ORBIFEN FOR CHILDREN 100MG/5ML ORAL SUSPENSION (IBUPROFEN)

PL 17862/0010

UKPAR

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LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency (MHRA) granted Orbis Consumer Products Limited a Marketing Authorisation (licence) for the medicinal product Orbifen for Children 100mg/5ml Oral Suspension (PL 17862/0010) on 13th November 2007. This is a P licensed medicine available from pharmacies.

Orbifen for Children 100mg/5ml Oral Suspension contains the active ingredient ibuprofen, which is an analgesic (relieves pain), an anti-inflammatory (reduces inflammation), and an anti-pyretic (lowers your temperature when you have a fever). Orbifen for Children 100mg/5ml Oral Suspension is used to treat mild to moderate muscular pain and to bring down fever, including post-immunisation fever.

This application is a duplicate of a previously granted application for Ibuprofen 100 mg/5 ml Oral Suspension for Children (PL 17862/0001), held by Orbis Consumer Products Ltd. The test and reference product are identical.

No new or unexpected safety concerns arose from this simple application and it was therefore judged that the benefits of taking Orbifen for Children 100mg /5ml Oral Suspension outweigh the risks, hence a Marketing Authorisation has been granted.

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SCIENTIFIC DISCUSSION

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INTRODUCTION

The UK granted a marketing authorisation for the medicinal product Orbifen for Children 100mg/5ml Oral Suspension (PL 17862/0010) on 13th November 2007. This is a P licensed medicine available from pharmacies.

The application was submitted as a simple abridged application according to article 10c of Directive 2001/83/EC (as amended), cross-referring to Ibuprofen 100 mg/5 ml Oral Suspension for Children (PL 17862/0001), approved on 3rd July 2001. This standard abridged application had been approved as a generic medicinal product of Brufen syrup (PL 00014/0217, granted 06/09/1979) transferred to Knoll Ltd (PL 00169/0048).

No new data was submitted nor was it necessary for this simple application, as the data is identical to that of the previously granted cross-reference product. As the cross-reference product was granted prior to the introduction of current legislation, no PAR was generated for it.

Orbifen for Children 100mg/5ml Oral Suspension contains the active ingredient ibuprofen, which is an analgesic (relieves pain), an anti-inflammatory (reduces inflammation), and an anti-pyretic (lowers your temperature when you have a fever). Orbifen for Children 100mg/5ml Oral Suspension is used to treat mild to moderate muscular pain and to bring down fever, including post-immunisation fever.

PHARMACEUTICAL ASSESSMENT

LICENCE NUMBER:	PL 17862/0010
PROPRIETARY NAME:	Orbifen for Children 100mg/5ml Oral Suspension
ACTIVE INGREDIENTS:	Ibuprofen
COMPANY NAME:	Orbis Consumer Products Ltd
E.C. ARTICLE:	Article 10c of Directive 2001/83/EC (as amended)
LEGAL STATUS:	P

1. INTRODUCTION

This is a simple abridged application, submitted under Article 10c of Directive 2001/83/EC (as amended) for Orbifen for Children 100mg/5ml Oral Suspension. The proposed MA holder is 'Orbis Consumer Products Ltd, Cunard Road, Park Royal, London, NW10 6PN.'

The reference product is Ibuprofen 100 mg/5 ml Oral Suspension for Children (PL 17862/0001), held by Orbis Consumer Products Ltd. The test and reference product are identical.

2. MARKETING AUTHORISATION APPLICATION FORM

2.1 Name(s)

The proposed name of the product is Orbifen For Children 100 mg/5 ml Oral Suspension. The product has been named in line with current requirements.

2.2 Strength, pharmaceutical form, route of administration, container and pack sizes

The product contains the active ingredient ibuprofen. Each 5ml of suspension contains 100mg of ibuprofen. The container closure system is amber type III glass bottles, 100ml in size. The bottles are closed with a child resistant, tamper-evident high density polypropylene cap. A 5ml measuring spoon is provided as the administration device with all packs of the product.

