

Package leaflet: Information for the user

Ryhogen 400 mg 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Ryhogen is and what it is used for
2. What you need to know before you take Ryhogen
3. How to take Ryhogen
4. Possible side effects
5. How to store Ryhogen
6. Contents of the pack and other information

1. What Ryhogen is and what it is used for

Ryhogen contains 400 mg of ibuprofen. Ibuprofen belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAID). These medicine works by relieving pain, swelling and fever.

Ryhogen is used for the short-term symptomatic treatment of

- mild to moderate pain such as headaches, toothaches and period pains
- fever reduction

2. What you need to know before you take Ryhogen

Do not take Ryhogen

- if you are allergic to ibuprofen or any of the other ingredients of this medicine (listed in section 6);
- if you have ever suffered from shortness of breath, asthma, runny nose, swelling of your face and/or hands or hives after previously taking ibuprofen, acetylsalicylic acid or similar painkillers (NSAIDs);
- if you have severe liver or kidney failure or severe heart failure;
- if you have existing or have had recurrent gastric/duodenal ulcers (peptic ulcers) or bleeding (at least 2 different episodes of proven ulcers or bleeding);
- if you have a history of gastrointestinal bleeding or perforation in connection with therapy with non-steroidal anti-inflammatory drugs (NSAIDs);
- if you have brain bleeding (cerebrovascular haemorrhage) or other active bleeding;
- if you have unexplained blood formation disorders;
- if you are severely dehydrated (caused by vomiting, diarrhoea or insufficient fluid intake);
- if you are in the last three months of pregnancy (see below);
- in children under 12 years of age or in adolescents under 40 kg body weight, as this dose strength is not suitable due to the higher active substance content.

Warnings and precautions

Talk to your doctor or pharmacist before taking Ryhogen:

- if you have an infection – see heading “Infections” below.
- if you are suffering from certain skin diseases (systemic lupus erythematosus (SLE) or mixed connective tissue disease);
- if you have certain congenital blood formation disorders (e.g. acute intermittent porphyria);
- if you suffer from blood clotting disorders;
- if you are suffering or have suffered from gastro-intestinal disorders (ulcerative colitis, Crohn’s disease);
- if you have ever had high blood pressure and/or heart failure;
- if you have reduced kidney function;
- if you have liver dysfunction;
- if you are trying to become pregnant;
- if you suffer or have suffered from asthma or allergic reactions, you may experience shortness of breath;
- if you suffer from hay fever, nasal polyps or chronic obstructive respiratory disease an increased risk of allergic reactions exists. The allergic reactions can occur as asthma attacks (so-called analgesic asthma), Quincke’s oedema or hives;
- anti-inflammatories/painkillers such as ibuprofen may be associated with a small increased risk of heart attack or stroke, especially when used in high doses. Do not exceed the recommended dose or duration of treatment;
- if you have heart problems including heart failure and 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 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 chickenpox, you should avoid taking Ryhogen;
- in prolonged intake of Ryhogen your liver values, kidney function and blood count should be monitored regularly.

Take care when taking this medicine

- signs of an allergic reaction to this medicine, including breathing problems, swelling of the face and neck region (angioedema), chest pain have been reported with ibuprofen. Stop immediately Ryhogen and contact immediately your doctor or medical emergencies if you notice any of these signs;
- side effects can be reduced by taking the lowest effective dose for the shortest possible time;
- side effects may occur more frequently in older people;
- in general, the regular use of (different types of) painkillers can lead to permanent severe kidney damage. Physical stress combined with salt loss and dehydration can increase the risk. This should be avoided.
- prolonged use of any type of analgesics for headaches can make them worse. If this situation is experienced or suspected, tell your doctor as your treatment should be stopped. The diagnosis of medication overuse headache (MOH) should be suspected in patients who have frequent or daily headaches despite (or because of) the regular use of headache medications.
- taking Ryhogen at the same time as other NSAIDs, including COX-2 inhibitors (cyclooxygenase-2 inhibitors), increases the risk of side effects (see section ‘Taking with other medicines’) and should therefore be avoided.
- there is a risk of kidney problems in dehydrated adolescents;
- special medical supervision is necessary immediately after major surgery.

Infections

Ryhogen can hide signs of infection such as fever and pain. It is therefore possible that Ryhogen may delay appropriate treatment of the 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 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 Ryhogen and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Adolescents

This medicine is contraindicated in children under 12 years of age and adolescents under 40 kg body weight, as this dose strength is not suitable due to the higher active substance content. Please note the information in section 2: "Do not take Ryhogen".

Other medicines and Ryhogen

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

Ryhogen may affect or be affected by some medicines. For example:

- medicines that are anticoagulants (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);
- some medicines for pain and inflammation (e.g. acetylsalicylic acid, unless your doctor has advised you to take a low dose);
- other non-steroidal anti-inflammatory drugs (NSAIDs) including COX-2 inhibitors (cyclooxygenase-2 inhibitors).

