

Package leaflet: Information for the user

Ibuprofen Strides 200 mg filmomhulde tabletten

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

1. What Ibuprofen Strides is and what it is used for

Ibuprofen Strides contains the active substance ibuprofen. Ibuprofen belongs to a group of medicines called NSAIDs (non-steroidal anti-inflammatory drugs). Ibuprofen Strides reduces pain and fever.

Ibuprofen Strides is used for the short-term symptomatic treatment of:

- mild to moderate pain such as headache, period pain, dental pain
- fever associated with common cold.

Ibuprofen Strides is indicated in adults and adolescents from 40 kg body weight (12 years and above).

2. What you need to know before you take Ibuprofen Strides

Do not take Ibuprofen Strides if you:

- are allergic to ibuprofen or any of the other ingredients of this medicine listed in section 6.
- have ever had an allergic reaction (such as bronchospasm (tightening of the muscles in the lungs that may cause asthma and shortness of breath), asthma attacks, runny nose, swollen nasal passages, skin rash or sudden facial swelling) after taking acetylsalicylic acid or other similar painkillers (NSAIDs).
- suffer from severe liver, kidney or heart failure
- are in your last three months of pregnancy (see section "Pregnancy and Lactation")
- if you have an active, or history of recurrent stomach/duodenal ulcers (peptic ulcers) or bleeding (at least 2 different episodes of confirmed ulcers or bleeding)
- if you have a history of gastrointestinal bleeding or perforation associated with previous treatment with NSAIDs
- have bleeding in the brain (cerebrovascular bleeding) or other active bleeding
- are severely dehydrated (e.g. caused by vomiting, diarrhoea or insufficient fluid intake)
- have unclarified blood-formation disturbances
- have a condition which increases your tendency to bleeding

Warnings and precautions

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.

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 Ibuprofen Strides and contact immediately your doctor or medical emergencies if you notice any of these signs.

Take special care with Ibuprofen Strides:

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 Ibuprofen Strides and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Talk to your doctor or pharmacist before taking Ibuprofen Strides if:

- you have heart problems including heart failure, angina pectoris (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”)
- you have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker
- you have problems with your liver or kidneys function. In case of prolonged use, monitoring of kidney function, liver values, as well as of the blood count is required. In general, the habitual use of (several types of) painkillers can lead to lasting kidney problems. This risk may be increased under physical strain associated with loss of salt and dehydration (e.g. caused by vomiting, diarrhoea or insufficient fluid intake).
- you have or have had problems with the digestive tract or a chronic bowel inflammation that is inflammation of the colon (colitis ulcerosa) or Crohn’s Disease.
- caution should be advised if you are taking other medicines which could increase the risk of ulceration or bleeding, such as oral corticosteroids (such as prednisolone), medicines for thinning the blood (such as warfarin), selective serotonin-reuptake inhibitors (a medicine for depression) or anti-platelet agents (such as acetylsalicylic acid).
- are taking another NSAID medicine (including COX-2 inhibitors such as celecoxib or etoricoxib) as taking these together should be avoided (see section “Other medicines and Ibuprofen Strides”).
- you have mixed connective tissue disease (an autoimmune disease) or systemic lupus erythematosus (an autoimmune disease)
- have certain hereditary blood formation disorder (e.g. acute intermittent porphyria)
- suffer from coagulation disturbances
- have just had major surgery
- you have or have had asthma or any allergic diseases as shortness of breath may occur.
- you suffer from hay fever, nasal polyps or chronic obstructive respiratory disorders an increased risk of allergic reactions exists. The allergic reactions may present as asthma attacks (so-called analgesic asthma), Quincke’s oedema or urticaria.
- if you are dehydrated, as there is a risk of renal impairment, especially in dehydrated adolescents and the elderly.
- you have an infection - please see heading "Infections" below.
- Prolonged use of any type of painkillers for headaches can make them worse. If this situation is experienced or suspected, medical advice should be obtained, and treatment should be discontinued.

Skin reactions

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

The risk of side effects is minimized by using the lowest effective dosing for the shortest possible time. Elderly patients are subject to an increased risk of side effects to NSAIDs, especially gastrointestinal bleeding and perforation, which may be fatal. Do not use different pain killers at the same time unless your doctor has told you to do so.

