

Package leaflet: Information for the user

EASOFEN 200 mg FILM-COATED TABLETS

Ibuprofen

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

What is in this leaflet

1. What Easofen 200 mg film-coated tablets are and what they are used for
2. What you need to know before you take Easofen 200 mg film-coated tablets
3. How to take Easofen 200 mg film-coated tablets
4. Possible side effects
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1. WHAT EASOFEN 200 mg FILM-COATED TABLETS ARE AND WHAT THEY ARE USED FOR

Easofen 200 mg contains the active substance ibuprofen, which belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). These medicines reduce pain and inflammation, and bring down a high temperature.

Easofen is used for the relief of headaches, dental pain, period pain, muscle strain and cold and flu symptoms.

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 EASOFEN 200 mg FILM-COATED TABLETS

Do not take Easofen

- 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 or have ever had a stomach or duodenal ulcer, perforation or bleeding, or other stomach or bowel problems, such as an active ulcer
- if you have ever had bleeding of your stomach or perforations 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)
- are allergic to any other ingredients in this medicine (listed in section 6)
- if you are already taking another NSAID
- if you are under 12 years old
- if you are pregnant and in the last three months of pregnancy
- if you have severe liver or kidney problems

Warnings and precautions – Take special care with Easofen Tablets

Talk to your doctor or pharmacist before taking Easofen 200 mg film-coated tablets

- if you have asthma or wheezing attacks (or if you have had asthma in the past)
- if you have any liver or kidney problems
- if you have a bleeding disorder or bleeding in the skull, 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 are pregnant or trying to become pregnant or breast-feeding
- if you have ulcerative colitis or Crohn's disease or other stomach or intestinal problems
- if you have previously experienced stomach bleeding or perforation after taking ibuprofen or other NSAIDs
- 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 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 Easofen 200 mg film-coated tablets.
- if you have an infection - please see heading "Infections" below.

Skin reactions

Serious skin reactions including exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS), acute generalized exanthematous pustulosis (AGEP) have been reported in association with ibuprofen treatment. Stop using Easofen Tablets and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Infections

Easofen 200 mg film-coated tablets may hide signs of infections such as fever and pain. It is therefore possible that Easofen 200 mg film-coated tablets 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.

This product should only be used when clearly necessary.

There is a risk of renal impairment in dehydrated adolescents.

If you are taking painkiller medication and find that you still have frequent or daily headaches despite taking medication, please speak to your doctor.

If you are elderly, you should consult your doctor before taking this medicine. You are more likely to experience side effects such as bleeding of the stomach and perforation, which can be fatal.

You may experience side effects such as bleeding of the stomach, ulcers or perforation while taking Easofen even though you never had these side effects before. **STOP taking Easofen and consult your doctor if this happens.**

If you have had stomach problems in the past, contact your doctor immediately if you experience side effects such as bleeding of the stomach while taking Easofen (see section 4. Possible Side Effects).

Your doctor may wish to carry out some kidney function tests before and during therapy particularly if you have a kidney disorder.

Anti-inflammatory/pain-killer medicines such as Easofen 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.

Signs of an allergic reaction to this medicine, including breathing problems, swelling of the face and neck region (angioedema) and chest pain have been reported with ibuprofen. Stop Easofen Tablets and contact your doctor or emergency services immediately if you notice any of these signs.

Other medicines and Easofen

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

Easofen may affect or be affected by the following medicines:

- **Medicines that are anticoagulants** (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)
- **ACE inhibitors**
- Medicines for the treatment of **heart failure** and **irregular heartbeat** 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** or COX-2 inhibitor (such as **aspirin, diclofenac, celecoxib**)
- **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 Easofen. You should therefore always seek the advice of your doctor or pharmacist before you use Easofen with other medicines.

Easofen with food, drink and alcohol

Easofen 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 Easofen. Do not take Easofen 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 Easofen 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, Easofen 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

Easofen 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.

Easofen 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 EASOFEN 200 mg FILM-COATED TABLETS

Swallow the tablets with a drink of water, with or after food.

Always take this medicine exactly as described in this leaflet or as your doctor, or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Adults and adolescents (over 12 years)

The recommended dose is 2 tablets at first and then if necessary 1 or 2 tablets every four hours.

