

Package leaflet: Information for the user

MELFEN 200mg FILM-COATED TABLETS MELFEN 400mg FILM-COATED TABLETS

Ibuprofen

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

What is in this leaflet

1. What Melfen is and what it is used for
2. What you need to know before you take Melfen
3. How to take Melfen
4. Possible side effects
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1. What Melfen is and what it is used for

Melfen Tablets contain the active substance ibuprofen, which belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). These medicines reduce pain and inflammation.

Melfen tablets are used:

For the treatment of arthritis (an inflammation of a joint that may cause swelling, redness and pain) and other conditions affecting the joints and muscles.

You must talk to a doctor if you do not feel better or if you feel worse.

2. What you need to know before you take Melfen

Do not take Melfen Tablets

- if you are allergic to ibuprofen or any of the other ingredients of this medicine (listed in section 6)
- if you previously suffered an allergic reaction (e.g. skin rash, runny nose or wheezing/breathlessness, swelling of the lips, face, tongue or throat) after taking aspirin or any other NSAIDs
- if you have an active peptic ulcer, which is an ulcer in your stomach or intestines, or bleeding in your stomach, or have had two or more episodes of peptic ulcers, stomach bleeding or perforation in the past
- if you have ever had stomach bleeding or perforation after taking ibuprofen, aspirin, or any other NSAIDs
- if you suffer from severe heart failure (the heart is unable to pump sufficient blood around the body)
- if you have severe liver or kidney problems
- if you are in the last three months of pregnancy
- if you are already taking another NSAID
- if you are under 12 years of age.

Warnings and precautions

Talk to your doctor or pharmacist before taking Melfen Tablets

- if you have had an ulcer or some other problem affecting your stomach or intestines in the past
- if you have stomach or intestinal problems (such as Crohn's disease or ulcerative colitis)
- if you have previously experienced stomach bleeding or perforation after taking ibuprofen or other NSAIDs
- if you have asthma or wheezing attacks (or if you have had asthma in the past)

- if you have any heart, liver or kidney problems
- if you have a bleeding disorder
- if you have a head injury, unexplained bleeding or raised intracranial pressure
- if you 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 heart problems including heart failure, angina (chest pain), or 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 attack ‘TIA’)
- if you are receiving regular treatment from your doctor
- if you suffer from a connective tissue disease such as Systemic Lupus Erythematosus (SLE) (Lupus)
- if you have chicken pox as it is advisable to avoid the use of Melfen 200mg and 400mg tablets.
- if you are taking painkiller medication and find that you still have frequent or daily headaches despite taking medication
- if you have an infection - please see heading “Infections” below.

Skin reactions

Serious skin reactions have been reported in association with Melfen treatment. You should stop taking Melfen 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.

Infections

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

Anti-inflammatory/pain-killer medicines such as Melfen may be associated with a small increased risk of heart attack (“myocardial infarction”) or stroke, particularly when used at high doses. Do not exceed the recommended dose or duration of treatment.

There is a risk of renal impairment in dehydrated children and adolescents.

Other medicines and Melfen

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Melfen may affect or be affected by the following medicines:

- **Medicines that are anticoagulant** tablets (i.e. thin blood/ prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, ticlopidine)
- **Selective serotonin reuptake inhibitors (SSRI’s)** (a medicine for depression) as these medicines may increase the risk of gastrointestinal side effects
- Medicines that reduce **high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan)**
- **Diuretics** (to make you pass more water)
- Medicines for the treatment of **heart failure** e.g. **digoxin**
- **Steroids**, e.g. **prednisolone**, which may be used to treat inflammatory conditions such as **arthritis** and **asthma**
- **Ciclosporin** or **tacrolimus** (to suppress the body’s immune system, e.g. following transplants or in diseases such as **psoriasis** or **rheumatoid arthritis**)
- **Lithium** (for certain mood disorders)
- **Methotrexate** (which can be used to treat certain **tumours** and other diseases including **psoriasis** and **rheumatoid arthritis**)
- **Antibiotics** such as **ciprofloxacin** or **ofloxacin** (known as quinolone antibiotics)

- Any other **NSAID** (such as **aspirin, diclofenac**), or COX-2 inhibitor
- **Aminoglycosides** (drugs used to **treat infections**)
- Medicines used to treat **gout (probenecid)**
- **Drugs** used in the treatment of **diabetes**
- **Zidovudine** (a medicine to treat HIV)
- **Mifepristone** (now or in the last 12 days)

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

Melfen with food, drink and alcohol

Melfen tablets should be taken with a drink of water, preferably after food. Alcohol may increase the risk of stomach irritation.

Pregnancy, breast-feeding and fertility

Ask your doctor or pharmacist for advice before taking any medicines. 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.

Pregnancy

Tell your doctor if you become pregnant during treatment with Melfen. Do not take Melfen 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 Melfen 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, Melfen 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.

