

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### Easofen for Children Strawberry 100mg/5ml oral suspension

#### 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 have 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, pharmacist or nurse. 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 Easofen oral suspension is and what it is used for
- 2 What you need to know before you use Easofen oral suspension
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- 4 Possible side effects
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#### 1. WHAT EASOFEN ORAL SUSPENSION IS AND WHAT IT IS USED FOR

Easofen oral suspension is a medicine that reduces pain and fever (non-steroidal anti-inflammatory drug, NSAID).

Easofen oral suspension is used as an analgesic (pain killer) for relief of teething pain, earache, headache, muscular minor aches and sprains, sore throats and cold and flu symptoms

**Do not give to babies under 3 months or babies weighing less than 5 kg.**

#### 2. WHAT YOU NEED TO KNOW BEFORE YOU USE EASOFEN ORAL SUSPENSION

This medicine is suitable for the majority of people but certain people should not use it. Talk to your doctor or pharmacist if you are unsure.

##### Do not use this medicine

- if your child is allergic to ibuprofen or any of the other ingredients of this medicine (listed in section 6)
- if your child previously suffered an allergic reaction (e.g. skin rash, runny nose or wheezing/breathlessness, swelling of the lips, face, tongue or throat) **after taking aspirin or other non-steroidal anti-inflammatory (NSAID) medicines**
- if your child weighs **less than 5kg** or is under **3 months** of age
- if your child is taking any other **anti-inflammatory (NSAID) painkillers or aspirin**
- if your child has (or has had two or more episodes of) a **stomach ulcer, perforation or bleeding from an ulcer or elsewhere**
- if your child has severe **kidney, heart or liver failure**
- if your child has **inherited problems coping with fructose/fruit sugar** (hereditary fructose intolerance). This is because the body can make some fructose from the ingredient maltitol.
- if your child suffers from blood clotting disorders as ibuprofen may increase bleeding time
- if your child has unclarified blood-formation disturbances such as thrombocytopenia
- if your child has bleeding of the brain (cerebrovascular bleeding) or other active bleeding
- if your child has severe dehydration (caused by vomiting, diarrhoea or insufficient fluid intake)

##### Warnings and precautions

Talk to your doctor or pharmacist before using Easofen oral suspension

- if your child has or has had **high blood pressure, heart problems** or a **stroke** because there is a small increased risk of heart problems with ibuprofen
- if your child has a condition which may put them at risk of **heart problems**, such as **diabetes** or **high cholesterol**
- if your child has a condition which increases tendency to bleeding or they have bleeding in the skull
- if your child has had previous allergic reactions to other substances, **asthma** or any **allergic disease of the lungs**
- if your child suffers from hayfever, nasal polyps or chronic obstructive respiratory disorders as an increased risk of allergic reactions exists. The allergic reactions may present as asthma attacks (so called analgesic asthma), Quincke's oedema or urticaria (hives)
- if your child has, or has had **liver, kidney, heart or bowel problems**
- if your child has **SLE** (Systemic Lupus Erythematosus, a condition of the immune system), exfoliative dermatitis, Stevens-Johnson syndrome, or any similar disease
- if your child suffers from **chronic inflammatory bowel disease** such as Crohn's disease or ulcerative colitis
- if you previously experienced stomach bleeding or perforation after taking ibuprofen or other non-steroidal anti-inflammatory drugs (NSAIDs)
- if your child has just undergone major surgery
- if your child is dehydrated as there is an increased risk of kidney problems
- if your child has certain hereditary blood formation disorders (e.g. acute intermittent porphyria)
- When stomach ulcer or bleeding occurs in patients receiving Easofen oral suspension the treatment should be withdrawn.
- If you have chicken pox (varicella) as it is advisable to avoid use of Easofen oral suspension
- if you have an infection - please see heading "Infections" below.

#### *Skin reactions*

Serious skin reactions have been reported in association with Easofen oral suspension treatment. You should stop taking Easofen oral suspension 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.

#### *Infections*

Easofen oral suspension may hide signs of infections such as fever and pain. It is therefore possible that Easofen 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 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.

#### **Other medicines and Easofen oral suspension**

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

#### **Easofen oral suspension may affect or be affected by the following medicines**

- other **medicines containing ibuprofen, aspirin (acetylsalicylic acid) or other NSAID's** including those you can buy over the counter
- **diuretics** (to help you pass water)
- **anticoagulants** (blood thinning medicines e.g. warfarin)
- **medicines for high blood pressure** (e.g. captopril, atenolol, losartan)
- **lithium** (for mood disorders)
- **methotrexate** (for psoriasis, arthritis and types of cancer)
- **zidovudine** (for HIV)
- **corticosteroids** (an anti-inflammatory drug)

- **probenecid** and **sulfinpyrazone** (to treat gout)
- **aminoglycosides** (a type of antibiotic)
- **oral hypoglycaemic agents** (oral medicines to treat diabetes)
- **cardiac glycosides digoxin** (for heart problems)
- **ciclosporin or tacrolimus** (to prevent organ rejection after transplant)
- **SSRI (selective serotonin reuptake inhibitor) antidepressant drugs**
- **antiplatelet drugs** e.g. dipyridamole, clopidogrel
- **quinolone antibiotics** (used to treat infections)
- **cholestyramine** (used to treat diarrhoea)
- **variconazole and fluconazole** (used to treat fungal infections)
- **baclofen** (used to treat muscle spasm)
- **phenytoin** (for epilepsy)
- if you have taken **mifepristone** now or in the last 12 days
- **ritonavir**

