Package leaflet: Information for the user
Actiprofen 200mg tablets IBUPROFEN

Read all of this leaflet carefully before you start to take Actiprofen tablets because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any questions, or if you do not understand anything, ask your doctor or pharmacist.
- If you get any side effects, talk to your doctor or pharmacist. This included any possible side effects not listed in this leaflet.

IN THIS LEAFLET

1. WHAT ACTIPROFEN TABLETS ARE AND WHAT THEY ARE USED FOR

Actiprofen 200 mg tablets contain the active ingredient ibuprofen. Ibuprofen is an analgesic (pain reliever) and anti-inflammatory which relieves pain and eases stiffness. Actiprofen tablets are used for the short term management of mild to moderate pain associated with rheumatic and muscular pain, backache, nerve pain , migraine, headache, toothache, period pain, feverishness and symptoms of cold and flu.

You must talk to a doctor if you do not feel better or if you feel worse after 3 days, if you have a fever, or 10 days, for pain, at a time.

Patients aged 12 to 18 years should not use Actiprofen 200mg tablets for more than 3 days.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ACTIPROFEN TABLETS

Check before you take this medicine.
Do not take Actiprofen tablets:

- If you are allergic to ibuprofen or any of the other ingredients of Actiprofen tablets, aspirin or other pain relievers.
- If you are taking any other products containing ibuprofen or other NSAID medicines, including drugs known as COX-2 inhibitors.
- If you suffer from asthma.
- If you have had or are suffering from stomach ulcers, perforation or bleeding of the stomach or other stomach disorders.
- If it is to be administered to children under the age of 12.
- If you have severe liver, kidney or heart failure.
- If you are in the last 3 months of pregnancy.

Anti-inflammatory/pain-killer medicines like ibuprofen 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.

- **Ask your doctor before you take this medicine 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 attach "TIA").
- have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker.
- If you have a liver or kidney problem.
- If you have an infection – please see heading 'Infections' below.

- If you are elderly, as elderly people are more likely to experience unwanted effects with this medicine especially gastrointestinal bleeding and perforation which may be fatal.
- If you have a stomach disorder or have suffered in the past with stomach ulcers or bowel disease (e.g. ulcerative colitis or Crohn's disease) or have had recent stomach surgery.
- If you have a bleeding disorder or intracranial bleeding.
- If you have a previous history of allergic disease or nasal polyps
- If you have Systemic Lupus Erythematosus (SLE) or mixed connective tissue disorders a condition of the immune system resulting in joint pains, skin changes and disorders of other organs.
- If symptoms persist or if you develop any new symptoms unrelated to your original problem discontinue treatment and consult your doctor.
- If you are 12 to 18 years old and dehydrated, there is a risk of kidney problems.

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 taking Actiprofen and contact immediately your doctor or medical emergencies if you notice any of these signs.

Infections

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

During chicken pox (varicella) it is advisable to avoid the use of ibuprofen.

Serious skin reactions including exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrosis, drug reaction with eosinophilia and systemic symptoms (DRESS), acute generalized exanthematous pustulosis (AGEP) have been reported in association with Actiprofen treatment. Stop taking Actiprofen 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).

Keep out of sight and reach of children.

Can you take Actiprofen tablets with other medicines?

Some medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, ticlopidine), some medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta blockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan), or CYP2C9 inhibitors (such as voriconazole and fluconazole) may affect or be affected by treatment with ibuprofen. Talk to your doctor if you have been prescribed drugs for heart disease (cardiac glycosides) or to remove excess water from the body (diuretics), to treat depression (lithium or selective serotonin reuptake inhibitors (SSRIs)), to suppress the immune system (e.g. cyclosporins, corticosteroids, methotrexate), to treat certain infections (aminoglycoside antibiotics e.g. streptomycin and quinolones), to treat gout (probenicid), to treat diabetes (sulfonureas e.g. glibenclamide), to treat HIV (such as zidovudine), or to treat arthritis or other inflammatory conditions (non steroidal anti-inflammatories) or antiplatelet agent (aspirin).