Gastro-intestinal bleeding, ulceration or perforation, which can be fatal, has been reported with all NSAIDs at any time during treatment, with or without warning symptoms or a previous history of serious gastro-intestinal events. When gastrointestinal bleeding or ulceration occurs, the treatment should be stopped immediately. The risk of gastrointestinal bleeding, ulceration or perforation is higher with increasing NSAID doses, in patients with a history of ulcer, particularly if complicated with haemorrhage or perforation (see section 2 Do not use Ibuprofen Strides and in the elderly. These patients should commence treatment on the lowest dose available. Combination therapy with protective agents (e.g. misoprostol or proton pump inhibitors) should be considered for those patients, and also those requiring concomitant low-dose acetylsalicylic acid, or other drugs likely to increase gastrointestinal risk.

Patients with a history of gastro-intestinal toxicity, particularly when elderly, should report any unusual abdominal symptoms (especially gastrointestinal bleeding) particularly in the initial stages of treatment.

Infections

Ibuprofen may hide signs of infections such as fever and pain. It is therefore possible that Ibuprofen 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. During chicken pox (varicella) it is advisable to avoid use of this medicine.

Consult a doctor if any of the above-mentioned conditions concerns you.

Children and Adolescents

This medicinal product is not intended for adolescents weighing less than 40 kg or children under 12 years of age.

Other medicines and Ibuprofen Strides

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

Ibuprofen Strides may affect or be affected by some other medicines.

For example:

- anticoagulants (i.e. medicines to thin blood/prevent clotting, e.g. acetylsalicylic acid, warfarin, ticlopidine)
- medicines that reduce high blood pressure (ACE-inhibitors such as captopril, betablockers such as atenolol, angiotensin II receptor antagonists such as losartan)

Some other medicines may also affect or be affected by the treatment of Ibuprofen Strides tablets.

You should therefore always seek the advice of your doctor or pharmacist before you use Ibuprofen Strides tablets with other medicines.

Especially if it regards one of the following medicines:

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| Other NSAIDs including COX-2 inhibitors | Since this may increase the risk of side effects |
| Digoxin (for heart insufficiency) | Since the effect of digoxin may be enhanced |
| Glucocorticoids (medicinal products containing cortisone or cortisone-like substances) | Since this may increase the risk of gastrointestinal ulcers or bleeding |
| Anti-platelet agents | Since this may increase the risk of bleeding |
| Acetylsalicylic acid (low dose) | Since the blood-thinning effect may be impaired |
| Medicines for thinning the blood (such as warfarin) | Since ibuprofen may enhance the effects of these medicines |
| Phenytoin (for epilepsy) | Since the effect of phenytoin may be enhanced |
| Selective serotonin reuptake inhibitors (medicines used for depression) | As these may increase the risk of gastrointestinal bleeding |
| Lithium (a medicine for manic depressive illness and depression) | Since the effect of lithium may be enhanced |
| Probenecid and sulfinpyrazones (medicines for gout) | Since the excretion of ibuprofen may be delayed |
| Medicines for high blood pressure and water tablets | Since ibuprofens may diminish the effects of these medicines and there could be a possible increased risk for the kidney |
| Potassium sparing diuretics e.g. amiloride, potassium canrenoate, spironolactone, triamterene. | Since this may lead to hyperkalaemia |
| Methotrexate (a medicine for cancer or rheumatism) | Since the effect of methotrexate may be enhanced |
| Tacrolimus and cyclosporine (immunosuppressive medicines) | Since kidney damage may occur |
| Zidovudine: (a medicine for treating HIV/AIDS) | Since the use of Ibuprofen Strides may result in an increased risk of bleeding into a joint or a bleeding that leads to swelling in HIV (+) haemophiliacs |
| Sulfonylureas (antidiabetic medicines) | Since the blood sugar levels can be affected |
| Quinolone antibiotics | Since the risk for convulsions (fits) may be increased |
| Voriconazole and fluconazole (CYP2C9 inhibitors) used for fungal infections | Since the effect of ibuprofen may increase. Reduction of the ibuprofen dose should be considered, particularly when high-dose ibuprofen is administered with either voriconazole or fluconazole. |
| Aminoglycosides | NSAIDs may decrease the excretion of aminoglycosides |
| Baclofen (medicine for treating spasticity) | Baclofen toxicity may develop after starting ibuprofen |
| Ritonavir (medicine for treating HIV infection) | Ritonavir may increase the plasma concentrations of NSAIDs |
| Cholestyramine | At concomitant administration of ibuprofen and cholestyramine the absorption of ibuprofen is delayed and decreased. The medicines should be administered with a few hours interval. |
| Ginkgo biloba | Ginkgo can increase the risk of bleeding with NSAIDs |

