

PACKAGE LEAFLET: INFORMATION FOR THE USER

Ibuprofen AKTIV (Ibuprofen) **100 mg/5 ml syrup**

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:

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

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

Ibuprofen AKTIV syrup belong to a group of medicines called anti-inflammatory pain killers. It 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.

Ibuprofen AKTIV syrup can also be used to treat other painful conditions such as toothache, pain after operations, period pain and headache, including migraine. It can also be used for the short term treatment of fever in children over the age of 1 year.

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).
- have had an allergic reaction or wheezing after taking aspirin or other non-steroidal anti-inflammatory painkillers (Symptoms of a rare allergic reaction are given under section 4: Possible side effects).
- have ever had a stomach ulcer or a history of bleeding into, or perforation of, the intestine especially after previous NSAID treatment (symptoms may include severe stomach pain or vomiting blood that contains dark particles).
are taking any other non-steroidal anti-inflammatory painkillers (NSAIDs).
- have ever had severe kidney, heart or liver problems.

If any of these apply, ask for advice from a doctor or pharmacist before taking this medicine.

Warnings and precautions

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. Stop using Ibuprofen AKTIV 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 and contact immediately your doctor or medical emergencies if you notice any of these signs.

There is a risk of renal (kidney) impairment in dehydrated children.

If you are taking Ibuprofen AKTIV 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).

You should discuss your child's treatment with your doctor or pharmacist before giving Ibuprofen AKTIV if your child:

- has high blood pressure, kidney or liver problems,
- has asthma or diabetes,
- has lupus or a mixed connective tissue disease,
- has a chronic inflammatory intestinal disease such as ulcerative colitis or Crohn's disease or gastrointestinal bleeding,
- has chickenpox,
- has an infection - please see heading "Infections" below.

If you are an **adult** taking this product

The above warnings and information apply, and in addition the following also applies:

- **Do NOT** take this product if you are taking aspirin at doses above 75 mg daily. If you are on low dose aspirin (up to 75 mg daily) speak to your doctor or pharmacist before you take this product.

- Anti-inflammatory/pain-killer medicines like ibuprofen may be associated with a small increased risk of heart attack ('myocardial infarction') or stroke, particularly when used at high doses. Do not exceed the recommended dose or duration of treatment.

- Do not take if you are in the **last three months** of pregnancy.

Speak to your doctor or pharmacist before taking:

- If you are in the **first six months** of pregnancy.
- If you are elderly.
- If you are trying to get pregnant. Ibuprofen belongs to a group of medicines which may **impair fertility** in women. This effect is reversible on 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 becoming pregnant.
- If you have heart problems including heart failure, angina (chest pain), or if you have had a heart attack, bypass surgery, 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').
- If you have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker.

Infections

Ibuprofen AKTIV may hide signs of infections such as fever and pain. It is therefore possible that Ibuprofen AKTIV 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.

The use of painkillers for a long period of time has been linked to headaches in some patients, a condition called medication overuse headache (MOH). 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 AKTIV. Tell your doctor if you have been having headaches while taking this medicine.

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

Pregnancy and breast-feeding

Do not take Ibuprofen AKTIV syrup 20 mg/ml if you 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 syrup 20 mg/ml 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 syrup 20 mg/ml 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.

Driving and Using Machines

Ibuprofen AKTIV syrup may make you feel dizzy or drowsy. If it affects 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

The syrup contains the following ingredients for which you should be warned:

- methyl parahydroxybenzoate and propyl parahydroxybenzoate, which may cause allergic reactions (possible delayed reactions).
- small amounts of glycerol. In high doses, glycerol may sometimes cause headache, stomach upset and diarrhoea.
- sorbitol, so if you have been told by your doctor that you have an intolerance to some sugars, before you use this medicine contact your doctor. Also, sorbitol may have a mild laxative effect. Caloric value is 2.6 kcal / g of sorbitol.
- propylene glycol, which can cause symptoms similar to the effects of alcohol.
- 63 vol% ethanol (alcohol). Each measured teaspoon (5 ml) contains 300 mg of alcohol, corresponding to 6.04 ml beer and 2.54 ml wine. Harmful for those suffering from alcoholism. Should be taken into account when the medicine is given to pregnant women or nursing mothers, children and high risk groups such as patients with liver damage or epilepsy.
- color sunset yellow E 110, which may cause allergic reactions.
- saccharin sodium is a synthetic sweetening agent. If you have been told by your doctor that you have some hypersensitivity reactions (mainly dermatologic) and photosensitivity reactions with saccharin, before you use this medicine contact your doctor. Cross reactions between saccharin and sulphonamides have been demonstrated therefore it should be avoided in children with sulphonamide allergy. The group ADI (acceptable daily intake) for saccharin and its salts is 0-5 mg/kg.