The proposed shelf-life (2 years) and storage conditions (Do not store above 25^{o}C; Store in the original container) are consistent with the details registered for the cross-reference product.

2.3 Legal status

The product is a P licensed medicine available by supply through pharmacies.

2.4 Marketing authorisation holder/Contact Persons/Company

The proposed Marketing Authorisation holder is 'Orbis Consumer Products Ltd, Cunard Road, Park Royal, London, NW10 6PN'.

The QP responsible for pharmacovigilance is stated and their CV is included.

2.5 Manufacturers

The proposed manufacturing site is consistent with that registered for the cross-reference product and evidence of GMP compliance has been provided.

2.6 Qualitative and quantitative composition

The proposed composition is consistent with the details registered for the cross-reference product.

2.7 Manufacturing process

The proposed manufacturing process is consistent with the details registered for the cross-reference product and the maximum batch size is stated.

2.8 Finished product/shelf-life specification

The proposed finished product specification is in line with the details registered for the cross-reference product.

2.9 Drug substance specification

The proposed drug substance specification is consistent with the details registered for the cross-reference product.

2.10 TSE Compliance

No materials of animal or human origin are included in the product.

3. EXPERT REPORTS

Satisfactory expert reports and curriculum vitae of experts are provided.

4. PRODUCT NAME & APPEARANCE

See 2.1 for details of the proposed product name. The appearance of the product is identical to the cross-reference product.

5. SUMMARY OF PRODUCT CHARACTERISTICS

The approved SmPC is consistent with the details registered for the cross-reference product.

6. PATIENT INFORMATION LEAFLET (PIL) / CARTON

PIL

The patient information leaflet has been prepared in the user tested format and in line with the details registered for the cross-reference product. The approved PIL is satisfactory.

Carton and bottle label

The approved artwork is comparable to the artwork registered for the cross-reference product and complies with statutory requirements. In line with current legislation the applicant has included the name of the product in Braille on the outer packaging and has included sufficient space for a standard UK pharmacy dispensing label.

7. CONCLUSIONS

The grounds for this application are considered adequate. It is recommended that a Marketing Authorisation is granted for this application.

PRECLINICAL ASSESSMENT

The application was submitted as a simple abridged application according to article 10c of Directive 2001/83/EC (as amended).

No new preclinical data have been supplied with this application and none are required for an application of this type.

CLINICAL ASSESSMENT

The application was submitted as a simple abridged application according to article 10c of Directive 2001/83/EC (as amended).

As this is a duplicate application for PL 17862/0001, no new clinical data have been supplied with the application and none are required.

OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY

The data for this application is consistent with that previously assessed for the cross-reference product and as such has been judged to be satisfactory.

PRECLINICAL

No new preclinical data were submitted and none are required for an application of this type.

EFFICACY

Medicinal products containing ibuprofen have been available in the UK for much more than ten years. Their use is well established with recognised efficacy and acceptable safety.

Ibuprofen is a well known drug and has been used as an analgesic, anti-inflammatory, anti-pyretic agent for many years. This application is identical to the previously granted application for Ibuprofen 100 mg/5 ml Oral Suspension for Children (PL 17862/0001), which was demonstrated to be a generic medicinal product of the innovator product Brufen syrup (PL: 00014/0217 granted 06/09/1979) transferred to Knoll Ltd (PL 00169/0048).

No new or unexpected safety concerns arise from this application.

PRODUCT LITERATURE

The approved SPC, PIL and labelling are satisfactory and consistent with that for the cross-reference product.

A package leaflet has been submitted to the MHRA along with results of consultations with target patient groups ("user testing"), in accordance with Article 59 of Council Directive 2001/83/EC. The results indicate that the package leaflet is well-structured and organised, easy to understand and written in a comprehensive manner. The test shows that the patients/users are able to act upon the information that it contains.

