

PATIENT LEAFLET: INFORMATION FOR THE USER**Flurbiprofen 50 mg or 100 mg Tablets
Flurbiprofen**

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.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet (See section 4).

What is in this leaflet

1. What Flurbiprofen is and what it is used for
2. What you need to know before you take Flurbiprofen
3. How to take Flurbiprofen
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1. What Flurbiprofen is and what it is used for

The name of your medicine is Flurbiprofen 50 mg or 100 mg Tablets. The active ingredient is Flurbiprofen.

Flurbiprofen belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). It can be used to relieve pain and inflammation (redness, heat and swelling) in conditions such as:

- osteoarthritis (a bone disorder, which is seen mostly in older persons, in which the joints become painful and stiff)
- rheumatoid disease (inflammation of the joints and sometimes surrounding tissues)
- ankylosing spondylitis (arthritis of the spine)
- swollen joints, frozen shoulder, bursitis (inflammation of the bursa), tendinitis (inflammation of tendons), tenosynovitis (inflammation of the covering layer of a tendon)
- low back pain, sprains and strains.

Flurbiprofen can also be used to treat other painful conditions such as toothache, pain after operations, period pain and migraine.

2. What you need to know before you take Flurbiprofen**Do not take this medicine if:**

- You are sensitive (allergic) to any of the ingredients in the tablets listed in Section 6. Ingredients known to cause allergic reactions are also listed at the end of this section.
- You currently have a peptic ulcer (ulcer in your stomach or duodenum), ulcerative colitis, Crohn's disease or bleeding in your stomach, or have had two or more episodes of peptic ulcers, stomach bleeding or rupture in the past.
- You suffer from asthma or you have ever had an allergic reaction or suffered from wheezing after taking flurbiprofen, ibuprofen, aspirin or other anti-inflammatory pain killers.
- You are in the last trimester (last 3 months) of pregnancy.
- You have been told by your doctor that you have **severe** heart failure, liver failure or kidney failure.
- You currently have acute dehydration.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking this medicine if you:

- Are pregnant, planning to become pregnant or breastfeeding. Flurbiprofen 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.
- Have systemic lupus erythematosus (SLE, sometimes known as lupus) or a connective tissue disease (autoimmune diseases affecting connective tissue)
- Suffer from liver or kidney disease or if you have ever been told you have liver or kidney disease
- Suffer from heart problems or if you have you ever been told that you have heart problems.
- are elderly as you may be more prone to stomach/intestinal bleeding and damage to intestine.
- you have an infection - please see heading 'infections' below.

Infections

Non-steroidal anti-inflammatory drugs (NSAIDs) may hide signs of infections such as fever and pain. This may delay appropriate treatment of infection, which may lead to an increased risk of complications. If you take this medicine while you have an infection and your symptoms of the infection persist or worsen, consult a doctor or pharmacist without delay.

Do not give this medicine to children under 12 years.

Medicines such as Flurbiprofen 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.

- Have been diagnosed with a condition that affects the time it takes your blood to clot
- Have been told by your doctor that you have an intolerance to some sugars.

Other medicines and Flurbiprofen

Tell your doctor or pharmacist if you are taking, have recently taken or might take any of the following medicines:

- diuretics (known as water tablets e.g. furosemide, spironolactone)
- cardiac glycosides (medicines used for heart conditions, such as digoxin)
- ACE inhibitors (e.g. captopril) or Angiotensin II antagonists (e.g. losartan). These medicines are used to treat high blood pressure
- anti-coagulants (to prevent blood clots e.g. warfarin)
- lithium (used to treat depression)
- zidovudine (an anti-viral drug)
- methotrexate (used to treat certain cancers)
- ciclosporin and tacrolimus (immunosuppressants used to dampen down your immune response)
- medicines known as corticosteroids (used in the treatment of inflammatory diseases e.g. prednisolone, dexamethasone, hydrocortisone)
- anti-depressant medication known as selective serotonin reuptake inhibitors (SSRIs) (e.g. fluoxetine and paroxetine)
- antibiotics called quinolones (such as ciprofloxacin)
- aminoglycosides (a type of antibiotic e.g. streptomycin and gentamicin)
- mifepristone (now or in the last 12 days)
- any other anti-inflammatory pain killers, including aspirin and the group of drugs known as COX-2 inhibitors e.g. celecoxib, lumiracoxib.