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

This applies in particular to the following medicines:

- Acetylsalicylic acid or other NSAIDs (anti-inflammatory and painkilling drugs) as this may increase the risk of stomach and intestinal ulcers or bleeding;
- Digoxin (for heart failure), as the effect of digoxin may be increased;
- Corticosteroids (medicines containing cortisone or cortisone-like substances), as this may increase the risk of stomach and intestinal ulcers or bleeding;
- Antiplatelet medicines, as this may increase the risk of bleeding;
- Acetylsalicylic acid (low dose), as the blood-thinning effect may be reduced;
- Medicines used to thin the blood (such as warfarin), as ibuprofen can increase the blood-thinning effect of these medicines;
- Phenytoin (against epilepsy), as the effect of phenytoin may be increased;
- Selective serotonin re-uptake inhibitors (antidepressants), as this can increase the risk of stomach/intestinal bleeding;
- Lithium (a medicine for bipolar disorder and depression), as the effect of lithium may be increased;
- Probenecid and sulfinpyrazone (medicines for gout), as these may delay the excretion of ibuprofen;

- Medicines for high blood pressure and diuretic tablets, as ibuprofen can weaken the effect of these medicines, possibly resulting in an increased risk to the kidneys;
- Potassium-sparing diuretics, as this can cause hyperkalaemia (too much potassium in the blood);
- Methotrexate (a medicine used to treat cancer or rheumatism), as the effect of methotrexate may be increased;
- Tacrolimus and cyclosporine (immunosuppressive medicines), as this may cause kidney damage;
- Zidovudine (a medicine used to treat HIV/AIDS). In HIV-positive haemophilia patients (“haemophiliacs”), the risk of joint bleeding (haemarthrosis) or bleeding leading to swelling may be increased.
- Sulphonylureas (medicines for lowering blood sugar), as interactions are possible;
- Quinolone antibiotics, as there is an increased risk of seizures;

Voriconazole and fluconazole (CYP2C9 inhibitors) against fungal infections, as the effect of ibuprofen may be increased. Reduction of the ibuprofen dose should be considered, particularly when high dose ibuprofen is co-administered with either voriconazole or fluconazole.

Ryhogen with food, drink and alcohol

You should not drink alcohol while using Ryhogen. 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 Ryhogen.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or you are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

Do not take Ryhogen 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 may cause labour to be later or longer than expected.

You should not take Ryhogen 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, Ryhogen can cause kidney problems in your unborn baby, which 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

This medicine passes into breast milk but can be taken during breast-feeding if the recommended dose is followed and it is used for the shortest possible time.

Fertility

Ryhogen 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

As central nervous side effects such as tiredness and dizziness may occur on use of Ryhogen at higher dosage, the ability to react and the ability to take part actively in road traffic and to operate machines may be impaired in isolated cases. This applies to a greater extent in combination with alcohol. You cannot react quickly and intentionally to unexpected and sudden events. Do not drive a car or other vehicles in this case. Do not use any tools or machines. Do not work without secure support.

Ryhogen contains sodium

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

Ryhogen contains isomalt

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Ryhogen

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

The lowest effective dose should be used for the shortest duration required to relieve symptoms. If you have an infection, consult a doctor immediately if the symptoms (such as fever and pain) persist or get worse (see section 2).

Adolescents

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

Adults

If in adults this medicine is required for more than 3 days for fever or for more than 4 days for pain, or if symptoms worsen, a doctor should be consulted.

The recommended dose is:

Age	Single dose	Maximum daily dose
40 kg or more (Adolescents from 12 years and adults)	1 film-coated tablet (corresponding to 400 mg ibuprofen)	3 film-coated tablets (corresponding to 1200 mg ibuprofen)

If you have taken the maximum single dose, you should wait at least 6 hours before taking another dose.

How to take

- swallow the film-coated tablets whole with plenty of liquids (like a glass of water).
- if you have a sensitive stomach take Ryhogen with meals.
- if Ryhogen is taken during or shortly after a meal, the onset of action may be delayed. If this is the case for you, do not take more than the dose recommended and do not reduce the specified dosing interval.

Ask your doctor or pharmacist if you think that the effect of Ryhogen is stronger or weaker than you expect.

If you take more Ryhogen than you should

If you have taken more Ryhogen than you should, or if children have taken 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 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. Also agitation, somnolence, disorientation or coma may occur. Occasionally patients develop convulsions. At high doses, drowsiness, chest pain, palpitations, loss of consciousness, convulsions (mainly in children), weakness and dizziness, blood in urine, low levels

potassium in your blood, high levels of potassium, cold body feeling, and breathing problems have been reported. Further, 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, reduced breathing and blue-red discoloration of the skin and mucous membranes (cyanosis).

If you forget to take Ryhogen

If you forget to take it once, do not take more than the usual recommended amount at the next dose.

If you have any further questions about taking 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 can be reduced by using the lowest effective dose for the shortest period necessary for controlling symptoms. You may experience one or more of the known side effects known of NSAIDs (see below). If this is the case or if you have any concerns, stop taking this medicine and talk to your doctor as soon as possible. Elderly patients have a higher risk of developing problems due to side effects when taking this medicine.