RISK BENEFIT ASSESSMENT

The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. The applicant’s product is identical to the cross-reference product which, in turn, has been shown to be interchangeable with the innovator product. Extensive clinical experience with ibuprofen is considered to have demonstrated the therapeutic value of the compound. The risk benefit is therefore considered to be positive.

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STEPS TAKEN FOR ASSESMENT

1 The MHRA received the marketing authorisation application on 21st April 2007

2 Following standard checks and communication with the applicant the MHRA considered the application valid on 12th July 2007

3 Following assessment of the application the MHRA requested further information relating to the quality dossier on 23rd July 2007

4 The applicant responded to the MHRA's requests, providing further information for the quality sections on 6th August 2007

5 Following assessment of the response the MHRA requested further information relating to the quality sections on 14th August 2007

6 The applicant responded to the MHRA's request, providing further information for the quality sections on 2nd October 2007

7 Following assessment of the response the MHRA requested further information relating to the quality sections on 12th October 2007

8 The applicant responded to the MHRA's request, providing further information for the quality sections on 23rd October 2007

9 The application was determined on 13th November 2007

SUMMARY OF PRODUCT CHARACTERISTICS

The UK Summary of Product Characteristics (SPC) for Orbifen for Children 100mg/5ml Oral Suspension is as follows:

1 NAME OF THE MEDICINAL PRODUCT

Orbifen For Children 100mg/5ml Oral Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ibuprofen 100 mg / 5ml

For excipients- see section 6.1

3 PHARMACEUTICAL FORM

Oral Suspension

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

Ibuprofen suspension is used as an analgesic for relief of mild to moderate pain, post-immunisation pyrexia, reduction of fever, sore throats, teething pain, toothache, earache, minor aches and sprains.

4.2 POSOLOGY AND METHOD OF ADMINISTRATION

For oral administration and short-term use only.

Children: Not recommended for children weighing less than 7 kg.

For pain and fever - 20mg/kg/day in divided doses.

Infants 6-12 months: 2.5ml three times a day.

Children 1-2 years: 2.5ml three to four times a day

Children 3-7 years: 5ml three to four times a day

Children 8-12 years: 10ml three to four times a day.

If the child's symptoms persist for more than 3 days, consult a doctor.

Not to be given to children under 6 months of age except on the advice of a doctor.

4.3 CONTRAINDICATIONS

Hypersensitivity to ibuprofen or any of the constituents in the product.

Patients who have previously shown hypersensitivity reactions (e.g. asthma, rhinitis, angioedema or urticaria) in response to aspirin or other non-steroidal anti-inflammatory drugs.

Active or previous peptic ulcer.

History of upper gastrointestinal bleeding or perforation, related to previous NSAIDs therapy.

Use with concomitant NSAIDs including cyclo-oxygenase-2 specific inhibitors (See section 4.5 Interactions).

Severe hepatic failure, renal failure or heart failure (See section 4.4, Special warnings and precautions for use)

Last trimester of pregnancy (See section 4.6 Pregnancy and lactation)

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Caution (discussion with doctor or pharmacist) is required prior to starting treatment in patients with a history of hypertension and/or heart failure as fluid retention, hypertension and oedema have been reported in association with NSAID therapy.

Undesirable effects may be minimized by using the lowest effective dose for the shortest duration necessary to control symptoms (see GI and cardiovascular risks below).

Cardiovascular and cerebrovascular effects

Clinical trial and epidemiological data suggest that use of ibuprofen, particularly at high doses (2400mg daily) and in long-term treatment may be associated with a small increased risk of arterial thrombotic events (for example myocardial infarction or stroke). Overall, epidemiological studies do not suggest that low dose ibuprofen (e.g. ≤ 1200mg daily) is associated with an increased risk of myocardial infarction.

Bronchospasm may be precipitated in patients suffering from or with a previous history of bronchial asthma or allergic disease.

Undesirable effects may be minimised by using the minimum effective dose

for the shortest possible duration.

