

PACKAGE LEAFLET

Package leaflet: Information for the patient

Ibuprofen Viatris 400 mg oral suspension in sachet

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.

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.
- *Adults (over 18 years):* You must talk to a doctor if you do not feel better or if you feel worse after 3 days with fever or 5 days with pain.
- *Adolescents (over 12 years):* You must talk to a doctor if in children and in adolescents this medicinal product is required for more than 3 days, or if symptoms worsen.

What is in this leaflet

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

1. What <Invented name> is and what it is used for

The active ingredient (which makes the medicine work) is ibuprofen. It belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). <Invented name> reduces fever and relieves pain.

<Invented name> is used for short term treatment of mild to moderate pain and/or fever in adults and adolescents over 12 years (above 40 kg).

[For medicines available without a prescription:]

<Invented name> is used for short term treatment of mild to moderate pain such as:

- Headaches and migraine pain
- Toothache
- Period pain
- Muscular, joint and back pain
- Fever when you have the common cold.

<Invented name> 400 mg is used for adults and adolescents over 12 years (above 40 kg).

2. What you need to know before you take <Invented name>

Do not take <Invented name>:

- if you are allergic to ibuprofen or any of the other ingredients of this medicine (listed in section 6)
- if you have ever had an allergic reaction (such as asthma, skin rash, swollen face or lips or shortness of breath) to ibuprofen, acetylsalicylic acid or other NSAIDs
- you have severe heart failure
- you have severe liver or kidney impairment
- you have active bleeding or an increased tendency to bleed
- you have (or have had two or more episodes of) a stomach ulcer, duodenal ulcer or bleeding
- you have or ever had an ulcer or bleeding in your stomach or small intestine when taking NSAIDs
- if you are in the last 3 months of pregnancy.

Warnings and precautions

Always aim for the lowest possible dose and shortest possible treatment time to reduce the risk of side effects. Higher than recommended doses can entail risks. This also means that the combination of several NSAID products at the same administration time should be avoided.

Talk to your doctor or pharmacist before taking <Invented name>:

- if you have certain disorders of the immune system (mixed connective tissue disorders and systemic lupus erythematosus (SLE), conditions of the immune system affecting connective tissue resulting in joint pain, skin change and disorders of other organs) as there may be an increased risk of aseptic meningitis
- if you have impaired kidney or liver function
- 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 of 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 asthma, chronic rhinitis (chronic stuffy and runny nose) or allergic diseases since <Invented name> can cause difficulty breathing, hives or a serious allergic reaction when you have any of these conditions.
- if you have inflammatory bowel diseases, previous stomach ulcer or other increased tendency to bleed.
- if you have an infection - please see heading “Infections” below.

Ibuprofen may cause serious allergic reactions; especially if you are allergic to acetylsalicylic acid. The symptoms may include hives, swelling of the face, tongue or throat, difficulties swallowing, difficulties breathing. **Stop taking <Invented name> and contact a doctor immediately** if you develop any of these symptoms (see section 4 Possible side effects).

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 <Invented name> and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Ulcers and bleeding in the gastrointestinal tract

- Patients who have previously had gastrointestinal tract problems, especially elderly patients, should contact a doctor in the event of abdominal symptoms (especially gastrointestinal bleeding), particularly at the start of treatment. Bleeding, ulceration or perforation in the stomach or intestines may occur without any warning signs even in patients who have never had such problems before.
- Elderly patients should be aware of their increased risk of adverse events, especially bleeding and perforation in the digestive tract, which may be fatal.
- Treatment must be stopped, and a doctor consulted when gastrointestinal bleeding or ulceration occurs during treatment with <Invented name>.

Cardiovascular effects

- 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 <Invented name> and contact immediately your doctor or medical emergencies if you notice any of these signs.

Infections

- <Invented name> may hide signs of infections such as fever and pain. It is therefore possible that <Invented name> 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 it is advisable to avoid use of this medicine.

If you are dehydrated

- Caution should be exercised with regards to dehydrated patients, as there is a risk of renal impairment, especially in dehydrated adolescents and the elderly.

Headache

- Prolonged use of any type of painkiller for headaches can make them worse. If this situation is experienced or suspected, medical advice should be obtained, and treatment should be discontinued.

Children and adolescents

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

<Invented name> 400 mg should not be taken by children under 12 years of age (below 40 kg). For children other, more appropriate, strength and dosage forms are available.

Other medicines and <Invented name>

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

Do not use different types of pain-relieving medicines at the same time unless directed by a doctor.