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| Mifepristone (for pregnancy termination) | If NSAIDs are used within 8-12 days after mifepristone administration, they can reduce the effect of mifepristone. |
| Alcohol, bisphosphonates and oxpentifillin (pentoxifylline) | May potentiate the gastrointestinal side effects and the risk of bleeding and ulceration. |

Ibuprofen Strides with food, drink and alcohol

You should limit or avoid drinking alcohol when you are taking Ibuprofen Strides as this may increase gastrointestinal side effects.

Pregnancy, breastfeeding 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

Do not take Ibuprofen Strides 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 Ibuprofen Strides 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, Ibuprofen Strides 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.

Breastfeeding

Ibuprofen passes into breast milk but is not likely to have an effect on the breastfeeding child when used for short-term treatment. However, consult a doctor if using Ibuprofen Strides more than occasionally while breastfeeding is required..

Fertility

The use of ibuprofen may affect fertility. The use of ibuprofen is not recommended while attempting to conceive or during investigation of infertility.

Driving and using machines

Ibuprofen generally has no or negligible influence on the ability to drive and use machines. However, since at higher dose central nervous undesirable effects such as tiredness and dizziness may occur, the ability to react and the ability to take part actively in road traffic and to operate machines may be impaired in individual cases. This applies to a greater extent in combination with alcohol

Ibuprofen Strides contains lactose

This medicinal product contains a type of sugar called lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Ibuprofen Strides contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per capsule, i.e. essentially 'sodium free'.

3. How to take Ibuprofen Strides

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

This medicine is only for short-term use

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).

Adults and adolescents from 40 kg body weight (12 years of age and above):

The recommended dose is 1-2 tablets (200 mg – 400 mg) 1 – 3 times daily. Allow 6 hours between doses. Maximum daily dose: 6 tablets (1200 mg) per 24 hours.

Period pain:

The recommended dose is 2 tablets (400 mg) 1 – 3 times daily. Allow 6 hours between doses.

Maximum daily dose: 6 tablets (1200 mg) per 24 hours. Start treatment at the first signs of menstrual pain.

Duration of treatment:

You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

Children and adolescents

This medicinal product is not intended for use in children under 12 years of age and adolescents below 40 kg body weight.

Elderly

If you are elderly, you should always consult your doctor before using Ibuprofen Strides. If you are elderly, you will be more prone to side effects, especially bleeding, ulcers and perforation in the gastrointestinal tract, which may be fatal. Your doctor will advise you accordingly.

Reduced liver or kidney function

If you have reduced kidney or liver function, always consult a doctor before using Ibuprofen Strides. Do not take this medicine if you suffer from severe liver or kidney failure.

Method of administration

The tablets should be swallowed whole with a glass of water. People with a sensitive stomach are advised to take Ibuprofen Strides with some food.

The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

If you take more Ibuprofen Strides than you should

If you have taken more Ibuprofen Strides 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, stomach pain, vomiting (may be blood streaked), or more rarely diarrhoea. In addition, headache, gastrointestinal bleeding, blurred vision, ringing in the ears, confusion and shaky eye movement, and exacerbation of asthma in asthmatics. At high doses, drowsiness excitation, disorientation, chest pain, palpitations, loss of consciousness, convulsions (mainly in children), weakness and dizziness, blood in urine, low blood pressure, increased potassium levels in the blood, increased prothrombin time/INR, acute renal failure, liver damage, respiratory depression, cyanosis, cold body feeling, and breathing problems have been reported.

