**For adults and children & adolescents between 12 and 18 years:**
- Take one tablet with water up to three times a day as required.
- To be taken preferably with food.
- Leave at least 4 hours between doses.
- Do not take more than three tablets in any 24 hour period.
- Do not exceed the stated dose.

**Children under 12 years:**
- Not suitable for children under 12 years.

**If you have taken more medicine than you should, or if children have taken this medicine by accident, always contact a doctor or nearest hospital to get an opinion of the risk and advice on action to be taken.**
The symptoms can include nausea, stomach pain, vomiting (may be blood streaked), headache, ringing in the ears, confusion and shaky eye movement. At high doses, drowsiness, chest pain, palpitations, loss of consciousness, convulsions (mainly in children), weakness and dizziness, blood in urine, cold body feeling, and breathing problems have been reported.

## Possible side effects

As with all medicines, these tablets can have side effects in some people. The elderly are more likely to suffer such effects.

If you suffer from any of the following at any time during your treatment **STOP TAKING** the medicine and seek immediate medical help:
- Passing blood in your faeces (stools/motions).
- Passing black tarry stools.
- Vomiting any blood or dark particles that look like coffee grounds.
- Allergic reactions, which can include the following: bruising or facial swelling; swelling of the lips, throat and tongue causing difficulty swallowing or breathing; breathing problems, e.g. unexplained wheezing, shortness of breath, asthma or worsening of asthma; skin reactions, e.g. skin rashes, itching, urticaria (hives) which can be severe with blistering and peeling of the skin; rapid heart rate/palpitations, collapsing or low blood pressure. Seek medical help immediately.
- Severe skin reaction known as DRESS syndrome. Symptoms of DRESS include: skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cells) (frequency not known).
- 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) (frequency not known). See also section 2.

Like all medicines, this medicine can cause side-effects, although not everybody gets them. Tell your doctor or pharmacist if you notice any of the following:
- Liver, kidney problems or difficulty urinating

This medicine, especially when taken at higher than recommended doses or for a prolonged period of time, can cause damage to your kidneys and affect them removing acids properly from your blood into the urine (renal tubular acidosis). It can also cause very low levels of potassium in your blood (see section 2). This is a very serious condition and will require immediate treatment. Signs and symptoms include muscle weakness and light-headedness.

**STOP TAKING** the medicine and tell your doctor if you experience:
- Indigestion or heartburn.
- Abdominal pain (pain in your stomach) or other abdominal stomach symptoms.
- Blood disorders such as anaemia, low white blood cells, low platelet count, suppressed bone marrow function or reduction in granulocytes (a type of white blood cell) which could result in the following symptoms: unexplained bruising or bleeding, sore throat, mouth ulcers, fever, extreme paleness, weakness or exhaustion.
- Very rarely may cause blood in urine, kidney damage or kidney failure or liver problems such as hepatitis or jaundice (yellowing of the skin).
- There have been rare reports of aseptic meningitis, which can include symptoms such as headache, stiff neck, disorientation, fever and eye sensitivity to light, particularly in patients with existing auto-immune disorders such as Lupus. Seek medical help immediately.

The following side effects could also occur; tell your doctor if you experience these effects:
**Uncommon:** may affect up to 1 in 100 people:
- nausea and indigestion
- skin rashes

**Rare:** may affect up to 1 in 1,000 people
- diarrhoea, constipation, vomiting or flatulence

**Very rare:** may affect up to 1 in 10,000 people
- worsening of existing bowel disease (ulcerative colitis or Crohn's disease)

**Not known:** frequency cannot be estimated from the available data
- headache
- skin becomes sensitive to light

Medicines such as Cuprofen Maximum Strength Tablets may be associated with a small increased risk of heart attack (myocardial infarction) or stroke. Fluid retention (oedema), high blood pressure, and heart failure have also been reported.

If you are concerned about these effects, or if this medicine affects you in any other way, stop taking it 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 Yellow Card Scheme at: 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.

## How to store Cuprofen Maximum Strength Tablets

- Keep out if the sight and reach of children.
- Do not use after the expiry date shown on the label.
- Do not store above 25°C.
- If you find that you still have this medicine after its expiry date, return it to your local pharmacist who will dispose of it properly.

## What Cuprofen Maximum Strength Tablets contain

Each tablet contains 400 mg of the active ingredient Ibuprofen.
They also contain Lactose, Croscarmellose sodium, Methylcellulose,Magnesium stearate, Hypromellose, Talc, Titanium Dioxide, Erythrosine Aluminium Lake, Hydroxypropylmethyl Cellulose.

