

Package Leaflet:  
Information for the Patient

Flurbiprofen 50 mg  
Coated Tablets  
Flurbiprofen 100 mg  
Coated Tablets

Flurbiprofen



**IMPORTANT INFORMATION**

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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**

1. What Flurbiprofen Coated Tablets are and what they are used for
2. What you need to know before you take Flurbiprofen Coated Tablets
3. How to take Flurbiprofen Coated Tablets
4. Possible side effects
5. How to store Flurbiprofen Coated Tablets
6. Contents of the pack and other information

**1. What Flurbiprofen Coated Tablets are and what they are used for**

Flurbiprofen Coated Tablets belong to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). They 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 Coated Tablets can also be used to treat other painful conditions such as toothache, pain after operations, period pain and migraine.

The active substance in Flurbiprofen Coated Tablets is flurbiprofen. Flurbiprofen 50 mg Coated Tablets contains 50 mg of flurbiprofen and Flurbiprofen 100mg Coated Tablets contains 100 mg of flurbiprofen.

**2. What you need to know before you take Flurbiprofen Coated Tablets**

**Do not take Flurbiprofen Coated Tablets:**



- If you are sensitive (allergic) to any of the ingredients in the tablets. These are listed in Section 6. Ingredients known to cause allergic reactions are also listed at the end of this section.
- If you have, or have had 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 perforation in the past.
- If 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.

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Description		Flurbiprofen_100mg_50mg_100		Date: 01 Nov 23	Time: 02:20
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- If you are in the last trimester (last 3 months) of pregnancy.
- If you have been told by your doctor that you have **severe** heart failure, liver failure or kidney failure.
- If you currently have acute dehydration.

**Warnings and precautions**

**Talk to your doctor or pharmacist before taking Flurbiprofen Coated Tablets**

- If you are pregnant or planning to become pregnant, or you are breastfeeding Flurbiprofen Coated Tablets 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.
- If you have systemic lupus erythematosus (SLE, sometimes known as lupus) or a connective tissue disease (autoimmune diseases affecting connective tissue).
- If you suffer from liver or kidney disease or have you ever been told you have liver or kidney disease.
- If you suffer from heart problems or have you ever been told you have heart problems. Medicines such as Flurbiprofen Coated Tablets 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.
- If you have you been diagnosed as having a condition that affects the time it takes your blood to clot
- If you have been told by your doctor that you have an intolerance to some sugars. **Please see “Flurbiprofen Coated Tablets contain glucose, sucrose and lactose”** at the end of this section.
- If you have an infection – please see heading “infections” below

**Other medicines and Flurbiprofen Coated Tablets**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. In particular, tell your doctor or pharmacist if you are taking 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
- 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. prednisone, dexamethasone, hydrocortisone)
- Anti-depressant medication known as selective serotonin reuptake inhibitors (SSRIs) (e.g. fluoxetine and paroxetine)
- Antibiotics called quinolones (such as ciprofloxacin)
- 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 Coated Tablets 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.

**Driving and using machines**

Flurbiprofen Coated Tablets may make you feel dizzy, drowsy or tired and/or you may have problems with your sight. If the tablets affect you in this way do not drive, operate machinery or do anything that requires you to be alert.

**Flurbiprofen Coated Tablets contain glucose, sucrose and lactose**

If you have been told by your doctor that you have an intolerance to some sugars you

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should check with your doctor before taking Flurbiprofen Coated Tablets.

**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.

**Other information about Flurbiprofen Coated Tablets:**

Your doctor may give you another medicine to be taken with Flurbiprofen Coated 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 Coated Tablets, since this may increase the risk of some side-effects listed in Section 4 .

**3. How to take Flurbiprofen Coated Tablets**

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



**Take your Flurbiprofen Coated Tablets** with or after food with a glass of water.

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).

**The recommended dose is:**

**Adult** -The usual daily dose is 150 to 200 mg, spread throughout the day. If you are taking Flurbiprofen 50 mg Coated Tablets this will be three or four times a day. If you are taking Flurbiprofen 100 mg Coated Tablets 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.

**Period Pain** - At the start of the symptoms, 100 mg (either two Flurbiprofen 50 mg Coated Tablets or one Flurbiprofen 100 mg Coated Tablet), 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 side effects. Your doctor will take this into account when deciding the dose you will need and may monitor you for side effects.

**Children** - Flurbiprofen Coated Tablets are **not** recommended for children.

**If you take more Flurbiprofen Coated Tablets than you should (an overdose)** you should

contact a doctor or go to the nearest hospital casualty department **immediately** and take your tablets with you.

**If you forget to take Flurbiprofen Coated 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 a double dose to make up for a forgotten tablet.

**4. Possible side effects**

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

**If you suffer from any of the following at any time during your treatment stop taking Flurbiprofen Coated 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.
- 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 Coated Tablets).

**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 Coated Tablets).
- 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 Coated Tablets).
- 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 Coated Tablets 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.



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Medicines such as Flurbiprofen Coated Tablets may be associated with a small increased risk of heart attack (myocardial infarction) or stroke. Very rarely Flurbiprofen Coated Tablets 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)
- Hypersensitivity
- 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)

**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)

**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)
- Stroke
- 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 at: [www.mhra.gov.uk/yellowcard](http://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 Coated Tablets**

Your tablets should be stored in a safe place out of the sight and reach of children, your medicine could harm them. Do not use this medicine after the expiry date which is stated on the carton after "Exp". The expiry date refers to the last day of the month.

Do not store above 25°C and keep in the original packaging.

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 Coated Tablets contains**

The active substance in Flurbiprofen 50 mg and 100 mg Coated Tablets is flurbiprofen.

The other ingredients are sucrose, lactose, talc, maize starch, titanium dioxide (E171), povidone, liquid glucose, magnesium stearate, stearic acid, colloidal silica, sandarac gum and carnauba wax.

**What Flurbiprofen Coated Tablets looks like and contents of the pack**

Flurbiprofen 50 mg and 100 mg Coated Tablets are white, sugar-coated tablets. Flurbiprofen Coated Tablets are available in packs containing 10,20,30,100 and 500 tablets.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder:**

Mylan products Limited  
20 Station Close,  
Potters Bar,  
Hertfordshire, EN6 1TL,  
United Kingdom

**Manufacturer:**

Delpharm L' Aigle  
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61300 L'Aigle Cedex  
France

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