Some medicines that are anti-coagulants (i.e. thin blood/prevent clotting, e.g. aspirin/acetylsalicylic acid, warfarin, ticlopidine), some medicines that reduce high blood pressure (ACE inhibitors such as captopril, beta-blockers such as atenolol or angiotensin II receptor antagonists such as losartan) and other medicines that may affect or be affected by treatment with ibuprofen. You should therefore always seek the advice of your doctor or pharmacist before you use ibuprofen with other medicines.

**Seek the advice of your doctor or pharmacist if any of the above apply. If you are not sure what types of medicines your child is taking, show the medicine to your doctor or pharmacist.**

#### **Easofen oral suspension with food, drink and alcohol**

You should not drink alcohol while using Easofen oral suspension. Some side effects, such as those affecting the gastrointestinal tract or the central nervous system can be more likely when alcohol is taken at the same time as Easofen oral suspension.

The oral suspension can be taken without regard to meals. People with a sensitive stomach are recommended to take Easofen oral suspension with food.

#### **If you are an adult taking this medicine**

The warnings and information given in this section apply and in addition the following:

#### **Pregnancy, breast feeding and fertility**

- 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 Easofen oral suspension if you are in the last 3 months of your pregnancy
- **Breast-feeding:** Only small amounts of ibuprofen and the products it breaks down into in the body pass into breast milk. Easofen oral suspension may be used during breast-feeding, if it is used at the recommended dose and for the shortest possible time.

#### **Other warnings**

- Medicines such as Easofen oral suspension 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 3 days
- If you have (or have had two or more episodes of) a **stomach ulcer, perforation or bleeding**
- **Risk of a heart attack or stroke:** if you have heart problems, previous stroke or think that you might be at risk of these conditions (for example if you have high blood pressure, diabetes or high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist
- **Elderly:** elderly patients are more prone to side effects such as stomach bleeding and perforation which may be fatal. Talk to your doctor or pharmacist before taking this medicine.

- **Gastrointestinal** 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 gastrointestinal events. In this case treatment with Easofen oral suspension should be stopped immediately. The risk of gastrointestinal bleeding, ulceration or perforation is higher with increasing NSAID doses and in patients with a history of ulcer, particularly if complicated with haemorrhage or perforation 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 these patients, and also for patients requiring concomitant low dose acetylsalicylic acid, or other drugs likely to increase gastrointestinal risk.

#### **Driving and using machines**

There are no known side effects on driving or use of machines.

#### **Easofen oral suspension contains maltitol and sodium**

- If you have been told by a doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
- Maltitol may have a mild laxative effect. Calorific value 2.3 kcal/g maltitol
- This medicine contains 17.92mg sodium (main component of cooking/table salt) in each 5ml. This is equivalent to 0.9% of the recommended maximum daily dietary intake of sodium for an adult.

### **3. HOW TO USE EASOFEN ORAL SUSPENSION**

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

The recommended dose is:

<b>Age</b>	<b>Dose</b>
3 months – 6 months Weighing over 5 kg	One 2.5ml dose 3 times in 24 hours
6 months – 12 months	One 2.5ml dose 3 times in 24 hours
1 year – 3 years	One 5ml dose 3 times in 24 hours
4 years – 6 years	One 7.5 ml (5ml + 2.5ml) dose 3 times in 24 hours
7 years to 9 years	One 10ml (5ml + 5ml) dose 3 times in 24 hours
10 years to 12 years	One 15ml (5ml + 5ml + 5ml) dose 3 times in 24 hours
<ul style="list-style-type: none"> <li>• Doses should be given every 6 – 8 hours as needed. Leave at least 6 hours between doses.</li> </ul>	

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

#### **Talk to your doctor**

- **If you are not sure of your child's illness or it is accompanied by a rash, breathing difficulties, diarrhoea or excessive tiredness, speak to your doctor straight away.**

Oral use. The package includes a 5 ml oral syringe (graduated in 0.25 ml steps). Shake the bottle vigorously before use. The oral suspension can be taken without regard to meals. People with a sensitive stomach are recommended to take Easofen oral suspension during meals.

Please talk to your doctor or pharmacist if you feel that the effect of Easofen oral suspension is too strong or too weak.

#### Duration of treatment

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 children aged 3 – 5 months medical advice should be sought if symptoms worsen or not later than 24 hours if symptoms persist. If in children aged from 6 months this medicinal product is required for more than 3 days, or if symptoms worsen a doctor should be consulted.

#### **If you give your child more Easofen oral suspension than you should**

If you have taken more Easofen oral suspension 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 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, convulsions (mainly in children), weakness and dizziness, blood in urine, cold body feeling, and breathing problems have been reported.

#### **If you forget to give your child Easofen oral suspension**

Do not give 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.

