

PACKAGE LEAFLET: INFORMATION FOR THE USER

Ibuprofen AKTIV (Ibuprofen) 400 mg film-coated tablets

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.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse, particularly if symptoms worsen or do not improve after 10 days.

What is in this leaflet

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1. WHAT Ibuprofen AKTIV IS AND WHAT IT IS USED FOR

Ibuprofen belongs to a group of medicines called Non-Steroidal Anti-inflammatory Drugs (NSAIDs) that work by relieving pain, reducing inflammation, swelling and fever.

Ibuprofen AKTIV tablets are effective for relief of mild to moderate pain including rheumatic and muscular pain, pain of some arthritic conditions, backache, neuralgia, migraine, headache, dental pain, period pains, feverishness and the symptoms of cold and flu.

You must talk to a doctor if you do not feel better or if you feel worse particularly if symptoms worsen or do not improve after 10 days.

2. BEFORE YOU TAKE Ibuprofen AKTIV

Do not take Ibuprofen AKTIV if you:

- are allergic to ibuprofen or any of the other ingredients of this medicine (listed in section 6), aspirin or other related painkillers. Ibuprofen should be discontinued at the first appearance of skin rash, mucosal damage, or any other sign of allergic reactions.
- have had a worsening of asthma, skin rash, itchy runny nose or facial swelling when previously taking ibuprofen, aspirin or similar medicines.
- have (or have had two or more episodes of) a stomach ulcer, perforation or bleeding or other gastric complaint due to NSAIDs. Do not take Ibuprofen AKTIV tablets 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. There is an increased risk of the elderly having these side effects.
- are taking other NSAID painkillers, or aspirin with a daily dose above 75 mg.
- suffer from liver or kidney disease.
- suffer from heart disease, high blood pressure.
- 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 AKTIV film-coated tablets 400 mg 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. From 20 weeks of pregnancy, Ibuprofen AKTIV film-coated tablets 400 mg can cause kidney problems in your unborn baby, if taken for more than a few days, which can lead to low levels of amniotic fluid that surrounds the baby (oligohydramnios). If you need treatment for longer than a few days, your doctor may recommend additional monitoring.

Warnings and precautions

Talk to your doctor or pharmacist before taking Ibuprofen AKTIV tablets:

- If you have or have had asthma, diabetes, high cholesterol, high blood pressure, a stroke, heart, liver, kidney or bowel problems.
- If you are a smoker.
- If you are pregnant.
- If you are suffering from gastrointestinal disorders or long term inflammation of the intestines (for example, ulcerative colitis or Crohn's disease). See "Do not take Ibuprofen AKTIV" section.
- If you are suffering from Systemic Lupus Erythematosus (SLE) a condition of the immune system affecting connective tissue resulting in joint pain, skin change and disorders of other organs.
- Medicines such as ibuprofen may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke. Do not exceed the recommended dose or duration of treatment. Any risk is more likely with high doses and prolonged treatment. If you have had heart problems, have had a 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. Therefore ask a doctor before use if you have not been drinking fluids or have lost fluid due to continuous vomiting or diarrhea.
- If you are 65 years and older. The elderly have an increased frequency of side effects to NSAIDs, especially stomach bleeding and perforation, which may be fatal. Inform your doctor if you have unusual abdominal symptoms particularly in the initial stages of treatment.
- If you have an infection - please see heading "Infections" below.
- Skin reactions

Serious skin reactions have been reported in association with ibuprofen treatment. You should stop taking Ibuprofen AKTIV tablets and seek medical attention immediately, if you develop any 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.

- 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. Stop using Ibuprofen AKTIV tablets and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in 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 AKTIV tablets and contact immediately your doctor or medical emergencies if you notice any of these signs.
- Infections

Ibuprofen AKTIV tablets may hide signs of infections such as fever and pain. It is therefore possible that Ibuprofen AKTIV tablets 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 this medicine while you have an infection and your symptoms of the infection persist or worsen, consult a doctor without delay.

- If you are taking Ibuprofen AKTIV tablets 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).

