

PACKAGE LEAFLET: INFORMATION FOR THE USER

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

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to use it carefully to get the best results.

Keep this leaflet. You may need to read it again.

Ask your doctor or pharmacist if you need more information or advice.

You must contact a doctor if your symptoms worsen or do not improve.

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1. WHAT IS Ibuprofen AKTIV 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. WHAT SHOULD YOU KNOW BEFORE TAKING Ibuprofen AKTIV?

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

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

Do not take Ibuprofen AKTIV 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 liver or kidney disease?
- Do you suffer from heart disease?

Medicines such as Ibuprofen AKTIV 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 might be at risk of these conditions (e.g. if you have high blood pressure, diabetes, high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist.

- Do you have systemic lupus erythematosus (SLE, sometimes known as lupus) or a connective tissue disease (autoimmune diseases affecting connective tissue)?
- Have you been told by your doctor that you have an intolerance to some sugars?

Can you take Ibuprofen AKTIV 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),
- 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),
- Gingko biloba herbal medicine (there is a chance you may bleed more easily if you are taking this with ibuprofen).

Other information about Ibuprofen AKTIV syrup:

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.

Pregnancy and breast-feeding

The use of Ibuprofen AKTIV whilst pregnant or breast feeding should be avoided.

Ibuprofen AKTIV 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

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.

3. HOW SHOULD YOU TAKE Ibuprofen AKTIV syrup?

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.

DOSAGE:

Adults - The usual dosage is 4 to 6 spoonfuls (5 ml) taken three times a day. Your doctor may choose to increase or decrease this depending on what you are being treated for, but no more than 24 spoonfuls (120 ml/2400 mg) should be taken in one day.

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 PRESCRIBED

(AN OVERDOSE) you should contact a doctor or go to the nearest hospital casualty department **IMMEDIATELY** taking your syrup with you.

IF YOU FORGET TO TAKE YOUR 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 OF IBUPROFEN AKTIV

As with all medicines, Ibuprofen AKTIV 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 syrup for the shortest amount of time necessary to control your symptoms.

If you suffer from any of the following at any time during your treatment **STOP TAKING** Ibuprofen AKTIV syrup and *seek immediate medical help*:

- Severe headache, high temperature, stiffness of the neck or intolerance to light,
- Pass blood in your faeces (stools/motions),
- Pass black tarry stools,
- Vomit any blood or dark particles that look like coffee grounds.

TELL YOUR DOCTOR AND STOP TAKING THE SYRUP 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,
- Yellowing of the eyes and/or skin,

- Severe sore throat with high fever,
- Blurred or disturbed vision or seeing/hearing strange things,
- Fluid retention (e.g. swollen ankles).

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

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

Very rarely ibuprofen may cause aseptic meningitis (inflammation of the protective membrane surrounding the brain).

Other unusual effects may include 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 and swelling and irritation inside the nose.

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

5. HOW SHOULD YOU 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 ABOUT Ibuprofen AKTIV

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 Macedonia

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