Systemic lupus erythematosus and mixed connective tissue disease - increased risk of aseptic meningitis (see section 4.8 Undesirable effects)

Chronic inflammatory intestinal disease (ulcerative colitis, Crohn's disease) – as these conditions may be exacerbated (See section 4.8 Undesirable effects).

Hypertension and/or cardiac impairment as renal function may deteriorate and/or fluid retention occur.

Renal impairment as renal function may further deteriorate (See section 4.3 Contraindications and Section 4.8 Undesirable effects)

Hepatic dysfunction (See section 4.3 Contraindications and Section 4.8 Undesirable effects)

There is limited evidence that drugs which inhibit cyclo-oxygenase/ prostaglandin synthesis may cause impairment of female fertility by an effect on ovulation. This is reversible upon withdrawal of treatment.

GI bleeding, ulceration or perforation, which can be fatal, has been reported with all NSAIDs at anytime during treatment, with or without warning symptoms or a previous history of serious GI events.

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

Caution should be advised in patients receiving concomitant medications which could increase the risk of gastrotoxicity or bleeding, such as corticosteroids, or anticoagulants such as warfarin or anti-platelet agents such as aspirin (see section 4.5 Interactions).

When GI bleeding or ulceration occurs in patients receiving ibuprofen, the treatment should be withdrawn.

4.5 INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

Ibuprofen should not be used in combination with:

Aspirin: Unless low-dose aspirin (not above 75mg daily) has been advised by a doctor, as this may increase the risk of adverse reactions (See section 4.3 Contraindications).

Other NSAIDS: As these may increase the risk of adverse effects (See section 4.3 Contraindications).

Ibuprofen should be used with caution in combination with:

Anticoagulants: NSAIDS may enhance the effects of anti-coagulants, such as warfarin (See section 4.4).

Antihypertensives and diuretics: NSAIDs may diminish the effect of these drugs.

Corticosteroids: May increase the risk of adverse reactions in the gastrointestinal tract (See section 4.4 Special warnings).

Lithium: There is evidence for potential increases in plasma levels of lithium.

Methotrexate: There is a potential for an increase in plasma methotrexate.

Zidovudine: There is evidence of an increased risk of haemarthroses and haematoma in HIV (+) haemophiliacs receiving concurrent treatment with zidovudine and ibuprofen.

4.6 PREGNANCY AND LACTATION

Whilst no teratogenic effects have been demonstrated in animal experiments, the use of Orbifen should, if possible, be avoided during the first 6 months of pregnancy.

During the 3rd trimester, ibuprofen is contraindicated as there is there is a risk of premature closure of the foetal ductus arteriosus with possible persistent pulmonary hypertension. The onset of labour may be delayed and the duration increased with an increased bleeding tendency in both mother and child. (See section 4.3 Contraindications).

In limited studies, ibuprofen appears in the breast milk in very low concentration and is unlikely to affect the breast-fed infant adversely.

See section 4.4 regarding female fertility.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

None expected at recommended doses and duration of therapy.

4.8 UNDESIRABLE EFFECTS

Clinical trial and epidemiological data suggest that use of ibuprofen (particularly at high doses 2400mg daily) and in long-term treatment may be associated with a small increased risk of arterial thrombotic events (for example myocardial infarction or stroke) (see section 4.4).

Hypersensitivity reactions have been reported and these may consist of:

(a) Non-specific allergic reactions and anaphylaxis

(b) Respiratory tract reactivity, eg asthma, aggravated asthma, bronchospasm, dyspnoea

(c) Various skin reactions, e.g. pruritus, urticaria, angioedema and more rarely exfoliative and bullous dermatoses (including epidermal necrolysis and erythema multiforme)

The following list of adverse effects relates to those experienced with ibuprofen at OTC doses, for short-term use. In the treatment of chronic conditions, under long-term treatment, additional adverse effects may occur.

Hypersensitivity reactions:

Uncommon: Hypersensitivity reactions with urticaria and pruritus.