Take special care with Ibuprofen AKTIV tablets.

- The use of ibuprofen simultaneously with other NSAIDs, including celecoxib, rofecoxib, etoricoxib (cyclooxygenase-2 selective inhibitors), should be avoided due to the increased risk of ulceration or bleeding (see section "Taking other medicines").
- When using concomitantly with certain medications (see section "Taking other medicines").

Children and adolescents

Take special care and talk to a pharmacist or your doctor before taking this medicine if you are 12-18 years old as there is a risk of renal impairment. Therefore ask a doctor before use if you have not been drinking fluid or have lost fluids due to continuous vomiting or diarrhea. This medicine is not to be used in children under 12 years of age.

Taking other medicines

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

Some medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetyl salicylic acid, warfarin, ticlodipine), some medicines that reduce high blood pressure (ACE-inhibitors such as captopril, β -blockers such as atenolol, or angiotensin-II receptor antagonists such as losartan) and any other ibuprofen preparations, such as those you can buy without a prescription 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 that are prescribed:

- to help you passing water (water tablets),
- for the treatment of inflammatory conditions (steroids),
- for mania or depression (e.g. lithium or selective serotonin reuptake inhibitors),
- to treat heart conditions (cardiac glycosides, such as digoxin),
- to treat certain cancers (methotrexate),
- for the temporary suppression of immune system (e.g. ciclosporin and tacrolimus),
- for pregnancy termination (mifepristone),
- for HIV treatment (zidovudine),
- antibiotics called quinolones such as ciprofloxacin,
- Ginkgo biloba herbal medicine (there is a chance you may bleed more easily if you are taking this with ibuprofen).

Do not use this medicine if you are taking other NSAID painkillers, or aspirin with a daily dose above 75 mg.

Pregnancy, breast-feeding and fertility

Pregnancy

The use of Ibuprofen AKTIV tablets whilst pregnant should be avoided. Ibuprofen AKTIV tablets 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.

Breast-feeding

In limited studies, ibuprofen appears in the breast milk in very low concentration and is unlikely to affect the breast-fed infant adversely. If you are breast-feeding, ask your doctor or pharmacist for advice before taking this medicine.

Fertility

Ibuprofen AKTIV tablets belong to a group of medicines which may impair fertility in women. This effect is reversible on stopping the medicine. It is unlikely that Ibuprofen AKTIV tablets, 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

Ibuprofen AKTIV 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.

Important information about some of the ingredients of Ibuprofen AKTIV

Ibuprofen AKTIV film-coated tablets contain lactose. If your doctor has told you that you are intolerant of some sugars, discuss it with them before taking this medicine.

Also, Ibuprofen AKTIV film-coated tablets contain color azorubine 85 E 122 and color cochineal red 80 E 124. The colours may cause allergic reactions.

3. HOW TO TAKE Ibuprofen AKTIV

Always take this medicine exactly as described in the leaflet or as your pharmacist has told you. Check with your pharmacist if you are not sure.

This medicine is for oral administration only.

Take your Ibuprofen AKTIV tablets with or after food, with a glass of water. Ibuprofen AKTIV tablets should be swallowed whole and not chewed, broken, crushed or sucked to help prevent discomfort in the mouth or irritation in the throat.

This product is intended for short term use only. Take the lowest dose for the shortest time necessary to relieve your symptoms. You should not take Ibuprofen AKTIV tablets for longer than 10 days unless your doctor tells you to. If symptoms persist or worsen consult your doctor.

The lowest effective dose should be used for the shortest duration necessary to relieve symptoms. If you have an infection, consult a doctor without delay if symptoms (such as fever and pain) persist or worsen (see section 2).

The recommended dose is:

Dosage in adults, the elderly and children over 12 years:

Take 1 tablet upto three times a day as required. Leave at least four hours between doses. Do not take more than 3 tablets in any 24 hour period.

Do not give these tablets to children under 12 years old except on the advice of a doctor.