<Invented name> may affect or be affected by treatment with certain medicines, including those to treat/prevent:

- tumours and immune system disorders (methotrexate)
- manic depressive illness (lithium)
- heart conditions (e.g. digoxin)
- acetylsalicylic acid to treat pain
- pain and inflammation (NSAIDs such as etoricoxib, naproxen, diclofenac)
- thromboembolic disorders (medicines that are anti-coagulants, i.e. thin blood/prevent clotting, e.g., clopidogrel, acetylsalicylic acid, warfarin, ticlopidine)

- depression (medicines called SSRIs - selective serotonin reuptake inhibitors)
- high blood pressure (medicines that reduce high blood pressure, e.g. ACE-inhibitors, beta-blockers, angiotensin-II receptor antagonists and diuretics)
- rejection in patients receiving organ transplants (medicines that suppress your immune system, such as ciclosporine or tacrolimus)
- inflammation (corticosteroids)
- bacterial infections (some antibiotics including aminoglycosides and quinolones)
- fungal infections (antifungals particularly voriconazole or fluconazole)
- diabetes mellitus (sulphonylureas)
- high cholesterol (cholestyramine)
- human immunodeficiency virus (HIV) infection (zidovudine)
- mifepristone
- herbal remedy called ginkgo biloba (there is a risk that you may bleed more easily if you are taking ibuprofen and ginkgo biloba at the same time).

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

<Invented name> with alcohol

If <Invented name> is taken together with alcohol, side effects may be increased.

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

Do not take ibuprofen 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 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, <Invented name> 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.

In addition to the effect that ibuprofen may have on the baby, <Invented name> also contains benzyl alcohol that may cause side effects. Treatment at any time in pregnancy should only take place as directed by a doctor.

Breast-feeding

<Invented name> 400 mg sachets may not be appropriate to use if you are breast-feeding. Ask your doctor for advice if you are breast-feeding before taking this medicine. Ibuprofen passes into breast milk but is unlikely to affect the child if used at the recommended dose during short term. However, this medicine also contains benzyl alcohol and may not be suitable during breast-feeding. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called "metabolic acidosis") in the child.

Fertility

The use of ibuprofen may impair fertility. This effect is reversible on stopping the medicine. The use of ibuprofen is not recommended while attempting to conceive or during investigation of infertility.

Driving and using machines

<Invented name> may impair reactions in some people, for example due to side effects such as visual disturbances, dizziness or drowsiness. This should be taken into consideration on occasions when high alertness is required, e.g. driving, and applies to a greater extent in combination with alcohol. . If you experience these side effect or any other any side effects affecting you alertness, you should not drive or operate machinery.

<Invented name> contains maltitol , sodium benzoate, benzyl alcohol and sodium

This medicine contains:

- maltitol (E 965). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
- 10 mg benzoate salt (E 211) in each sachet which is equivalent to 1 mg/ml.
- 0.0017 mg benzyl alcohol in each 10 ml sachet.
 - o Benzyl alcohol may cause allergic reactions.
 - o Ask your doctor for advice if you are **pregnant, breast-feeding** or if you have **liver** or **kidney disease**. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called “metabolic acidosis”). Also see section ‘Pregnancy, breast-feeding and fertility’.
- 58 mg sodium (main component of cooking/table salt) in each sachet. This is equivalent to 3% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to take <Invented name>

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

[For medicines available without a prescription]

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

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).

[For medicines available without a prescription]

Adults: (over 18 years): You must talk to a doctor if you do not feel better or if you feel worse after 3 days with fever or 5 days with pain.

Adolescents (over 12 years): You must talk to a doctor if in children and in adolescents this medicinal product is required for more than 3 days, or if symptoms worsen.

Adults and adolescents older than 12 years (over 40 kg)

The recommended dose is 1 sachet up to 3 times a day as required. Leave at least 4-6 hours between doses. Do not take more than 3 sachets in 24 hours.

Taking more than 1 sachet as a single dose does not give you a better pain-relieving effect and should be avoided.

Method of administration

For oral use. The sachet should be mixed before taking by pressing the top and bottom of the sachet with your fingers several times. You can take the medicine directly from the sachet. The contents of the sachet cannot be divided between doses and should be taken as a whole. For a faster onset of

action, <Invented name> may be taken on empty stomach. If you have a sensitive stomach, take <Invented name> with food.

If you take more <Invented name> than you should

If you have taken more <Invented name> 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.

The symptoms of overdose can include nausea (feeling sick), stomach pain, vomiting (may be blood streaked), headache, ringing in the ears, confusion and shaky eye movement. At high doses, drowsiness, chest pain, palpitations, loss of consciousness, convulsions (mainly in children), weakness and dizziness, blood in urine, low levels of potassium in your blood, cold body feeling, and breathing problems have been reported.