Very rare: severe hypersensitivity reactions. Symptoms could be: facial, tongue and laryngeal swelling, dyspnoea, tachycardia, hypotension, (anaphylaxis, angioedema or severe shock).

Exacerbation of asthma and bronchospasm.

Gastrointestinal:

Uncommon: abdominal pain, nausea and dyspepsia.

Rare: diarrhoea, flatulence, constipation and vomiting.

Very rare: peptic ulcer, perforation or gastrointestinal haemorrhage, sometimes fatal, particularly in the elderly. Exacerbation of ulcerative colitis and Crohn's disease (See section 4.4).

Nervous System:

Uncommon: Headache

Renal:

Very rare: Acute renal failure, papillary necrosis, especially in long-term use, associated with increased serum urea and oedema.

Hepatic:

Very rare: liver disorders.

Haematological:

Very rare: Haematopoietic disorders (anaemia, leucopenia, thrombocytopenia, pancytopenia, agranulocytosis). First signs are: fever, sore throat, superficial mouth ulcers, flu-like symptoms, severe exhaustion, unexplained bleeding and bruising.

Skin:

Uncommon: Various skin rashes

Very rare: Severe forms of skin reactions such as erythema multiforme and epidermal necrolysis can occur.

Immune System:

In patients with existing auto-immune disorders (such as systemic lupus erythematosus, mixed connective tissue disease) during treatment with ibuprofen, single cases of symptoms of aseptic meningitis, such as stiff neck, headache, nausea, vomiting, fever or disorientation have been observed (See section 4.4)

4.9 OVERDOSE

In children ingestion of more than 400 mg/kg may cause symptoms. In adults the dose response effect is less clear cut. The half-life in overdose is 1.5-3 hours.

Symptoms

Most patients who have ingested clinically important amounts of NSAIDs will develop no more than nausea, vomiting, epigastric pain, or more rarely diarrhoea. Tinnitus, headache and gastrointestinal bleeding are also possible. In more serious poisoning, toxicity is seen in the central nervous system, manifesting as drowsiness, occasionally excitation and disorientation or coma. Occasionally patients develop convulsions. In serious poisoning metabolic acidosis may occur and the prothrombin time/ INR may be prolonged, probably due to interference with the actions of circulating clotting factors. Acute renal failure and liver damage may occur. Exacerbation of asthma is possible in asthmatics.

Management

Management should be symptomatic and supportive and include the maintainance of a clear airway and monitoring of cardiac and vital signs until stable. Consider oral administration of activated charcoal if the patient presents within 1 hour of ingestion of a potentially toxic amount. If frequent or prolonged, convulsions should be treated with intravenous diazepam or lorazepam. Give bronchodilators for asthma.

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Ibuprofen is a propionic acid derivative NSAID that has demonstrated its efficacy by inhibition of prostaglandin synthesis. In humans ibuprofen reduces inflammatory pain, swellings and fever. Furthermore, ibuprofen reversibly inhibits platelet aggregation.

5.2 PHARMACOKINETIC PROPERTIES

Ibuprofen is rapidly absorbed following administration and is rapidly distributed throughout the whole body. The excretion is rapid and complete via the kidneys.

Maximum plasma concentrations are reached 45 minutes after ingestion if taken on an empty stomach. When taken with food, peak levels are observed after 1 to 2 hours. These times may vary with different dosage forms.

The half-life of ibuprofen is about 2 hours.

In limited studies, ibuprofen appears in the breast milk in very low concentrations.

5.3 PRECLINICAL SAFETY DATA

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Glycerol

xanthan gum

maltitol liquid

polysorbate 80

saccharin sodium

citric acid monohydrate

sodium methyl parahydroxybenzoate

sodium propyl parahydroxybenzoate

purified water

strawberry flavour.

6.2 INCOMPATIBILITIES

Not Applicable.

6.3 SHELF LIFE

24 months.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Do not store above 25ºC.

