

Package leaflet: Information for the user

Easofen Rapid Relief Max Strength 400 mg soft capsules 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 has 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must contact a doctor if your symptoms worsen or do not improve
 - after 3 days in adolescents
 - after 3 days if you have fever and 4 days for the treatment of pain in adults

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1. What Easofen Rapid Relief Max Strength is and what it is used for

Ibuprofen belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). These medicines provide relief by changing how the body responds to pain and fever.

Easofen Rapid Relief Max Strength is used in adults and adolescents weighing from 40 kg (12 years of age and above) for the short-term symptomatic treatment of mild to moderate pain such as:

- headache
- period pain
- dental pain
- fever and pain associated with the common cold.

You must contact a doctor if your symptoms worsen or do not improve

- after 3 days in adolescents
- after 3 days if you have fever and 4 days for the treatment of pain in adults

2. What you need to know before you take Easofen Rapid Relief Max Strength

DO NOT take Easofen Rapid Relief Max Strength if you

- are allergic to ibuprofen or any of the other ingredients of this medicine (listed in section 6)
- have ever suffered from shortness of breath, asthma, a runny nose, swelling or hives after using acetylsalicylic acid or other similar painkillers (NSAIDs).
- have (or have had two or more distinct episodes of) a stomach/duodenal ulcer (peptic ulcer) or bleeding.
- have had gastrointestinal bleeding or perforation when previously taking NSAIDs (Nonsteroidal anti-inflammatory drugs)
- suffer from unclarified blood-formation disturbances
- have severe liver, kidney or heart failure.
- are in the last three months of pregnancy (see section 'Pregnancy and breast-feeding').
- suffer from severe dehydration (caused by vomiting, diarrhoea or insufficient fluid intake).
- suffer from bleeding on the brain (cerebrovascular bleeding) or other active bleeding.

Warnings and precautions

Talk to your doctor or pharmacist before taking Easofen Rapid Relief Max Strength if you

- have systemic lupus erythematosus (SLE) or mixed connective tissue disease (conditions of the immune system causing joint pain, skin rashes and fever).
- have certain hereditary blood formation disorder (e.g. acute intermittent porphyria) or problems with your blood clotting.
- have or have ever had bowel disease (ulcerative colitis or Crohn's disease).
- have reduced kidney function.
- have liver problems.
- have recently undergone major surgery.
- have or have had asthma or allergic disease as shortness of breath may occur.
- suffer from hayfever, nasal polyps or chronic obstructive respiratory disorders as an increased risk of allergic reactions exists. The allergic reactions may present as asthma attacks (so-called analgesic asthma), acute swellings (Quincke's oedema) or a skin rash.
- are taking other medicines which could increase the risk of ulceration or bleeding such as oral corticosteroids, medicines for thinning the blood (such as warfarin), selective serotonin-reuptake inhibitors (medicines for depression) or anti-platelet agents such as acetylsalicylic acid.
- have an infection – please see heading “Infections” below.

Infections

Easofen Rapid Relief Max Strength may hide signs of infection such as fever and pain. It is therefore possible that Easofen Rapid Relief Max Strength 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.

Other warnings

Prolonged use of painkillers for headaches can make them worse. If this situation is experienced or suspected, you should stop taking Easofen Rapid Relief Max Strength and contact your doctor.

- You should avoid taking Easofen Rapid Relief Max Strength if you have chicken pox (varicella).
- When Easofen Rapid Relief Max Strength is taken over a longer period of time, regular liver, kidney and blood checks should be done.
- Taking Easofen Rapid Relief Max Strength in combination with other NSAIDS including cyclooxygenase-2 specific inhibitors can increase the risk of side effects and should be avoided (see section “Other medicines and Easofen Rapid Relief Max Strength” below).
- In general, the habitual use of (several sorts of) analgesics can lead to lasting severe kidney problems and should be avoided. The risk is increased further by loss of salt and dehydration.
- There is a risk of renal impairment in dehydrated adolescents.

Skin reactions

Serious skin reactions have been reported in association with Easofen Rapid Relief Max Strength treatment. You should stop taking Easofen Rapid Relief Max Strength 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.

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 Easofen Rapid Relief Max Strength 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”).
- have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker.

Undesirable effects are minimised by using the minimum effective dose for the shortest period of time. The elderly are at increased risk of side effects.

Consult a doctor before using Easofen Rapid Relief Max Strength if any above-mentioned conditions concerns you.

