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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.
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 dehydrations.

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 doses 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.

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 and 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. Flurbiprofen Coated Tablets should not be used in late (the last three months) pregnancy. If you are pregnant or breast-feeding, think the 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 should check with your doctor before taking Flurbiprofen Coated Tablets.

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 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.

**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, 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)
- Swelling of the face, lips or tongue, or skin rash.
- Indigestion, nausea, vomiting, diarrhoea, constipation, wind
- Pass black tarry stools
- Vomit any blood or dark particles that look like coffee grounds
- Fluid retention
- Tingling or numbness in the hands or feet (paraesthesia)
- 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 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.
- 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.

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)
### 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:**
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