6.5 NATURE AND CONTENTS OF CONTAINER

Amber Type III glass bottle.

Child resistant, tamper-evident polypropylene cap.

5ml-measuring spoon is supplied

Pack sizes available:100ml

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

None

7 MARKETING AUTHORISATION HOLDER

Orbis Consumer Products Limited
Cunard Road
London NW10 6PN

8 MARKETING AUTHORISATION NUMBER(S)

PL 17862/0010

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

13/11/2007

10 DATE OF REVISION OF THE TEXT

13/11/2007

PATIENT INFORMATION LEAFLET

Patient Information Leaflet
Orbifen For Children 100mg/5ml Oral Suspension
Ibuprofen

This leaflet contains important information about Orbifen For Children. Read this leaflet carefully before you start using this medicine.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact your doctor if your/ your child's symptoms worsen or do not improve in 3 days.

1. What this medicine is for

Orbifen For Children belongs to a group of medicines called anti-inflammatory pain killers.
It is used as a pain killer (an analgesic) to relieve pain. This pain could be mild to moderate muscular pain such as teething pain, toothache, earache and minor injuries such as sprains and strains.

Orbifen For Children can also be used to bring down fever (high temperature) – including post-immunisation fever.

2. Before using this medicine

This medicine is suitable for most people but a few people should not use it. If you are in any doubt, talk to your doctor or pharmacist.

X Do not give this medicine to babies or children who....
- weigh less than 7 kg.
- **have ever had** a bad reaction to any of the ingredients (see section 6).
- **have or ever had** a stomach ulcer or other gastric complaint.
- **have or ever had** an allergic reaction or wheezing after taking Ibuprofen, Asprin or other anti-inflammatory pain killers.
- are taking other NSAID painkillers.
- suffer from severe kidney, liver or heart problems.

Adults taking this product should be aware of these factors and additionally not take the product if you:
- are taking other NSAID painkillers, or aspirin with a daily dose above 75mg
- are in the last 3 months of pregnancy.

Talk to your doctor or pharmacist before giving Orbifen For Children if they/you...
- **have** asthma or have suffered from asthma.
- **have** kidney, liver, heart or blood pressure problems.
- **have** bowel problems.
- **have** Systemic Lupus Erythematosus (SLE) – a condition to the immune system affecting connective tissue resulting in joint pains, skin changes and disorder of other organs.
- **are** taking other medicines including:
  - Diuretics (water tablets)
  - Tablets for high blood pressure
  - Medicine such as warfarin, to prevent blood clots
  - Digoxin, lithium, steroid tablets, methotrexate, cyclosporin or mifepristone
  - Antibiotics called quinolones (such as ciprofloxacin)
  - Any other Ibuprofen preparations, including those you can buy without prescription
  - Any other anti-inflammatory pain killers
  - low-dose aspirin (up to 75mg daily)

  If you are not sure about the medicines your child is taking, show the bottle or pack to your pharmacist.
- **If you are** in the first 6 months of pregnancy.
- **If you are** planning to become pregnant. Orbifen belongs to a group of medicines which may impair fertility in women. This effect is reversible on stopping the medicine. It is unlikely that Orbifen, used occasionally, will affect your chances of becoming pregnant, however, tell your doctor before taking this medicine if you have problems becoming pregnant.
- **If you are** breast feeding.
- Medicines such as Orbifen 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 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.

Driving and operating machinery
- Your medicine is unlikely to affect your ability to drive or to operate machinery.

Important information about some of the ingredients of Orbifen For Children
- Maltitol liquid(E965): If you have been told by your doctor that your child has intolerance to some sugars, contact your doctor before taking this medicinal product.

Important information about some of the ingredients of Orbifen For Children (continued...)

- Sodium methyl parahydroxybenzoate (E219) and Sodium propyl parahydroxybenzoate (E217): May cause allergic reactions (possibly delayed).
- Glycerol may cause headache, stomach ache or diarrhoea.