Other medicines and Easofen Rapid Relief Max Strength

Easofen Rapid Relief Max Strength may affect or be affected by some other medicines. For example:

- medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. 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)

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. In particular, tell them if you are taking:

other NSAIDs (anti-inflammatories and analgesics), including cyclooxygenase-2 selective inhibitors	may increase the risk of gastrointestinal ulcers or bleeding
digoxin (for heart insufficiency)	effect of digoxin may be enhanced
glucocorticoids (medicinal products containing cortisone or cortisone-like substances)	may increase the risk of gastrointestinal ulcers or bleeding
Anti-platelet agents	may increase the risk of gastrointestinal ulcers or bleeding
phenytoin (for epilepsy)	effect of phenytoin may be enhanced
selective serotonin reuptake inhibitors (medicines used for depression)	may increase the risk of bleeding
lithium (a medicine for manic depressive illness and depression)	effect of lithium may be enhanced
probenecid and sulfinpyrazones (medicines for gout)	it may take longer for ibuprofen to be broken down by the body
potassium sparing diuretics	may lead to high blood potassium levels (hyperkalaemia)
methotrexate (a medicine for cancer or rheumatism)	effect of methotrexate may be enhanced
tacrolimus and cyclosporine (immunosuppressive medicines)	kidney damage may occur
zidovudine (a medicine for treating Aids)	use of Easofen Rapid Relief Max Strength may result in an increased risk of bleeding into a joint or a bleeding that leads to swelling in HIV (+) haemophiliacs
sulfonylureas (antidiabetic medicines)	interactions may be possible
quinolone antibiotics	risk of convulsions (fits) may be increased

mifepristone (used to terminate pregnancies)	effect of mifepristone can be reduced.
Acetylsalicylic acid (low dose)	the blood-thinning effect may be impaired
Medicines for thinning the blood (such as warfarin)	ibuprofen may enhance the effects of these medicines
Voriconazole and fluconazole (CYP2C9 inhibitors) used for fungal infections	the effect of ibuprofen may increase. Reduction of the ibuprofen dose should be considered particularly when high-dose ibuprofen is used either with voriconazole and fluconazole

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

Taking Easofen Rapid Relief Max Strength with alcohol

You should not drink alcohol while using Easofen Rapid Relief Max Strength. Some side effects, such as those affecting the gastrointestinal tract or the central nervous system can be more likely when alcohol is taken at the same time as Easofen Rapid Relief Max Strength.

Pregnancy, breast-feeding and fertility

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 whilst taking Easofen Rapid Relief Max Strength.

Do not take this medicine 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 use 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, Easofen Rapid Relief Max Strength 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.

Female fertility

Easofen Rapid Relief Max Strength 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

For short-term use and at normal dosage this medicine has no or negligible influence on the ability to drive and use machines.

Patients who experience dizziness, drowsiness, vertigo or visual disturbances while they are taking Easofen Rapid Relief Max Strength, should avoid driving or using machinery. These effects may be worse when taken in combination with alcohol.

Easofen Rapid Relief Max Strength contains sorbitol

This medicine contains 72 mg sorbitol in each capsule. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

3. How to take Easofen Rapid Relief Max Strength

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. Unless otherwise prescribed by your doctor, the standard dose is:

Dosage

Adults and adolescents weighing from 40 kg (12 years old and above)

As initial dose take 1 capsule (400 mg ibuprofen), then if necessary 1 capsule (400 mg ibuprofen) can be taken every six hours. Do not take more than 3 capsules (1,200 mg ibuprofen) in any 24 hour period.

Children under 12 years of age and adolescents weighing less than 40 kg

Easofen Rapid Relief Max Strength is not intended for use in adolescents weighing less than 40 kg or children under 12 years of age.

Method of administration

For oral use. Take Easofen Rapid Relief Max Strength with a glass of water. Do not chew.

It is recommended that patients with a sensitive stomach take Easofen Rapid Relief Max Strength with food. If taken shortly after eating, the onset of action of Easofen Rapid Relief Max Strength may be delayed. If this happens, do not take more Easofen Rapid Relief Max Strength than recommended within this section or until the correct re-dosing interval has passed.

Duration of treatment

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).

Adolescents

If in adolescents Easofen Rapid Relief Max Strength is required for more than 3 days, or if symptoms worsen a doctor should be consulted.

Adults

If Easofen Rapid Relief Max Strength is required for longer than 3 days for the treatment of fever and 4 days for treatment of pain or if the symptoms worsen, consult your doctor.

Please speak to the doctor or pharmacist if you feel that the effect of this medicine is greater or less than you expected.

If you take more Easofen Rapid Relief Max Strength than you should

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

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. You may suffer one of the known side effects of NSAIDs (see below). If you do, or if you have concerns, stop taking this medicine and talk to your doctor as soon as possible. Elderly people using this product are at increased risk of developing problems associated with side effects.

STOP TAKING this medicine and seek immediate medical help if you develop:

- **signs of intestinal bleeding** such as: severe pain in the abdomen, black tarry stools, vomiting blood or dark particles that look like coffee grounds
- **signs of very rare but serious allergic reaction** such as worsening of asthma, unexplained wheezing or shortness of breath, swelling of the face, tongue or throat, difficulty breathing, racing heart, drop in blood pressure leading to shock. These can happen even on first use of this medicine.
- **severe skin reactions** such as rashes covering the whole body, peeling, blistering or flaking skin including a **severe skin reaction known as DRESS syndrome** (frequency not known). Symptoms of DRESS include: skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cells).
- **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.

Tell your doctor if you have any of the following side effects, they become worse or you notice any effects not listed.