Some other medicines may also affect or be affected by the treatment of Actiprofen tablets. You should therefore always seek the advice of your doctor or pharmacist before you use Actiprofen tablets with other medicines.

Pregnancy, breast feeding and fertility

If you are pregnant or think you may be pregnant or are planning to have a baby, ask your pharmacist for advice before taking this medicine.

Do not take Actiprofen if you are in the last 3 months of pregnancy as it could harm your unborn child or cause problems at delivery. Ask your doctor or pharmacist for advice before taking Actiprofen tablets if you are in the first six months of your pregnancy or you are breastfeeding. Actiprofen 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 Actiprofen during the first 6 months of pregnancy unless absolutely necessary and advised by your doctor. If taken for more than a few days from 20 weeks of pregnancy onward,

Actiprofen can cause kidney problems in your unborn baby that may lead to low levels of amniotic fluid that surrounds the baby (oligohydramnios) or narrowing of a blood vessel (ductus arteriosus) in the heart of the baby. If you need treatment for longer than a few days, your doctor may recommend additional monitoring.

Ibuprofen belongs to a group of medicines called NSAIDs which may impair fertility in women. This effect is reversible on stopping the medicine. You should inform your doctor if you are planning to become pregnant or if you have problems in becoming pregnant. If you need treatment while you are trying to get pregnant, the lowest dose for the shortest time possible should be used.

Driving and using machines
Actiprofen may make you feel drowsy or dizzy. You should not drive or operate machinery until you know how they affect you.

Important information about some of the ingredients of Actiprofen tablets
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before you take Actiprofen tablets as they contain lactose. Actiprofen tablets also contain carmosine (E122) in the print ink which may cause allergic reactions.

3. HOW TO TAKE ACTIPROFEN TABLETS

Adults, elderly and children 12 years and over:
Take two tablets with water, then if necessary 1-2 tablets every 4 – 6 hours. Do not take more than 6 tablets in a 24 hour period. Do not give to children under the age of 12 unless your doctor tells you to.

Do not take more than the stated dose.

Do not take more frequently than every 4 – 6 hours.
Do not use with other ibuprofen or other NSAID containing products.

Should be taken preferably with or after food.
This product should be taken at the lowest dose for the shortest time necessary to relieve your symptoms, especially in the elderly.
If you have an infection, consult a doctor without delay if symptoms (such as fever and pain) persist or worse (see section 2).
If symptoms persist or worsen or if the product is required for more than 3 days for fever and 10 days for pain, please consult your doctor.

For children 12 to 18 years, if this medicine is required for more than 3 days, or if symptoms worsen please consult your doctor.

NSAIDs should be used with particular caution in elderly patients who are more prone to adverse events.

If you take more Actiprofen than you should

If you take more tablets than you should or if children have taken the medicine by accident always consult a doctor or nearest hospital to get an opinion of the risk and advice on action to be taken.

Bring any remaining tablets with you to show your doctor.

The symptoms of overdose can include nausea, stomach pain, vomiting (may be blood streaked), gastrointestinal bleeding, diarrhoea, headache, ringing in the ears, confusion and shaky eye movement. Also, agitation, sleepiness, disorientation or coma may occur. Occasionally patients develop seizures. At high doses, drowsiness, chest pain, palpitations, loss of consciousness, seizures (mainly in children), weakness and dizziness, blood in urine, altered levels of potassium in your blood, cold body feeling, and breathing problems have been reported. It may also lead to an increase in acidity in your blood. Further, the blood clotting time (prothrombin time/INR) may be prolonged, probably due to interference with the actions of circulating clotting factors. Acute

kidney failure and liver damage may occur. An asthma flare-up is possible in asthmatics. Furthermore, there may be low blood pressure and reduced breathing.

If you forget to take Actiprofen tablets
Take your normal dose as soon as you remember.
Do NOT take a double dose to make up for forgotten tablets. You must allow at least 4-6 hours between doses.

