

Package leaflet: Information for the user

Ibuprofen Twelve Plus pain relief 200mg/5ml oral suspension

Ibuprofen

The name of your medicine is Ibuprofen Twelve Plus pain relief 200mg/5ml oral suspension which will be referred to as 'Twelve Plus pain relief' throughout this leaflet.

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, pharmacist or nurse 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 for children and adolescents aged 12 to 18 years, and after 10 days for adults.

What is in this leaflet:

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

① What this medicine is and what it is used for

The active ingredient (which makes this medicine work) is Ibuprofen. It belongs to a group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs provide relief by changing the body's response to pain, swelling and high temperature.

This medicine is used for the relief of:

- Headaches and migraine pain
- Dental pain and neuralgia
- Period pain
- Rheumatic, muscular and back pain
- Feverishness and symptoms of cold and flu
- The pain of non-serious arthritis

② What you need to know before you take this medicine

This medicine is suitable for the majority of people, but certain people should not use it. Talk to your pharmacist or doctor if you are at all unsure or if you have an infection (please see heading 'Infections' below).

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 Twelve Plus pain relief and contact immediately your doctor or medical emergencies if you notice any of these signs.

Do not take this medicine if you or your child:

- are allergic to ibuprofen or any of the other ingredients of this medicine (listed in section 6).
- have ever had a stomach ulcer, perforation or bleeding.
- have had a worsening of asthma, skin rash, itchy, runny nose or facial swelling when previously taking ibuprofen, aspirin or similar medicines.
- have had gastrointestinal bleeding or perforation when previously taking NSAIDs (Non-steroidal Anti-inflammatory Drugs).
- are taking other NSAIDs (Non-steroidal Anti-inflammatory Drugs).
- are taking more than 75mg of aspirin a day. If you are on a low-dose aspirin (up to 75mg daily) speak to your doctor or pharmacist before you take this medicine.
- have severe liver or kidney problems.
- have heart problems, high blood pressure or blood coagulation disorder.
- have breathing difficulties.
- are in the last 3 months of pregnancy.
- are under 12 years old.

Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine if you or your child:

- have or have had asthma.
- have kidney, heart, liver or bowel problems.
- have high cholesterol or previously have had a heart attack or stroke.
- have a history of gastrointestinal disease (such as ulcerative colitis, Crohn's disease).
- have Systemic Lupus Erythematosus (a condition of the immune system causing joint pain, skin changes and other organ disorders).
- have chicken pox.
- are elderly.
- are a smoker.
- are trying to get pregnant.
- are in the first 6 months of pregnancy.
- have an infection - please see heading 'Infections' below.

Skin reactions

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

Do not exceed the recommended dose or duration of treatment.

If you are taking Twelve Plus pain relief for longer than the recommended time or at higher than recommended doses you are at risk of serious harm. These include serious harms to the stomach/gut and kidneys, as well as low levels of potassium in your blood. These can be fatal (see section 4).

Other medicines and Twelve Plus pain relief

To reduce the risk of side effects, do not take this product with other NSAID containing products (e.g. aspirin, ibuprofen or naproxen). If you are on low-dose aspirin (up to 75mg daily), speak to your doctor or pharmacist before taking this medicine.

Ibuprofen may affect or be affected by some other medicines.

For example:

Avoid taking this product with corticosteroid tablets, quinolone, antibiotics or drugs that are prescribed:

- Medicines that are anti-coagulants (i.e. thin blood/prevent clotting, e.g. aspirin, warfarin, ticlopidine).
- To stimulate your heart (e.g. glycosides).
- Medicines that reduce high blood pressure (ACE inhibitors such as captopril, beta-blockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan).
- To help you pass water (diuretics).
- For the temporary suppression of your immune system (e.g. methotrexate, cyclosporine, tacrolimus).
- For mania or depression (e.g. lithium or serotonin selective reuptake inhibitors [SSRIs]).
- For pregnancy termination (e.g. mifepristone).
- For HIV treatment (e.g. zidovudine).
- Quinolone antibiotics to treat a wide range of infections (e.g. ciprofloxacin).
- Antiplatelet drugs (e.g. dipyridamole, clopidogrel).