3. How to use this medicine

If this medicine has been prescribed by your doctor, your doctor will have decided what dose your child should take each day depending on the medical condition.

- Give with or after food
- Shake the bottle well before measuring the dose. A measuring spoon is provided to ensure accuracy.

The usual daily dose in children is 20mg per kg of bodyweight in divided doses which can be given as follows:

DOSAGE: CHILDREN (1 spoonful= 5ml)	
6 months - 1 year:	Half a spoonful three times a day
1 year - 2 years:	Half a spoonful three to four times a day
3 years - 7 years:	One spoonful three to four times a day
8 years - 12 years:	Two spoonfuls three to four times a day

Warning: Do NOT exceed the stated dose

- If the symptoms persist for more than 3 days consult your doctor.
- Not suitable for children under 6 months.
- Do not give to your child if s/he weighs less than 7kg

If you take more Orbifen For Children than you should

If you, your child or someone you know accidentally takes alot more than the stated dose (an overdose) of this medicine, either call your doctor straight away, or go to your nearest hospital casualty department. Always take any remaining medicine, the container and the label with you, so that the medicine can be identified.

If you forget to give Orbifen For Children

If you forget to give a dose, give the next dose as soon as you remember unless it is time for the next dose. Don't give two doses at the same time.
If you are worried, or not sure of when or how to use this medicine, ask your doctor or pharmacist for advice.

4. Possible side effects

As well as benefits, all medicines may sometimes have effects you do not want. Many years' experience has shown that problems with this type of medicine (containing Ibuprofen) are uncommon.

The most common side-effect is irritation of the stomach which can cause problems in some patients. If side effects do occur, they are usually mild, but If you suffer from any of the following at any time during your treatment **STOP TAKING** the medicine and **seek immediate** medical help:

- Pass blood in your faeces (stools/motions)
- Pass black tarry stools
- Vomit any blood or dark particles that look like coffee grounds

STOP TAKING the medicine and tell your doctor if you experience:

- Indigestion or heartburn
- Abdominal pain (pains in your stomach) or other abnormal stomach symptoms
- Unexplained wheezing, shortness of breath, skin rash, itching or bruising.
- Yellowing of the eyes and/or skin.
- Severe sore throat with high fever.
- Blurred or disturbed vision.
- Fluid retention, e.g.swollen ankles.

Rarely, blood disorders and kidney problems may occur with Ibuprofen.
Other, unusual effects may include headache, dizziness, tingling of the hands and feet, ringing in the ears, diarrhoea, tiredness, malaise, mood swings and confusion. If any of these become troublesome or last more than a few days, tell your doctor.
Medicines such as Orbifen may be associated with a small increased risk of heart attack (myocardial infarction) or stroke.
If your child experience any other unusual symptoms while taking this medicine, tell your doctor or pharmacist.

5. Storing your medicine

- Keep out of the reach and sight of children
- Do not store above 25ºC
- Do not take your medicine after the "use by" or expiry date shown on the label.
- Return any unused or unwanted medicine to the pharmacy for safe disposal.

6. Further information

Each 5ml of suspension contains 100mg Ibuprofen .
It also contains purified water, glycerol, xanthan gum,maltitol liquid, polysorbate 80, saccharin sodium, citric acid monohydrate, sodium methyl parahydroxybenzoate, sodium propyl parahydroxybenzoate and strawberry flavour.

Each bottle contains 100ml of oral suspension.
Product licence holder (PL 17862/0010) and manufacturer of Orbifen For Children is:
Orbis Consumer Products Ltd., Cunard Road, Park Royal, London, NW10 6PN

Remember: This medicine is for your child. Never give it to anybody else, even if their symptoms are the same as yours. This leaflet does not contain the complete information about your medicine. If you have any other questions or are not sure about anything, ask your doctor or pharmacist.