Breast-feeding

Only small amounts of ibuprofen and its metabolites pass into breast-milk. This may be taken during breast-feeding if it is used at the recommended dose and for the shortest possible time.

Fertility

Melfen belongs to a group of medicines (NSAIDs) which may impair the fertility in women. This effect is reversible on stopping the medicine.

Driving and using machines

NSAIDs may sometimes cause symptoms such as drowsiness or dizziness which could make it unsafe to drive or use machines. If you notice any such symptoms, do not drive or operate machinery and ask your doctor or pharmacist for advice.

Melfen contains sodium

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

3. How to take Melfen

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

The recommended dose is:

Adults only

The recommended dose is 200mg or 400mg ibuprofen three times daily. If necessary, your doctor may prescribe a dose of up to 600mg ibuprofen three or four times daily.

Elderly

If you are elderly, your doctor may want to reduce the recommended adult dose and to check that the medicine is suiting you, especially during the first four weeks of treatment. Make sure to follow your doctor's instructions carefully and keep your appointment. Elderly patients are more prone to side effects such as stomach bleeding and perforation which may be fatal.

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 should not exceed the dose prescribed by your doctor.

Melfen tablets should be taken with a drink of water, preferably after food.

- Patients taking Melfen on a long-term basis, particularly older people, should be under regular supervision by their doctor.

If you take more Melfen Tablets than you should

If you have taken more Melfen Tablets 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. Bring the pack and any remaining tablets with you.

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.

If you forget to take Melfen Tablets

If you miss a dose, leave it out and take the next dose whenever it is due. Do not take a double dose to make up for a forgotten dose. After that, just carry on as before.

If you have any further questions on the use of 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. Side effects may be minimised by taking the lowest dose for the shortest time necessary to relieve the symptoms.

All medicines can cause allergic reactions, although serious allergic reactions are rare. Any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body), severe blistering or peeling of the skin should be reported to a doctor immediately.

STOP TAKING this medicine and tell your doctor if you experience:

- Persistent sickness, or feeling sick, heartburn, constipation or diarrhoea
- Abdominal pain, bringing up blood or passing black stools, sore mouth or swelling of the mouth or tongue
- Swelling of the ankles or any other parts of the body
- Passing too much or too little urine
- Yellowing of the skin or whites of the eyes
- Problems with your eyesight or noises in the ears
- Headaches, dizziness, drowsiness or feeling abnormally tired
- Tingling in the fingers or toes, or other odd sensations
- Feeling depressed or confused, or imagining things that are not really there

- An unexplained fever or persistent sore throat, bruising of the skin, or any signs of anaemia (such as faintness or feeling very tired)
- Skin irritation or rash due to sunlight.

Not known: frequency cannot be estimated from the available data

- A red, scaly widespread rash with bumps under the skin and blisters mainly localized on the skin folds, trunk, and upper extremities accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis). Stop using Melfen if you develop these symptoms and seek medical attention immediately. See also section 2.
- skin becomes sensitive to light

Medicines such as ibuprofen may be associated with a small increased risk of heart attack ('myocardial infarction') or stroke.

Other side effects include confusion, depression, dizziness and vertigo (spinning sensation), headache, hearing disturbance, blood disorders, kidney problems, inflammation of the bowel (colitis), sore mouth and mouth ulcers (stomatitis), duodenal ulcer, stomach perforation, vomiting, flatulence, inflammation of the stomach lining (gastritis), or Crohn's disease, kidney problems (including reduced kidney function and kidney failure), oedema, high blood pressure and heart failure, severe skin reactions (such as blistering of the skin, mouth, eyes and genitals), aseptic meningitis in patients with existing auto-immune disorders, and allergic reactions with itching and hives.

Ibuprofen can reduce the number of certain types of blood cells. If you have any blood tests carried out, remember to tell the doctor that you are taking ibuprofen.

Melfen Tablets may also cause your blood pressure to increase.

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).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

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 Melfen

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister strip after (EXP). The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original package in order to protect from light.

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 Melfen contains

The active substance is ibuprofen.

Each film-coated tablet contains 200mg or 400mg of ibuprofen.

The other ingredients are:

Tablet core: Maize starch, sodium starch glycolate and magnesium stearate.

Film-coat: Hypromellose, Macrogol 400 and Macrogol 6000.

What Melfen looks like and contents of the pack

Melfen 200mg Tablets: Round, white, biconvex film-coated tablets. Each tablet contains 200mg ibuprofen.

Melfen 400mg Tablets: Round, white, biconvex film-coated tablets. Each tablet contains 400mg ibuprofen.

Pack size: 10, 20, 50, 100 and 250 tablets

Not all pack sizes may be marketed.

Marketing Authorisation holder and Manufacturer

Marketing Authorisation Holder

Clonmel Healthcare Ltd

Waterford Road

Clonmel

Co. Tipperary

Manufacturers

Clonmel Healthcare Ltd

Waterford Road

Clonmel

Co. Tipperary

And

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