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

Other warnings

- Anti-inflammatory/painkiller medicines such as ibuprofen may be associated with a **small** increased risk of heart attack ('myocardial infarction') or stroke. Any risk is more likely with high doses or prolonged treatment. Do not exceed the recommended dose or duration of treatment.
- You should discuss your treatment with your doctor or pharmacist before taking Ibuprofen 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.
- There is a risk of renal impairment in dehydrated children and adolescents.

Ibuprofen with alcohol

You should avoid alcohol while taking this medicine.

Pregnancy, breast-feeding and fertility

Pregnancy

Tell your doctor if you become pregnant whilst taking this medicine.

Ibuprofen belongs to a group of medicines which may **impair fertility in women**. This is reversible on stopping the medicine. It is unlikely that this medicine, used occasionally will affect your chances of becoming pregnant. However, tell your doctor before taking this medicine if you have problems becoming pregnant.

You should only take this product on a doctor's advice during the first 6 months of pregnancy.

DO NOT take Ibuprofen oral suspension 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 oral suspension 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 oral suspension 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

Speak to your doctor or pharmacist before taking this medicine if you are breast-feeding.

This medicine contains maltitol liquid and sodium

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

This medicine contains 57.9mg of sodium (main component of cooking/table salt) in each 10ml dose. This is equivalent to 2.9% of the recommended maximum daily dietary intake of sodium for an adult.

Infections

Ibuprofen oral suspension may hide signs of infections such as fever and pain. It is therefore possible that Ibuprofen oral suspension 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 chicken pox. If you take this medicine while you have an infection and your symptoms of the infection persist or worsen, consult a doctor without delay.

③ How to take this medicine

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.

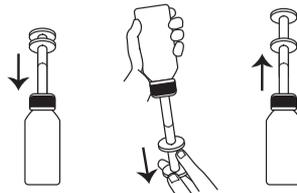
The lowest effective dose should be used for the shortest duration necessary to relieve symptoms. If you have an infection, consult a doctor without delay if symptoms (such as fever and pain) persist or worsen (see section 2).

Always shake the bottle vigorously before use.

To remove the cap, push it down and turn it anti-clockwise. There is a 5ml oral syringe (graduated in 0.25ml steps), which should be used to give the medicine.

Using the 5ml dosing syringe

- Push the syringe firmly into the plug (hole) in the neck of the bottle.
- To fill the syringe, turn the bottle upside down. Whilst holding the syringe in place, gently pull the plunger down drawing the medicine to the correct mark on the syringe (see section overleaf).
- Turn the bottle the right way up, remove the syringe from the bottle plug by gently twisting the syringe.
- Place the end of the syringe into your or your child's mouth and gently press down the plunger slowly to gently release the medicine.



- After use, replace the bottle cap. Wash the syringe in warm water and allow it to dry. Store out of the sight and reach of children.

Adults, the elderly and children and adolescents aged 12 to 18 years.

One 5ml to 10ml dose up to three times a day as required. Leave at least four hours between doses. Do not take more than 30ml (1200mg) in 24 hours. Ibuprofen should be taken with or after food.

Duration of treatment

This product is intended for short term use only. You should only take the lowest dose for the shortest time necessary to relieve your symptoms.

If in children and adolescents between 12 and 18 years this medicinal product is required for more than 3 days, or if symptoms worsen, a doctor should be consulted.

Adults must not take this product for more than 10 days unless your doctor tells you to. If symptoms persist or worsen consult your doctor.

Do not give to children under 12 years

If you take more medicine than you should

If you have taken more medicine 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 an overdose can include nausea, 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, coma, convulsions (mainly in children), weakness and dizziness, blood in urine, cold body feeling, and breathing problems have been reported.

If you forget to take this medicine

If you forget a dose, take the next dose when needed, provided that the last dose was taken at least 4 hours ago. Do not take more than advised. 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. Tell your doctor or pharmacist if you notice any of the following:

- Liver, kidney problems or difficulty urinating.