If you forget to take <Invented name>

Do not take a double dose to make up for a forgotten dose.

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.

Stop taking this medicine and contact a doctor or go to the nearest emergency department **immediately** if you notice any of the following serious side effects - you may need urgent medical attention:

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

- if you develop any of the following symptoms (signs of anaphylactic, angioedema or severe shock)
 - swelling of the face, tongue or throat,
 - difficulties swallowing,
 - hives and difficulties breathing.
- if you develop a reduction in the number of white blood cells (agranulocytosis) with decreased resistance to infection. You should see your doctor immediately if you experience an infection with symptoms such as
 - fever and serious deterioration of your general condition, or fever with local infection symptoms such as sore throat/pharynx/mouth or urinary problems.
- Non-bacterial meningitis symptoms may include
 - headache, stiff neck, nausea, sensitivity to light and sound and fever

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].

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

- Exceptionally, serious infections of the skin in case of chicken pox. When an NSAID is used, an infection-related inflammation of the skin could develop or become more severe (e.g. a condition such as necrotising fasciitis may develop characterized by intense pain, high fever, swollen and hot skin, blistering, necrosis). If signs of an infection of the skin occur or get worse during use of <Invented name> you are recommended to see your doctor immediately.

- A red, scaly widespread rash with bumps under the skin and blisters mainly localized on the skin folds, trunk, and upper extremities accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis). Stop using <Invented name> if you develop these symptoms and seek medical attention immediately. See also section 2.
- In addition, 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 cell). Symptoms of DRESS syndrome usually appear approximately 2–6 weeks (possibly up to 8 weeks) after treatment begins.
- Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome

Other side effects that may occur:

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

- Headache, lightheadedness
- Gastrointestinal side effects (indigestion, diarrhoea, nausea (feeling sick), vomiting (being sick), stomach pain, flatulence (wind), constipation, black stools, bleeding in stomach and intestine, vomiting blood)
- Rash
- Tiredness

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

- Rhinitis (itchy, runny or blocked nose, sneezing)
- Hypersensitivity
- Insomnia (difficulty sleeping), anxiety
- Drowsiness
- Visual disturbances
- Hearing loss, tinnitus (ringing in ears)
- Dizziness
- Coughing, breathing difficulty and pain in the chest (Bronchial spasm), asthma, shortness of breath (dyspnea)
- Mouth ulceration
- Stomach ulcer, intestinal ulcer, ruptured stomach ulcer, inflammation of mucous membrane of stomach
- Hepatitis (inflammation of the liver), jaundice, abnormal liver function
- Rash, itching, small bruises in skin and mucous membranes
- Photosensitivity (sensitivity to the sun)
- Impaired kidney function
- Tingling sensation

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

- Depression, confusion
- Impaired vision,
- Vision loss, eye pain which is worsened by eye movement, loss of colour vision cause by inflammation or damage of the optic nerve (optic neuritis, toxic optic neuropathy)
- Fluid retention in body
- Changes in blood count
- Anaemia (a reduction in red blood cells or hemoglobin)

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

- Inflammation of the pancreas, liver failure
- Heart failure, heart attack
- High blood pressure

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

- Worsening of ulcers in the large intestine (colitis) and Crohn's Disease (bowel disease)
- A distinctive cutaneous allergic reaction known as fixed drug eruption, that usually recurs at the same site(s) on re-exposure to the medication and may look like round or oval patches of redness and swelling of the skin, blistering (hives), itching

Please note that <Invented name> can prolong bleeding time.

Medicines like <Invented name> may entail a slightly increased risk of heart attack 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 [the national reporting system listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store <Invented name>

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

This medicinal product does not require any special storage conditions

Do not use this medicine after the expiry date which is stated on the carton after EXP. 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 <Invented name> contains

The active substances is ibuprofen. Each sachet (10 ml) contains: 400 mg ibuprofen.

The other ingredients are: glycerol, liquid maltitol E965, xanthan gum, citric acid, sodium citrate, sodium benzoate E211, sodium saccharin, purified water, sodium chloride, hypromellose, thaumatin E957, strawberry flavour which contains benzyl alcohol . See section 2 ('<Invented name> contains maltitol, sodium benzoate, benzyl alcohol and sodium').

What <Invented name> looks like and contents of the pack

<Invented name> is a white, viscous, strawberry flavoured oral suspension.

<Invented name> is available in packs of 10 and 20 sachets of 10 ml.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

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

Italy	Brufenlik
Portugal	Brufen Liq
Sweden	Ibuprofen Viatris 400 mg oral suspension i dospåse

This leaflet was last revised in 01/2026.