If you forget to take Ibuprofen Strides

Do not take a double dose to make up for a tablet you have forgotten to take. Take the next tablet as usual.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Ibuprofen Strides can cause side effects, although not everybody gets them.

Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome.

Tissue fluid accumulation (oedema), high blood pressure and heart failure have been reported in association with treatment with NSAIDs. Medicines such as Ibuprofen Strides may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke.

The most commonly observed side effects affect the digestive tract. Stomach/duodenal ulcers (peptic ulcers), perforation or bleeding, sometimes fatal, may occur, especially in elderly patients (see section 2 "Warnings and precautions"). Nausea, vomiting, diarrhoea, flatulence, constipation, digestive complaints, abdominal pain, tarry stools, vomiting of blood, wounds (ulceration) in the mouth and throat region (ulcerative stomatitis), worsening of colitis and Crohn's disease (see section 2 "Warnings and precautions") have been reported after use. Less commonly, inflammation of the stomach lining (gastritis) has been observed. In particular, the risk of developing gastrointestinal bleeding depends on the dose level and duration of treatment.

Stop taking Ibuprofen Strides and contact a doctor immediately if you develop any of the following symptoms:

- severe general hypersensitivity reactions (very rare: may affect up to 1 in 10,000 people). These may manifest as: swelling of face, tongue and throat, shortness of breath, accelerated heartbeat, drop in blood pressure, up to a life-threatening shock. If one of these symptoms occur, which can happen even on first use, immediate medical assistance is required.
- severe stomach ache, especially when you start taking Ibuprofen Strides (uncommon: may affect up to 1 in 100 people).
- black stool, bloody diarrhoea or if you are vomiting blood (uncommon: may affect up to 1 in 100 people).
- fever, sore throat and mouth, flu like symptoms, feeling tired, nose and skin bleed. These can be caused by a reduction of white blood cells in your body (agranulocytosis) (very rare: may affect up to 1 in 10,000 people).
- severe or persistent headache (very rare: may affect up to 1 in 10,000 people).
- 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).
- Serious skin and mucous membrane changes such as epidermal necrolysis and/or erythema multiforme have been reported (very rare: may affect up to 1 in 10,000 people).
- if you develop a rash or mucous membrane lesions. The severe rashes may include blisters on the skin, especially on the legs, arms, hands and feet which can also involve the face and lips. This can get even more severe, where the blisters get larger and spread out and parts of the skin may slough off (toxic epidermal necrolysis). There may also be severe infection with destruction (necrosis) of skin, subcutaneous tissue and muscle (very rare: may affect up to 1 in 10,000 people).
- 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). See also section 2 (frequency not known: frequency cannot be estimated from the available data).