Pregnancy, breast feeding and fertility

- The use of Flurbiprofen whilst pregnant or breast-feeding should be avoided.
- Do not take Flurbiprofen 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 Flurbiprofen 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. If taken for more than a few days from 20 weeks of pregnancy onward, Flurbiprofen 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.
- If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
- This medicine is not recommended in women attempting to conceive or are undergoing investigation of infertility.

Driving and Using Machines

Flurbiprofen may make you dizzy, drowsy, confused, tired and/or affect your vision. If any of these apply to you do not drive, operate machinery or take part in activities where these effects may put you or others at risk.

Other information about Flurbiprofen Tablets

Your doctor may give you another medicine to be taken with Flurbiprofen tablets to help protect your stomach, if they think you are at risk of getting a stomach ulcer or bleeding in your stomach.

If you take a painkiller for headaches for a prolonged length of time, it can make them worse.

Avoid alcohol intake while taking Flurbiprofen, since this may increase the risk of bleeding in the stomach and intestines.

Stop taking this medicine at the first appearance of skin rash, mucosal wounds, or any other sign of allergies.

Flurbiprofen Tablets contain Sunset yellow FCF (E110), Sugar and Sodium

- Flurbiprofen tablets contain sunset yellow FCF (E110) which may cause allergic reactions.
- Also contains sucrose, glucose and lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product

Information on sodium content

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium free'.

Check with your doctor if you know you are allergic to any of the ingredients.

3. How to take Flurbiprofen

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Take your Flurbiprofen tablets with or after food with a glass of water.

Dosage:

Adult -The usual daily dose is 150 to 200 mg, spread throughout the day.

If you are taking Flurbiprofen 50mg this will be three or four times a day. If you are taking Flurbiprofen 100mg this will be one or two tablets a day. Sometimes a mixture of the two strengths of tablet will be prescribed.

The dose may be increased by your doctor to a maximum of 300 mg a day.

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Period Pain -At the start of the symptoms, 100 mg followed by 50 mg or 100 mg every 4 to 6 hours. The maximum dose is 300 mg a day.

Elderly -Some elderly patients may be more prone to stomach/intestinal bleeding and damage to intestine. Your doctor will take this into account when deciding the dose you will need and may monitor you for side effects.

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

If you forget to take your Flurbiprofen tablets, 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 double dose to make up for a forgotten dose.

If you take more Flurbiprofen tablets than you should, contact a doctor or go to the nearest hospital casualty department **immediately** and take your tablets with you.

You may experience symptoms like headache, nausea, vomiting, upper abdominal pain, stomach/intestinal bleeding, diarrhoea (rarely), confusion, excitation, coma, drowsiness, dizziness, ringing in ears, pass out, fits (rarely).

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets 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.

If you suffer from any of the following at any time during your treatment stop taking Flurbiprofen and seek immediate medical help:

- Severe headache, high temperature, stiffness of the neck or intolerance to bright light
- Pass blood in your faeces (stools/motions)
- Pass black tarry stools
- Vomit any blood or dark particles that look like coffee grounds.
- Swelling of the face, lips or tongue, unexplained wheezing, shortness of breath or skin rash (anaphylactic reactions).
- Severe skin reactions such as blistering of the skin, mouth, eyes and genitals (symptoms of some severe skin conditions that may occur rarely with Flurbiprofen).