Cuprofen Maximum Strength Tablets are pink, film coated tablets, packed in blister packs of 12, 24, 48 and 96 tablets.

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Manufacturers:
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# Cuprofen *MAXIMUM STRENGTH TABLETS* Ibuprofen 400 mg

**PATIENT INFORMATION LEAFLET**

Please read this leaflet carefully before taking Cuprofen Maximum Strength Tablets.
- Keep this leaflet, you may wish to read it again.
- Ask your pharmacist if you need more information or advice.

## What are Cuprofen Maximum Strength Tablets and what are they used for?

Cuprofen Maximum Strength Tablets contain 400 mg of the active ingredient ibuprofen. Ibuprofen belongs to the class of medicines called non-steroidal anti-inflammatory agents which reduce pain, fever and inflammation.

Cuprofen Maximum Strength tablets are used for the relief of rheumatic, muscular, dental and period pains and pain in backache, neuralgia, migraine and headache, and for the symptomatic relief of colds, flu and feverishness.

## Before taking Cuprofen Maximum Strength Tablets

**Do not take if you...**
- are allergic to ibuprofen or to any other ingredient in this product, aspirin or other related painkillers. See 'What these tablets contain' for the full list of ingredients.
- have (or have had 2 or more episodes) a stomach ulcer, perforation or bleeding of the stomach.
- are taking aspirin at doses of above 75 mg daily. If you are on low-dose aspirin (up to 75 mg daily) speak to your doctor or pharmacist before you take these tablets.
- are taking other non-steroidal anti-inflammatory drugs (NSAIDs), as these may increase the risk of side effects.
- suffer from severe heart, kidney or liver failure.
- 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 this medicine 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, this medicine 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.

**Talk to your doctor or pharmacist if you...**
- are elderly.
- suffer or have suffered from asthma or allergic disease e.g. hayfever.
- suffer from a mixed connective tissue disease e.g. Systemic Lupus Erythematosus.
- have liver or kidney problems.
- have heart problems, previous stroke or think you might be at risk for these conditions (for example if you have high blood pressure, diabetes, high cholesterol or are a smoker).
- Cuprofen Maximum Strength Tablets belong to a group of medicines which may impair fertility in women. This effect is reversible on stopping the medicine. It is unlikely that Cuprofen Maximum Strength Tablets, used occasionally, will affect your chances of becoming pregnant, however, tell your doctor before taking this medicine if you have problems becoming pregnant.
- suffer from stomach or bowel problems, e.g. stomach ulcers or bleeding, ulcerative colitis, Crohn's disease.
- **have an infection.** This medicine may hide signs of infections such as fever and pain. It is therefore possible that this medicine 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.

**Skin reactions**
- Serious skin reactions have been reported in association with this medicine. You should stop taking this medicine and seek medical attention immediately, if you develop any skin rash, lesion 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.

## Take special care if you are taking...

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.
You should discuss your treatment with your doctor or pharmacist before taking Cuprofen 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 of feet due to narrow or blocked arteries), or any kind of stroke (including 'mini-stroke' or transient ischaemic attack 'TIA').
- have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker.
- There is a risk of renal impairment in dehydrated children and adolescents.
- If you are taking this medicine for longer than the recommended time or at higher than recommended doses you are at risk of serious harm. These include serious harm to the stomach/gut and kidneys, as well as very low levels of potassium in your blood. These can be fatal (see section 4).

**If you are pregnant or breast feeding...**
- Do not take this product if you are in the last 3 months of pregnancy.
- Speak to your doctor or pharmacist before taking this product if you are breast feeding.
- Speak to your doctor or pharmacist before taking this product if you are in the first 6 months of pregnancy.

**Important information about some of the ingredients...**
- This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, speak to your doctor before taking.
- This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

## Can you take Cuprofen Maximum Strength Tablets with other medicines?

**Cuprofen may affect or be affected by some other medicines. For example:**
- medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, ticlopidine)
- medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan)
- corticosteroids (e.g. prednisolone); selective serotonin re-uptake inhibitors (SSRIs); cardiac glycoside (e.g. digoxin); lithium; methotrexate; ciclosporin; mifepristone; tacrolimus; zidovudine or quinolone antibiotics (e.g. norfloxacine).

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

## How to take Cuprofen Maximum Strength Tablets

For oral use. This product is intended for short term use only. The lowest effective dose should be used for the shortest duration necessary to relieve symptoms. If you have an infection, consult a doctor without delay if symptoms (such as fever and pain) persist or worsen (see section 2). You must contact a doctor if your symptoms worsen or do not improve after 3 days for children and adolescents between 12 and 18 years and after 10 days for adults.

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