Common (may affect up to 1 in 10 people)

- gastrointestinal complaints, such as heart burn, abdominal pain, feeling sick and indigestion, vomiting, wind (flatulence), diarrhoea, constipation, and slight blood losses in stomach and/or bowel that may cause anaemia in exceptional cases.

Uncommon (may affect up to 1 in 100 people)

- stomach or intestinal ulcers, sometimes with bleeding and perforation, inflammation of the lining of the mouth with ulceration (ulcerative stomatitis), inflammation of the stomach (gastritis), worsening of colitis and Crohn's disease
- central nervous disturbances such as headache, dizziness, sleeplessness, agitation, irritability or tiredness
- visual disturbances
- allergic reactions, such as skin rashes, itching and asthma attacks. You must stop taking Easofen Rapid Relief Max Strength and inform your doctor at once.
- various skin rashes

Rare (may affect up to 1 in 1,000 people)

- tinnitus (ringing in the ears)
- kidney damage (papillary necrosis) and elevated uric acid concentrations in the blood
- hearing impaired
- increased urea concentrations in the blood
- decrease haemoglobin levels

Very rare (may affect up to 1 in 10,000 people)

- swelling (oedema), high blood pressure (hypertension) and cardiac failure have been reported in association with NSAID treatment.
- inflammation of the oesophagus or pancreas, formation of membrane-like narrowing in the small and large intestines (intestinal, diaphragm-like strictures)
- severe infections of the skin and soft-tissue complications have occurred during chicken pox (varicella) infection.
- passing less urine than normal and swelling (especially in patients with high blood pressure or reduced kidney function); swelling (oedema) and cloudy urine (nephrotic syndrome); inflammatory kidney disease (interstitial nephritis) that **may** lead to acute kidney failure. If one of the above-mentioned symptoms occur or if you have a general miserable feeling, stop taking Easofen Rapid

Relief Max Strength and consult your doctor immediately as these could be first signs of a kidney damage or kidney failure.

- problems in the blood cell production - first signs are: fever, sore throat, superficial mouth ulcers, flu-like symptoms, severe exhaustion, nose and skin bleeding. In these cases you must stop the therapy immediately and consult a doctor. You must not treat these symptoms with pain killers or medicinal products that reduce fever (antipyretic products).
- psychotic reactions and depression
- worsening of infection-related inflammations (e.g. necrotising fasciitis) associated with use of certain painkillers (NSAIDs) has been described. If signs of an infection occur or get worse during use of Easofen Rapid Relief Max Strength, you must go to a doctor without delay to investigate whether there is a need for an anti-infective/antibiotic therapy.
- high blood pressure, palpitations, heart failure, heart attack.
- liver dysfunction, liver damage, especially during long-term treatment, liver failure, acute inflammation of the liver (hepatitis)
- symptoms of aseptic meningitis with neck stiffness, headache, feeling sick, being sick, fever or consciousness clouding have been observed when using ibuprofen. Patients with autoimmune disorders (SLE, mixed connective-tissue disease) may be more likely to be affected. Contact a doctor at once, if these occur.
- severe forms of skin reactions such as skin rash with redness and blistering (e.g. Stevens- Johnson syndrome, toxic epidermal necrolysis/Lyell's syndrome), hair loss (alopecia).
- severe general hypersensitivity reactions
- worsening of asthma and bronchospasm
- inflammation of the blood vessels (vasculitis)

Frequency not known (frequency cannot be estimated from the available data)

- skin becomes sensitive to light (photosensitivity reaction)

Medicines such as Easofen Rapid Relief Max Strength may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke.

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 Rapid Relief Max Strength

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 after "EXP". The expiry date refers to the last day of that month.

This medicine does not require any special temperature storage conditions. Store in the original package in order to protect from moisture.

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 Rapid Relief Max Strength contains

- The active substance is ibuprofen.
Each soft capsule contains 400 mg ibuprofen.
- The other ingredients are: macrogol 600 (E1521), potassium hydroxide (E525), purified water, gelatin (E441), liquid partially dehydrated sorbitol (E420) and printing ink (black iron oxide (E172), propylene glycol (E1520), hypromellose (E464)).

What Easofen Rapid Relief Max Strength looks like and contents of the pack

A transparent, oval shape, soft gelatine capsule (about 15.8 mm x 9.8 mm) containing clear colourless liquid, imprinted with L 160 in black ink.

Easofen Rapid Relief Max Strength are available in packs of 10 or 20 soft capsules in blister strips.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and ManufacturerMarketing authorisation holder

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

Manufacturer

STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel, Germany
Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

This medicine is authorised in the Member States of the European Economic Area under the following names

Bulgaria:	Parabol Max
Czech Republic:	IBOVAL RAPID
Ireland:	Easofen Rapid Relief Max Strength 400 mg soft capsules
The Netherlands:	Ibuprofen Healthypharm liquid caps 400 mg, zachte capsules
Slovenia:	Ibuprofen STADA 400 mg mehke kapsule
Romania:	BUPROFESS 400mg capsule moi

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