3. HOW TO TAKE Ibuprofen AKTIV

ALWAYS take Ibuprofen AKTIV syrup 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 with or after food.

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).

DOSAGE:

Adults, the elderly and children over 12 years: The recommended dose is 200 mg-400 mg (10-20 ml), up to three times a day as required. Leave at least four hours between doses and do not take more than 1200 mg (60 ml) in any 24 hour period.

Children: Ibuprofen should NOT be taken by children weighing less than 7 kg. When used to treat fever, the syrup should not be used long term or given to children under the age of 1 year.

The usual dose in children is 20 mg per kg of bodyweight each day, in divided doses. This can be given as follows:

1-2 years: One 2.5 ml (50 mg) dose three/four times a day

3-7 years: One 5 ml (100 mg) dose three/four times a day

8-12 years: Two 5 ml (200 mg) doses three/four times a day

The doctor may choose to increase this dose in children with juvenile rheumatoid arthritis.

This dose should not exceed 40mg/kg bodyweight daily in divided doses.

If you take more Ibuprofen AKTIV than you should

If you have taken more Ibuprofen AKTIV syrup 20 mg/ml 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. Never double up on a 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 should STOP giving Ibuprofen and seek advice from your doctor if your child experiences a very rare allergic reaction, including skin rashes, increased sensitivity to light, swelling of the face and tongue, inflammation of the blood vessels, fever or shock. Skin and mucous membrane reactions may also occur.

If your child suffers from the following, stop giving the medicine and seek immediate medical help:

- Passing blood in their faeces (stools/motions).
- Passing black tarry stools.
- Vomiting blood or dark particles that look like ground coffee.
- Stiff neck, intolerance to bright light, headache, nausea, vomiting, fever and disorientation.
- 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).
- Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome.

If your child experiences any of the following, stop giving the medicine and tell your doctor immediately:

- Unexplained stomach pain, indigestion, heartburn, feeling sick and/or vomiting.
- Unexplained wheezing, shortness of breath, skin rash (which may be severe and include blistering or peeling of the skin), itching or bruising, light-headedness, racing of the heart or fluid retention e.g. swollen ankles, not passing enough urine
- Loss of vision, blurred or disturbed vision (visual impairment) or seeing/hearing strange things (hallucinations)
- Yellowing of the eyes and/or skin.
- Severe sore throat with high fever or unexplained bleeding, bruising and tiredness.
- Liver, kidney problems or difficulty urinating.

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

This medicine 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: sore throat with high fever, mouth ulcers, flu-like symptoms, bleeding from the mouth, nose, ear and the skin.

Ibuprofen AKTIV, 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.

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.

Crohn's disease or ulcerative colitis or other stomach problems may be exacerbated.

Other unusual effects may include:

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

- Feeling dizzy or tired.
- Flatulence, diarrhoea, 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):

- Drowsiness.
- Anxiety.
- Feeling a tingling sensation or 'pins and needles'.
- Insomnia.
- Hives.
- Skin becomes sensitive to light.
- Hearing impairment.
- 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 ulcer.

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):

- Skin becomes sensitive to light.
- Fixed drug rash, which may progress to generalised blistering lesions.

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 ingredient in Ibuprofen AKTIV syrup is ibuprofen. Each 5 ml spoonful of Ibuprofen syrup contains 100 mg ibuprofen.

The other ingredients are: methyl parahydroxybenzoate, propyl parahydroxybenzoate, glycerol, benzalkonium chloride, sorbitol liquid 70% (non crystallising), saccharin sodium, propylene glycol, citric acid, sodium citrate, polysorbate 60, cellulose microcrystalline and carboxymethyl cellulose sodium, xantan gum, color sunset yellow E 110, aroma orange 2808 N/A, ethanol 96%, water purified.

What Ibuprofen AKTIV looks like and contents of the pack

Ibuprofen AKTIV syrup is fine, viscous, orange suspension, with characteristic fruity orange odor and bitterly-sweet taste.

Pack size:

Box with bottle of 100 ml syrup.

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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