The most common side effect is irritation of the stomach which can cause problems such as indigestion or heartburn.

#### **If your child experiences any of the following, stop giving this medicine and tell your doctor immediately:**

- blood in the stools (faeces/motions)
- severe pain in stomach
- black tarry stools
- vomiting blood or dark particles that look like coffee grounds
- **signs of rare but serious allergic reactions** such as worsening of asthma, unexplained wheezing or shortness of breath, swelling of the face, tongue or throat, difficulty breathing, skin rash (which may be severe with blistering and peeling of the skin), serious skin reaction (e.g. Steven-Johnson's Syndrome), itching or bruising, racing heart, drop in blood pressure leading to shock. These can happen even on first use of this medicine. If any of these symptoms occur, call a doctor at once.
- stiff neck, headache, nausea, vomiting, fever and disorientation.
- severe skin reactions such as rashes covering the whole body, peeling, blistering or flaking skin

#### **If your child experiences any of the following side effects, stop giving this medicine and tell your doctor**

- unexplained stomach pain, indigestion, heartburn, nausea or vomiting
- yellowing of the eyes, pale stools and dark urine, liver problems
- severe sore throat with high fever
- unexplained bleeding, or have bleeding in the skull, bruising or tiredness or getting more infections such as colds, than normal

#### **Other side effects which may occur are:**

##### **Common: may affect up to 1 in 10 people**

- Stomach pain, nausea, vomiting, heartburn, flatulence (wind), diarrhoea, constipation, and slight gastro-intestinal bleeding that may cause anaemia in certain cases.

##### **Uncommon: may affect up to 1 in 100 people**

- Central nervous system disturbances such as headache, dizziness, sleeplessness, agitation, irritability, or tiredness
- Visual disturbances
- Hypersensitivity (allergic) reactions with skin rashes and itching, as well as asthma attacks, and a possible drop in blood pressure
- Various skin rashes
- Gastrointestinal ulcers, bleeding or perforation, ulcerative stomatitis, worsening of existing bowel disease (Ulcerative Colitis or Crohn's disease), gastritis.

**Rare: may affect up to 1 in 1,000 people**

- Tinnitus (ringing in the ears)
- Increased urea concentrations in blood, pain in the flanks and/or the abdomen, blood in the urine and a fever
- Diarrhoea, wind or constipation. Tell your doctor if these last for more than a few days or become troublesome
- Increased uric acid concentrations in the blood
- Decreased haemoglobin levels

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

- Kidney problems, kidney failure may occur with ibuprofen
- Stroke or heart problems may occur with ibuprofen. This is unlikely at the dose level given to children
- Worsening of colitis and Crohn's disease
- High blood pressure, vasculitis
- Alopecia, severe skin reactions and soft tissue complications, such as erythema multiforme, Stevens Johnsons Syndrome, Toxic Epidermal Necrolysis, and complications during chicken pox (varicella) infection
- Severe general allergic reactions
- Severe skin infections and soft tissue complications during chicken pox (varicella) infection.
- Psychotic reactions, depression
- Blood disorders. First signs include: fever, sore throat, superficial mouth ulcers, flu-like symptoms, severe exhaustion, nose and skin bleeding. In such cases stop this medicine immediately and consult a doctor.
- Palpitations, heart failure, heart attack, oedema
- Liver dysfunction, damage to the liver (particularly during long-term treatment), liver failure, acute inflammation of the liver (hepatitis)
- Worsening of infection-related inflammation. If signs of an infection occur or get worse during treatment with this medicine, immediately consult a doctor
- Inflammation of the oesophagus or the pancreas, or formation of intestinal strictures.
- Increased urea in the blood, decreased excretion of urea
- Passing less urine than normal, cloudy urine (nephritic syndrome), inflammatory kidney disease (interstitial nephritis), that may lead to acute kidney failure.
- A type of damage to the kidneys (papillary necrosis).
- Aseptic meningitis

**Not known: frequency cannot be estimated from the available data**

- Respiratory tract reactivity comprising asthma, bronchospasm or dyspnoea.
- 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 Easofen oral suspension if you develop these symptoms and seek medical attention immediately. See also section 2.
- skin becomes sensitive to light

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 cells).

### Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); e-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. HOW TO STORE EASOFEN 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.

After first opening, store below 25°C. Use within 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 Easofen oral suspension contains**

The active substance is ibuprofen.

5 ml oral suspension contains 100 mg ibuprofen.

The other ingredients are: Sodium benzoate (E211), citric acid anhydrous, sodium citrate, saccharin sodium, sodium chloride, hypromellose, xanthan gum, maltitol liquid, glycerol (E422), strawberry flavour (natural flavouring preparations, maize maltodextrin, triethyl citrate (E-1505), propylene glycol (E-1520) and benzyl alcohol), purified water. Easofen oral suspension is sugar free.

### **What Easofen oral suspension looks like and contents of the pack**

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

Easofen oral suspension is available in plastic bottles of 100 ml, 150 ml and 200 ml with a child-resistant closure.

Not all pack-sizes may be marketed.

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

### **Marketing Authorisation Holder**

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

### **Manufacturers**

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

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