Leaflet Updated: August 2007

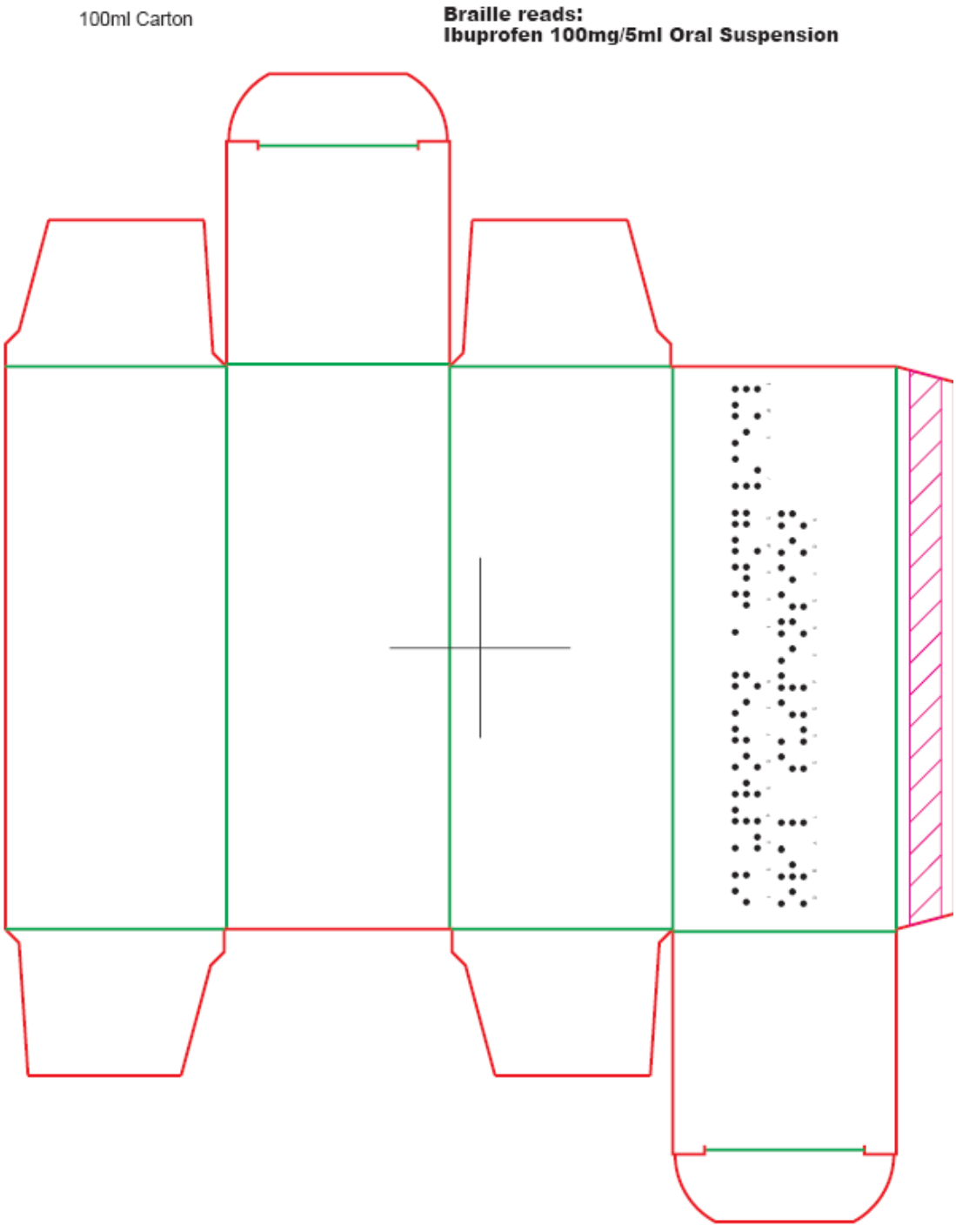
3107/1

Orbis

LABELLING

Carton

Braille


100ml Carton
Braille reads:
Ibuprofen 100mg/5ml Oral Suspension

Bottle label