains:

The active substance is: ibuprofen.

Nashat® 200: Each soft gelatin capsule contains ibuprofen USP 200mg.

Nashat® 400: Each soft gelatin capsule contains ibuprofen USP 400mg.

The other ingredients are:

Nashat® 200: Polyethylene glycol 600, Potassium hydroxide, Miglyol 812N, Printing Ink (Opacode White), Purified water.

Nashat® 400: Polyethylene glycol 600, Potassium hydroxide, Miglyol 812N, Printing Ink (black), Purified water.

b. what **Nashat®** look like and contents of the pack:

- **Pharmaceutical form:** Soft gelatin capsule.

- Physical Description:

NASHAT® 200:

- Green transparent, oblong shaped soft gelatin capsules containing clear colorless liquid imprinted "1200" with white edible ink on one side.

- Is available in pack size of 10 Capsules.

- Packed as Alu - PVC/PVDC clear film in carton box with a folded leaflet.

NASHAT® 400:

- Natural transparent, Oval shape, soft gelatin capsule containing clear colorless liquid, imprinted with "1160" in Black edible ink.

- Is available in pack size of 20 Capsules.

- Packed as Alu-PVC/PE/PVDC white opaque in carton box with a folded leaflet.

c. Marketing Authorization Holder

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d. This leaflet was last approved in 09/2018; I- Nashat- NST- LMO- RO/AE

This is a medicament

• A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.

• Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.

• The doctor and the pharmacist are experts in medicine, its benefits and risks.

• Do not by yourself interrupt the period of treatment prescribed for you.

• Do not repeat the same prescription without consulting your doctor.

• Keep medicament out of the reach of children.
COUNCIL OF ARAB HEALTH MINISTERS
UNION OF ARAB PHARMACISTS

