

## Package leaflet: Information for the user

# Ibuprofen Seven Plus Pain Relief 200mg/5ml oral suspension

## Ibuprofen

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

### Read all of this leaflet carefully before you start using this medicine because it contains important information for you and your child.

This medicine is available without prescription, but you still need to give this medicine carefully to get the best results from it. Always use 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 your doctor if your child does not feel better or feels worse after three days.

### What is in this leaflet:

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

### ① What Ibuprofen oral suspension is and what it is used for

This medicine contains ibuprofen as the active ingredient. Each 5ml of oral suspension contains 200mg of ibuprofen. **This is twice the strength of normal ibuprofen suspension and you should be careful that you use the correct dose.**

Ibuprofen belongs to a group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs).

This medicine is given to children aged 7-12 years as a painkiller for relief of:

- rheumatic or muscular pain
- headache and dental pain
- feverishness and symptoms of cold and flu

This medicine should not be used for more than 3 days.

### ② What you need to know before you give Ibuprofen oral suspension

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

### Do not give this medicine if your child:

- has an allergy or hypersensitivity to ibuprofen or any of the other ingredients of this medicine (See section 6 and section 2: Important information about ingredients).
- has had an allergic reaction such as wheezing, an asthma attack, runny nose, skin reaction or swelling after taking aspirin or other non-steroidal anti-inflammatory painkillers.
- has ever had a stomach ulcer or history of bleeding into, or perforation of, the intestine especially after previous NSAID treatment.
- is taking any other non-steroidal anti-inflammatory painkillers (NSAIDs) such as naproxen.
- is taking aspirin at doses above 75mg daily.
- has ever had severe kidney, heart or liver problems.
- has an inherited intolerance to some sugars.
- is less than seven years of age or weighs less than 20kg.

### Warnings and precautions

You should discuss your child's treatment with your doctor or pharmacist before giving this medicine if your child:

- has kidney, liver or bowel problems.
- has Systemic Lupus Erythematosus (a condition of the immune system causing joint pain, skin changes and other organ disorders) or mixed connective tissue disease.
- has a chronic inflammatory bowel disease such as ulcerative colitis or Crohn's disease.
- has asthma or allergic diseases of the lungs.
- has chicken pox.
- has or has had high blood pressure, heart problems or stroke because there is a small increased risk of heart problems with ibuprofen.
- has a condition which may put them at risk of heart problems such as diabetes or high cholesterol.
- is dehydrated as there is a risk of kidney problems.

If you are taking Ibuprofen oral suspension 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 very low levels of potassium in your blood. These can be fatal (see section 4).

### 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 Ibuprofen oral suspension 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. There is a risk of renal (kidney) impairment in dehydrated children.

### Ibuprofen with alcohol

Drinking alcohol while taking ibuprofen may increase the risk of certain side effects.

### Other medicines and Ibuprofen

Tell your doctor or pharmacist if your child is taking, has recently taken or might take any other medicines, including medicines obtained without a prescription.

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

- Any other ibuprofen preparations or NSAID painkillers, including those you can buy without a prescription.
- Low dose aspirin (up to 75mg a day).
- Medicines that are anticoagulants (i.e. thin blood/prevent clotting, e.g. aspirin, warfarin).
- Medicines that reduce high blood pressure (ACE inhibitors such as captopril, beta-blockers such as atenolol, angiotensin-II receptor antagonists such as losartan).
- Cardiac glycosides (used in the treatment of heart problems, such as digoxin).
- Ciclosporin or tacrolimus (used to suppress the body's immune system).
- Corticosteroids (anti-inflammatory drugs, such as prednisolone, or beclomethasone).
- Diuretics (to help pass water such as furosemide or bendroflumethiazide).
- Lithium, or selective serotonin reuptake inhibitors (SSRIs - such as fluoxetine used to treat mood disorders).
- Methotrexate (used to treat rheumatoid arthritis, psoriasis and some cancers).
- Mifepristone (used to terminate pregnancy).
- Quinolone antibiotics (used to treat a wide range of infections e.g. ciprofloxacin).
- Zidovudine (used to treat HIV).
- 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 child's doctor or pharmacist before you give ibuprofen with other medicines.

### Important information about some of the ingredients of this medicine:

#### This medicine contains maltitol liquid and sodium

- Maltitol (E965) may have a mild laxative effect (calorific value 2.3 kcal/g). If you have been told that your child has an intolerance to some sugars, contact your doctor before giving 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.

### Other warnings

The following warnings are less likely to apply to children but should be considered before giving this medicine.

- In limited studies, ibuprofen appears in the breast milk in very low concentrations and is unlikely to affect the breast-fed infant adversely.
- Ibuprofen may be associated with a small increased risk of heart attack ('myocardial infarction') or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment.
- You should discuss your treatment with your doctor or pharmacist if you have diabetes, high cholesterol, high blood pressure, 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'), or if you have a family history of heart disease or stroke, or if you are a smoker.

### Pregnancy and breast-feeding

#### 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.

### 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 give Ibuprofen oral suspension

#### This product is twice the strength of normal ibuprofen suspension and you should be careful that you use the correct dose.

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

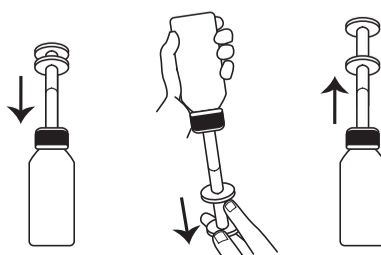
The lowest effective dose should be used for the shortest duration necessary to relieve symptoms. If you have an infection, consult a doctor without delay if symptoms (such as fever and pain) persist or worsen (see section 2).

#### 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 below).
- 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 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.

The recommended dose is:

Age	How much
Under seven years	Do not use
Seven - nine years	One 5ml dose up to three times in 24 hours
Ten - twelve years	One 5ml dose and one 2.5ml dose up to three times in 24 hours
<ul style="list-style-type: none"> <li>• <b>Do not give to children under 7 years of age or those weighing less than 20kg.</b></li> <li>• Separate the doses evenly (every 6-8 hours). Leave at least 4 hours between doses.</li> <li>• Do not give more than 3 doses in any 24 hour period.</li> </ul>	

**Warning: Do not exceed the stated dose.**

#### Duration of treatment

This product is intended for short term use only. You must talk to your doctor or pharmacist if your child **does not get better or feels worse after three days.**

#### If you give more medicine than you should

If you have given 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 give this medicine

If you forget to give a dose, give it as soon as you remember, unless it is almost time for the next dose. Do not give a double dose to make up for the missed dose.

#### For oral use only.

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.

**STOP TAKING the medicine and seek immediate medical help if your child develops:**

- **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 your child experiences the following side effects:**

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

**Tell your doctor if your child has 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 Ibuprofen oral suspension 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](http://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 Ibuprofen oral suspension

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 medicinal product does not require any special storage conditions.

Once opened, this medicine 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 this medicine 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 (E-1505), propylene glycol (E-1520) and benzyl alcohol), purified water.

##### What this medicine looks like and contents of the pack

Ibuprofen oral suspension is a white or off-white viscous suspension.

It 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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