Other side effects that might occur

- **Common:** may affect up to 1 in 10 people
 - gastrointestinal symptoms such as acid burn, stomach pain and nausea, diarrhoea, vomiting, flatulence (wind) and constipation
 - minor gastrointestinal bleeding that, in exceptional cases, may cause anaemia.
- **Uncommon:** may affect up to 1 in 100 people
 - gastrointestinal ulceration, potentially with bleeding and perforation, ulcerative stomatitis, worsening of existing bowel disease (colitis or Crohn's disease), gastritis.
 - hypersensitivity reactions with skin rash and itching, as well as asthma attacks (possibly with drop in blood pressure).
 - disorders of the central nervous system, such as headache, dizziness, insomnia, agitation, irritability and fatigue.
 - visual disturbances
- **Rare:** may affect up to 1 in 1,000 people
 - tinnitus, loss of hearing.
 - Pain in the flanks and/or abdomen, blood in the urine, and a fever may be signs of damage to the kidneys (papillary necrosis). Elevated uric acid concentrations in the blood, elevated urea concentrations in the blood.
- **Very rare:** may affect up to 1 in 10,000 people
 - If signs of an infection occur or get worse during use of Ibuprofen Strides, you must go to a doctor without delay. It is to be investigated whether there is an indication for an anti-infective/antibiotic therapy. The symptoms of aseptic meningitis with neck stiffness, headache, nausea, vomiting, fever or consciousness clouding have been observed under ibuprofen. Patients with autoimmune disorders (systemic lupus erythematosus (SLE), mixed connective-tissue disease) appear to be predisposed.
 - problems in the blood cell production (anaemia, leukopenia, thrombocytopenia, pancytopenia, agranulocytosis) eosinophilia, coagulopathy (changes in coagulation), aplastic anemia, haemolytic anemia, neutropenia - 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. Don't use any self-treatment with painkillers or medicinal products that reduce fever (antipyretic medicinal products).
 - hypoglycaemia, hyponatremia
 - psychotic reactions, hallucinations, confusion, depression
 - pins and needles (paresthesia) and inflammation of the optic nerve (optic neuritis)
 - palpitations, heart failure, myocardial infarction, oedema, hypertension and cardiac failure have been reported in association with NSAID treatment at high doses.
 - arterial hypertension, vasculitis.
 - asthma, dyspnoea, bronchospasm
 - esophagitis, pancreatitis, formation of intestinal diaphragm-like strictures. In case of relatively severe pain in the upper abdomen, vomiting of blood or black stools, you must stop the treatment and consult a doctor.
 - damage to the liver (first signs could be discoloration of the skin), especially in long-term therapy, liver failure, acute hepatitis, impaired liver function.
 - passing less urine than normal and swelling (especially in patients with high blood pressure or reduced kidney function); swelling (oedema) and turbid 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 Ibuprofen Strides and consult your doctor immediately as these could be first signs of a kidney damage or kidney failure.

- Severe forms of skin reactions including rash with redness and blistering, Stevens- Johnson syndrome and toxic epidermal necrolysis (Lyell's syndrome), hair loss (alopecia).
- In exceptional cases severe skin infections and soft-tissue complications may occur during chickenpox (varicella infection).

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

- skin becomes sensitive to light (photosensitivity)
- drug reaction with eosinophilia and systemic symptoms (DRESS syndrome)
- acute generalised exanthematous pustulosis (AGEP),
- inflammation of nasal mucus (rhinitis) Kounis syndrome
- impaired renal function
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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 Nederlands Bijwerkingen Centrum Lareb
Website: www.lareb.nl. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Ibuprofen Strides

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

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

This medicinal product does not require any special storage conditions

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 Ibuprofen Strides contains

The active substance in this medicinal product is ibuprofen. Each tablet contains ibuprofen.

The other ingredients are:

Tablet core: Silica colloidal anhydrous, microcrystalline cellulose, pregelatinised starch (maize), sodium starch glycolate, talc, magnesium stearate

Film-coating: Hypromellose, Titanium Dioxide (E171), Lactose Monohydrate, Macrogol, sodium citrate

What Ibuprofen Strides looks like and contents of the pack

White coloured round shaped biconvex film-coated tablet debossed '2' on one side and break line on other side and a diameter of approx. 9.7 mm.

The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

The packs are available in PVC-Aluminium blister packs and supplied as 10, 20, 24, 30, 40, 50, 60, 70, 80, 90 and 100 packs.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Strides Pharma (Cyprus) Limited
Themistokli Dervi, 3
Julia House, 1st Floor

Nicosia 1066
Cyprus

Fairmed Healthcare GmbH
Maria-Goeppert-Straße 3
23562 Luebeck
Duitsland

In het register ingeschreven onder
RVG 126781

This medicinal product is authorised in the Member States of the EEA under the following names:

| | |
|----------------|---|
| Finland | Ibuprofen STRIDES 200 mg Kalvopäällysteiset tabletit |
| Czech Republic | Ibuprofen Strides |
| Germany | Ibu-Fairmed 200 mg Filmtabletten |
| Denmark | Ibuprofen Strides |
| Poland | Ibuprofen Strides |
| Romania | Ibuprofen Strides Pharma 200 mg comprimate filmate |
| Hungary | Ibuprofen STRIDES 200 mg filmtabletta |
| Sweden | Ibuprofen Strides Pharma 200 mg filmdragerade tabletter |

Deze bijsluiter is voor het laatst goedgekeurd in februari 2024.