STOP taking this medicine and tell your doctor immediately if you get any of the following side effects:

- **Signs of gastrointestinal bleeding** such as severe abdominal pain, black stools, vomiting blood or dark particles that resemble coffee grounds in appearance.
- **Signs of very rare but serious allergic reactions** such as worsening of asthma, unexplained wheezing or shortness of breath, swelling of the face, tongue or throat, difficulty breathing, rapid heartbeat, drop in blood pressure leading to shock. This can happen even when you first take this medicine.
- **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) (Very rare - may affect up to 1 in 10,000 people).
- **Widespread rash**, high body temperature, enlarged lymph nodes and an increase of eosinophils (a type of white blood cells) (DRESS syndrome) (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. The symptoms usually appear at the initiation of treatment (acute generalised exanthematous pustulosis) (Not known - frequency cannot be estimated from the available data).

Talk to your doctor if you develop the other side effects described below.

Common: (may affect up to 1 in 10 people)

- stomach and intestinal complaints such as heartburn, abdominal pain and nausea, indigestion, diarrhoea, vomiting, bloating (flatulence), constipation; slight loss of blood in the stomach and/or intestines, which can cause anaemia in exceptional cases.

Uncommon: (may affect up to 1 in 100 people)

- Stomach and intestine ulcers, perforation or bleeding, inflammation of the mouth mucous membrane with ulceration (ulcerative stomatitis), worsening of existing intestinal diseases (colitis or Crohn's disease), inflammation of the mucous membrane of the stomach (gastritis)
- central nervous disturbances such as headaches, dizziness, insomnia, agitation, irritability or

- tiredness
- visual disturbances
- various skin rashes
- hypersensitivity reactions with hives and itching

Rare: (may affect up to 1 in 1000 people)

- ringing in the ears (tinnitus)
- increased uric acid concentration in the blood, pain in the side and/or abdomen, blood in the urine and fever can be signs of kidney damage (papillary necrosis)
- decreased haemoglobin value

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

- oesophagitis, inflammation of the pancreas and formation of membranous intestinal strictures (intestinal diaphragm-like strictures)
- heart failure (cardiac insufficiency), heart attack and swelling of the face and hands (oedema)
- reduced urination and swelling (especially in patients with high blood pressure or impaired kidney function), water retention in the body (oedema), cloudy urine (nephrotic syndrome); inflammation of the kidneys (interstitial nephritis), which may be accompanied by acute kidney dysfunction. If any of the above symptoms occur or you feel generally unwell, stop taking Ryhogen and see your doctor immediately, as these may be the first signs of kidney damage or failure.
- psychotic reactions, depression
- high blood pressure, vascular inflammation (vasculitis)
- palpitations
- liver dysfunction, liver damage (first signs may be skin discolouration), especially with long-term use, liver failure, acute liver inflammation (hepatitis)
- blood formation disorders – the first signs are: fever, sore throat, superficial mouth sores, flu-like symptoms, severe exhaustion, nasal and skin bleeding and unexplained bruising. In these cases, you should stop the therapy immediately and consult a doctor. Any self-treatment with painkillers or fever-reducing medication (antipyretics) should be avoided.
- severe skin infections and soft tissue complications during chickenpox (varicella infection)
- worsening of infection-related inflammation (e.g. necrotising fasciitis) has been described in temporal association with the use of certain NSAIDs. If signs of inflammation occur or worsen, you should go to your doctor immediately. It must be clarified whether anti-infective/antibiotic therapy is necessary.
- symptoms of aseptic meningitis (neck stiffness, headache, nausea, vomiting, fever or clouding of consciousness) have been observed after taking ibuprofen. Patients with existing autoimmune disorders (systemic lupus erythematosus, mixed connective tissue disease) may be more likely to be affected. Contact your doctor immediately if these symptoms occur.
- hair loss (alopecia).

Not known: (frequency cannot be estimated from the data available)

- respiratory tract reactions such as asthma, bronchial muscle cramps (bronchospasm) or shortness of breath.
- the skin becomes sensitive to light.
- hearing impairment.
- chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome.

Medicines like Ryhogen 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 to:

Ireland
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 Ryhogen

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

Store below 25 °C. Store in the original package in order to protect from moisture.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

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 Ryhogen contains

- The active substance is ibuprofen. 1 film-coated tablet contains 683.2 mg ibuprofen lysine equivalent to 400 mg ibuprofen.
- The other ingredients are:
Tablet core: sodium starch glycolate type A; povidone 30; magnesium stearate.
Coating: The coating premix consisting of: hypromellose; isomalt; calcium carbonate; stearic acid.

What Ryhogen looks like and contents of the pack

white to off-white to yellowish, oval, approx. 9.1 x 19.1 mm film-coated tablets, thickness approx. 6.4 mm.

The tablets are packed into PVC/PVDC//Alu blisters.

Pack sizes:
20 film-coated tablets

Marketing Authorisation Holder and Manufacturer

Zentiva, k.s.
U kabelovny 130,
Dolní Měcholupy,
102 37 Prague 10,
Czech Republic

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

Ireland: Ryhogen 400 mg film-coated tablets
Portugal: Ibysin

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