Do not exceed 6 tablets in any 24 hour period.

If in adolescents this medicinal product is required for more than 3 days, or if symptoms worsen a doctor should be consulted.

Ibuprofen tablets are not suitable for children under 12 years

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).

DO NOT EXCEED THE STATED DOSE.

If you take more Easofen 200 mg film-coated tablets than you should

If you have taken more Easofen 200mg film-coated 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 of overdose can include nausea, stomach pain, vomiting (may be blood streaked), gastrointestinal bleeding (see also part 4 below), diarrhoea, headache, ringing in the ears, confusion and shaky eye movement. Agitation, somnolence, disorientation or coma may also occur. At high doses, drowsiness, chest pain, palpitations, loss of consciousness, convulsions (mainly in children), weakness and dizziness, blood in urine, low levels of potassium in your blood, cold body feeling, and breathing problems have been reported. The prothrombin time/INR may be prolonged, probably due to interference with the actions of circulating clotting factors. Acute renal failure and liver damage may occur. Exacerbation of asthma is possible in asthmatics. Furthermore, there may be low blood pressure and reduced breathing.

If you forget to take Easofen 200 mg film-coated 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.

STOP TAKING this medicine and seek medical attention immediately if you develop:

- **signs of intestinal bleeding** such as bright red faeces (stools/motions), black tarry stools, vomiting blood or dark particles that look like coffee granules. Intestinal bleeding may occur more often in the elderly. This may be fatal in very rare cases.
- **signs of serious allergic reaction** such as:
 - difficulties breathing or unexplained wheezing
 - dizziness or faster heartbeat
 - severe skin reaction (skin lesions, rashes, itchiness)
 - swelling of your tongue, face or throat
 - Stevens Johnsons Syndrome (SJS) and Toxic Epidermal Necrolysis may occur very rarely. This is a hypersensitivity reaction affecting the mucous membranes of the skin.
- Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis Syndrome

Stop using ibuprofen and seek medical attention immediately if you notice any of the following symptoms:

- fever, flu-like symptoms, headache, sore throat, mouth ulcers, stiff neck, vomiting, unexplained bleeding and bruising, severe exhaustion, nose or skin bleeding. This may be a symptom of a blood or lymphatic disorder.
- skin reactions, such as redness, rashes, itchiness, or formation of skin lesions
- indigestion, stomach pain, constipation, diarrhoea, flatulence or if you feel sick. Chest pain or fast irregular heart beat.
- liver and kidney problems associated with swelling, decreased urine output and very rarely renal failure associated with long term use.
- hearing disturbances, or high blood pressure.
- reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms [exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis].
- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome).

- A red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the initiation of treatment (acute generalised exanthematous pustulosis).

Not known: frequency cannot be estimated from the available data

- skin becomes sensitive to light

Other side effects include confusion, depression, dizziness and vertigo (spinning sensation), headache, hearing disturbance, blood disorders, inflammation of the bowel (colitis), sore mouth and mouth ulcers (stomatitis), duodenal ulcer, stomach perforation, inflammation of the stomach lining (gastritis), or Crohn's disease, 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 autoimmune disorders, and allergic reactions with itching and hives.

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

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 EASOFEN 200 mg FILM-COATED TABLETS

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 Easofen 200 mg film-coated tablets contains

The active substance is ibuprofen. Each tablet contains 200 mg ibuprofen.

The other ingredients are maize starch, sodium starch glycolate (Type A) and magnesium stearate. The film-coating contains hypromellose, macrogol 400 and macrogol 6000.

What Easofen 200 mg film-coated tablets looks like and contents of the pack

Easofen 200 mg film-coated tablets are round, white, biconvex film-coated tablets.

Packaging:

Blister packs: 10, 12, 20, 24, 28, 30, 48, 50 and 60 tablets.

Not all pack sizes may be marketed.

Marketing authorisation holder and manufacturer

Marketing authorisation holder

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

Manufacturer

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

STADA Arzneimittel AG, Stadastrasse 2 – 18, D – 61118, Bad Vilbel, Germany

STADA M&D SRL, Str. Trascăului, nr 10, RO-401135, Turda, Romania

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