If you have any further questions about 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.

Will Actiprofen tablets suit you?
Side effects are unlikely but occasionally abdominal pain, nausea (feeling sick), vomiting (being sick), indigestion, diarrhoea, flatulence, constipation, drowsiness, dizziness, headache, blurred vision or hearing disturbances may occur. Ibuprofen may be associated with a small increased risk of heart attack or stroke. The risk is more likely with high doses and prolonged treatment. Taking any type of pain reliever for headaches for a long period of time can make them worse. If this situation is experienced or suspected, stop taking this medicine and talk to your doctor.

Stop taking this medicine and tell your doctor immediately if:
- you experience an allergic reaction such as skin rashes and itching, sometimes with breathing problems or swelling of the lips, tongue, throat or face.
- you experience a skin rash or peeling, or mouth ulcers. 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).
- Your skin becomes sensitive to light - frequency unknown
- you experience worsening of your asthma.
- you develop a stomach ulcer, vomit either blood or brown grit (like coffee grounds) or pass black tarry stools.
- your existing bowel disease (ulcerative colitis or Crohn's disease) worsens.
- you experience unexplained bruising or bleeding, fever, sore throat, mouth ulcers, extreme pallor or weakness.
- you have an existing auto-immune disorder (e.g. systemic lupus erythematosus, mixed connective tissue disease) and develop a stiff neck, headache, nausea, vomiting, fever or feel disorientated.
- you pass less or more urine than normal, your urine is cloudy, there is blood in your urine, or you experience pain in the back and/or swelling (particularly of the legs).
- you experience breathlessness and/or swelling of legs or feet, which can potentially be a sign of heart failure.
- you experience liver failure or liver problems including hepatitis or jaundice, symptoms could include yellowing of the skin and whites of the eyes.
- you experience visual disturbances
- you experience 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].
- you experience widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome).
- you experience a red, scaly widespread rash with bumps under the skin and blisters mainly localised on the skin folds, trunk, and upper extremities accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis).
- you experience chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome.
- you experience inflammation of the stomach (gastritis).
- your abdomen becomes abnormally swollen.
- you experience nervousness (feeling restless, tense, or anxious)
- you get the sensation of feeling dizzy or spinning (vertigo).
- you get a high blood pressure (hypertension).

Rarely, perforation or gastrointestinal bleeding can develop, which may be fatal, particularly in the elderly.

These side effects are more likely to occur with increasing dose and duration of use.

Taking any type of pain reliever for headaches for a long period of time can make them worse. If this situation is experienced or suspected, stop taking this medicine and talk to your doctor.

If you get these or any other unusual effects, stop taking Actiprofen tablets and talk to your doctor or pharmacist.

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. You can also report side effects directly via the HPRA Pharmacovigilance Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE ACTIPROFEN TABLETS

Keep all medicines out of reach and sight of children.

Do not use this medicine after the expiry date (EXP) which is stated on the outer carton and blisters. The expiry date refers to the last day of that month. Do not store above 25°C.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Actiprofen tablets contain
Each film-coated tablet contains the active ingredient Ibuprofen 200mg. The tablets also contain lactose monohydrate, microcrystalline cellulose, maize starch, croscarmellose sodium, magnesium stearate and silicon dioxide. The film coat contains hypromellose and triacetin. The print dye contains carmoisine (E122).

What is in the pack?
Actiprofen are white capsule-shaped tablets with flat edges printed with the name 'Actiprofen' in red on one face. Actiprofen tablets come in a push-through blister strip containing 12 tablets. Two blister strips are packed in the carton. They are available in packs of 4, 6, 12, 24, 48, 96 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
The Product Authorisation holder is:
Haleon Ireland Limited,
12 Riverwalk,
City West Business Campus,
Dublin 24,
Ireland

Manufactured by:
Haleon Ireland
Dungarvan
Limited,
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