Tell your doctor immediately and stop taking the tablets if you experience:

- Unexplained stomach pain or other abnormal stomach symptoms, indigestion, heartburn, feeling sick and/or vomiting.
- Increased bruising or bleeding, fever, sore throat, mouth ulcers, tiredness and a tendency to get infections (symptoms of blood disorders that may occur rarely with Flurbiprofen).
- Yellowing of the eyes and/or skin. This is a sign that your liver may not be working properly. You may also experience symptoms such as tiredness, flu-like symptoms, poor appetite/loss of appetite and pain in your abdomen (just under your ribs).
- Tiredness, swelling or puffiness in the face, abdomen, thighs or ankles, passing less urine or problems urinating and back pain (symptoms of kidney problems that may occur rarely with Flurbiprofen).
- Severe headache and/or blurred or disturbed vision (which may be due to an increase in your blood pressure) or seeing/hearing strange things.

Flurbiprofen has sometimes been associated with heart failure. This is when your heart does not function as well as it should. Symptoms can include tiredness and a lack of energy, breathlessness and swelling of the legs due to a build up of fluid.

Medicines such as Flurbiprofen may be associated with a small increased risk of heart attack (myocardial infarction) or stroke. Very rarely Flurbiprofen may cause aseptic meningitis (inflammation of the protective membrane surrounding the brain).

Other side effects which have also been reported may include:

Common (may affect up to 1 in 10 people)

- Headache, dizziness
- Indigestion, nausea, vomiting, diarrhoea, constipation, wind
- Tiredness, malaise (a general feeling of being unwell)
- Raised levels of liver enzymes in the blood
- Fluid retention

Uncommon (may affect up to 1 in 100 people)

- Anaemia (decreased amount of red blood cells)
- Allergic reaction
- Tingling or numbness in the hands or feet (paraesthesia)
- Ringing in the ears (tinnitus)
- Unexpected sensitivity of the skin to the sun
- Skin rash, itching, purpura (red or purple spots on the skin)
- Visual impairment, vertigo
- Asthma
- Mouth ulcers, stomach and lower gut ulcers
- Gastritis (inflammation, irritation or swelling of the stomach lining)
- Swelling (oedema)

Rare (may affect up to 1 in 1000 people)

- Depression, confusion
- Somnolence (feeling very sleepy)
- Insomnia (having difficulty with sleeping)
- Bronchospasm (difficulty in breathing or wheezing)
- kidney damage

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

- Hallucinations
- Inflammation of the pancreas
- Increase in blood clotting time
- Decrease in blood cell count (feeling tired, increased risk of bleeding or bruising, weakness, short of breath, increase in infections, fever, confusion, abnormal paleness)

Other effects which have been but for which the frequency is not known may include:

- Optic neuritis (inflammation of the optic nerve)
- Inflammation of kidney (glomerulonephritis)
- Worsening of colitis or Crohn's disease
- Hepatitis

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 Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Flurbiprofen

- Keep this medicine out of the sight and reach of children
- Do not use this medicine after the expiry date (EXP) which is stated on the carton. The expiry date refers to the last day of that month.
- Store in the original package
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Flurbiprofen tablets contain

- The active substance is flurbiprofen. Each coated tablet contains 50mg or 100mg Flurbiprofen.
- Sucrose, Lactose anhydrous, Maize starch, Titanium dioxide, Povidone, Liquid glucose, Magnesium stearate, Stearic acid, Colloidal silica dioxide, French chalk for tablets, Opalux ASF 2230 Yellow (contains Quinolone yellow Al Lake (E104), Sunset yellow FCF Al Lake (E110), Sodium benzoate), Sandarac tablet varnish, Carnauba wax powder.

What Flurbiprofen tablets look like and contents of the pack.

- Flurbiprofen 50mg and 100mg Tablets are yellow, sugar coated tablets smooth in texture with a polished surface.
 - The 50mg strength is available in packs of 10, 20, 100 or 500 tablets.
 - The 100mg strength is available in packs of 10, 30, 100 or 500 tablets.
- Not all pack sizes may be marketed.

Marketing Authorisation Holder

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Flurbiprofen 100mg Tablets; PL 17907/0325

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