This medicine, especially when taken at higher than recommended doses or for a prolonged period of time, can cause damage to your kidneys and affect them removing acids properly from your blood into the urine (renal tubular acidosis). It can also cause very low levels of potassium in your blood (see section 2). This is a very serious condition and will require immediate treatment. Signs and symptoms include muscle weakness and light-headedness.

You may suffer one of the known side effects of NSAIDs (see below). If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.

STOP TAKING the medicine and seek immediate medical help if you or your child develop:

- **Signs of intestinal bleeding** such as:
 - bright red faeces (stools/motions)
 - black tarry stools
 - vomiting blood or dark particles that look like coffee grounds.
- **Signs of a serious allergic reaction** such as:
 - difficulties in breathing or unexplained wheezing
 - asthma
 - dizziness or faster heartbeat
 - 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)
 - a severe skin reaction known as DRESS syndrome can occur. Symptoms of DRESS include widespread skin rash, high body temperature, enlarged lymph nodes and an increase of eosinophils (a type of white blood cell)
 - 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. The symptoms usually appear at the initiation of treatment (acute generalised exanthematous pustulosis)
 - swelling of your face, tongue or throat
 - chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome.
- **Signs of kidney problems** such as:
 - passing less or more urine
 - cloudy urine or blood in urine
 - pain in the back and/or swelling (particularly in the legs).
- **Signs of aseptic meningitis** such as:
 - neck stiffness
 - headache
 - feeling sick
 - being sick
 - fever or loss of consciousness
 - patients with autoimmune disorders (lupus, mixed connective-tissue disease) may be more likely to be affected.

STOP TAKING this medicine and tell your doctor if you or your child experience the following uncommon side effects WHICH may affect up to 1 in 100 people:

- Indigestion, heartburn or feeling sick.
- Pains in your stomach (abdomen) or other abnormal stomach problems.
- Heartburn.
- Nausea or vomiting.
- Yellowing of the eyes, pale stools and dark urine (these can be signs of kidney or liver problems).

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

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

- Allergic reactions, such as skin rashes (urticaria), itching, peeling.
- Headache.

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

- Flatulence (wind), diarrhoea, constipation or vomiting.

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

- Blood disorder resulting in unexplained or unusual bruising or bleeding, fever, sore throat, mouth ulcers, flu-like symptoms and severe exhaustion.
- Drop in blood pressure or irregular heartbeat.
- 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).
- Liver problems (e.g. yellowing of the eyes, pale stools and dark urine).
- Stroke or heart problems.

Side effects for which the frequency cannot be estimated from available data:

- Worsening of asthma or bronchospasm.
- Swelling (oedema), high blood pressure, heart failure or attack.
- Worsening of colitis and Crohn's disease.
- Serious infections of the skin and soft tissues have occurred during chicken pox (varicella).
- Skin becomes sensitive to light.

Medicines such as Twelve Plus pain relief may be associated with a small increased risk of heart attack ('myocardial infarction') or stroke. See section 2 'Other warnings'.

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 Yellow Card Scheme (website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store). By reporting side effects you can help provide more information on the safety of this medicine.

⑤ How to store this medicine

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

This medicine does not require any special storage conditions.

Once opened, this product is stable at room temperature for 6 months.

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 Twelve Plus pain relief contains

The active substance is ibuprofen.

5ml oral suspension contains 200mg ibuprofen.

The other ingredients are:

Sodium benzoate (E211), citric acid anhydrous, sodium citrate, saccharin sodium, sodium chloride, hypromellose, xanthan gum, maltitol liquid, glycerol (E422), thaumatin (E957), strawberry flavour (natural flavouring preparations, maize maltodextrin, triethyl citrate (E1505), propylene glycol (E1520) and benzyl alcohol), purified water.

What Twelve Plus pain relief looks like and contents of the pack

This medicine is a white or off-white viscous suspension.

Twelve Plus pain relief is available in bottles of 30ml and 100ml with a child-resistant closure.

Not all pack-sizes may be marketed.

For accurate dosing a polypropylene oral syringe for oral administration, graduated in 0.25ml steps up to 5ml, is included in the pack.

Marketing Authorisation Holder and Manufacturer

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