If you take more Ibuprofen AKTIV than you should

If you have taken more Ibuprofen AKTIV film-coated tablets 400 mg 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 Ibuprofen AKTIV

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 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, this medicine can cause side effects, although not everybody gets them.

The following effects are very rare (may affect up to 1 in 10,000 people), but if you suffer from any of the following at any time during your treatment **STOP TAKING THE TABLETS AND SEEK IMMEDIATE MEDICAL HELP:**

- Signs of serious allergic reaction such as difficulties in breathing or unexplained wheezing, dizziness or faster heartbeat, severe forms of skin reactions such as itchiness, skin rash with redness, peeling, flaking or blistering (e.g.: Steven-Johnson syndrome), swelling of your face, tongue and/or throat or shock.
- Signs of intestinal bleeding such as passing blood in your faeces (stools/motions), black tarry stools, vomiting blood or dark particles that look like coffee grounds.
- Indigestion or heartburn.
- Abdominal pain (pains in your stomach) or other abnormal stomach symptoms.
- Signs of aseptic meningitis (swelling of the protective membrane surrounding the brain) such as severe headache, high temperature, stiffness of the neck, nausea, vomiting, disorientation, or intolerance to light. Patients with autoimmune disorders (lupus, mixed connective-tissue disease) may be more likely to be affected.
- High blood pressure, heart failure or chest pain.
- Worsening of asthma and wheezing or difficulty breathing
- Liver, kidney problems or difficulty urinating.
- Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome.
- 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).

Ibuprofen AKTIV tablets, 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.

Other possible side effects

Uncommon: may affect up to 1 in 100 people

- Allergic reactions such as hives, skin rashes and itching.
- Feeling sick.
- Headache.

Rare: may affect up to 1 in 1,000 people

- Diarrhoea, wind, constipation and being sick.

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

- Reduction in blood cells, which can make the skin pale or yellow, cause fever, sore throat, mild mouth ulcers, flu-like symptoms, exhaustion or weakness, easy bruising, or bleeding from the skin or nose.
- Nervousness, visual disturbance, ringing in the ears and vertigo

- Ibuprofen have also been shown to sometimes worsen the symptoms of Crohn's disease or colitis.
- Yellowing of the skin or the whites of the eyes.
- Kidney problems: symptoms could include swelling of the ankles.
- Mouth ulcer.

Not known: frequency cannot be estimated from the available data

- 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 AKTIV tablets if you develop these symptoms and seek medical attention immediately. See also section 2.
- Medicines such as ibuprofen may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke.
- Skin becomes sensitive to light.

Reporting of side effects

If you get any side effect, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to the Center of Drug and Medical Technologies Expertise of MoH Armenia via www.pharm.am or you can call the hotline numbers (+374 10) 20 05 05, (+374 96) 22 05 05. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE Ibuprofen AKTIV

Keep out of the reach and sight of children.

Do not store above 25°C.

Do not use your medicine after the expiry date which is stamped on the pack. The expiry date refers to the last day of that month.

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

What Ibuprofen AKTIV contains

The active substance is ibuprofen.

Each Ibuprofen AKTIV film-coated tablet contains 400 mg of the active substance.

The other ingredients are: lactose monohydrate, maize starch, povidone, cellulose microcrystalline, dimeticone, croscarmellose sodium, silica colloidal anhydrous, talc, hypromellose, macrogol 6000, titanium dioxide, color azorubine 85 E 122, color cochineal red 80 E 124.

What Ibuprofen AKTIV looks like and contents of the pack

Ibuprofen AKTIV 400 mg are uniform, round, biconvex, shiny purple film-coated tablets.

Pack size:

Box of 30 film-coated tablets of 400 mg in blisters.

Dispensing status

Over the counter medicine (OTC).

Marketing Authorisation Holder and Manufacturer:

Marketing Authorisation Holder: ESCULAP Ltd.-Armenia, 17/2, 1 block, Davidashen, 0054, Yerevan, Armenia

Manufacturer: REPLEK FARM Ltd. Skopje, 188 Kozle str., 1000 Skopje, Republic of North Macedonia

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