Medicines & Healthcare products Regulatory Agency

MHRA

Public Assessment Report

National Procedure

IBUPROFEN 100 MG/5 ML ORAL SUSPENSION
TESCO HEALTH IBUPROFEN 100 MG/5 ML ORAL SUSPENSION
BELLS HEALTHCARE CHILDREN'S PAIN AND FEVER RELIEF 100 MG/5 ML ORAL SUSPENSION
(ibuprofen)

PL 20395/0329

Relonchem Limited

LAY SUMMARY

Ibuprofen 100 mg/5 ml oral suspension
Tesco Health Ibuprofen 100 mg/5 ml Oral Suspension
Bells Healthcare Children's Pain and Fever Relief 100 mg/5 ml Oral Suspension
(ibuprofen)

This is a summary of the Public Assessment Report (PAR) for Ibuprofen 100 mg/5 ml oral suspension/Tesco Health Ibuprofen 100 mg/5 ml Oral Suspension/Bells Healthcare Children's Pain and Fever Relief 100 mg/5 ml Oral Suspension. It explains how this product was assessed and its authorisation recommended, as well as its conditions of use. It is not intended to provide practical advice on how to use this product.

This product will be referred to as Ibuprofen oral suspension in this lay summary for ease of reading.

For practical information about using Ibuprofen oral suspension, patients should read the package leaflet or contact their doctor or pharmacist.

What is Ibuprofen oral suspension and what is it used for?
This application is the same as Ibuprofen 100 mg/ 5 ml oral suspension (PL 20395/0259) which is already authorised.

The Company responsible for Ibuprofen 100 mg/ 5 ml oral suspension (PL 20395/0259) has agreed that its scientific data can be used as the basis for the grant of an identical licence/licences for Ibuprofen oral suspension.

Ibuprofen oral suspension is used is used to relieve:

- Fever (high temperature) including post immunisation fever
- Mild to moderate pain including headache, sore throat, teething pain and toothache, cold and flu symptoms and minor aches and sprains.

How does Ibuprofen oral suspension work?
This medicine contains the active ingredient ibuprofen. Ibuprofen belongs to a group of medicines called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs). These medicines work by changing how the body responds to pain, swelling and high temperature.

How is Ibuprofen oral suspension used?
The pharmaceutical form of this medicine is an oral suspension and the route of administration is oral.

The bottle should be shaken thoroughly before use and the dose should be measured using the measuring spoon provided. This medicine must not be given to babies under 3 months or babies weighing less than 5 kg.

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

The recommended dose in children over 7 to 9 years is two 5 ml spoonful's, three times a day.

The recommended dose in children aged 4 to 6 years is one 5 ml spoonful plus one 2.5 ml spoonful (7.5 ml), three times a day.
The recommended dose in children aged 1 to 3 years is one 5 ml spoonful, three times a day.
The recommended dose in infants aged 6 months to 1 year is one 2.5 ml spoonful, 3-4 times a day.

If a child's symptoms persist for more than 3 days, or if new symptoms occur, a doctor should be consulted.

The recommended dose in babies aged 3-6 months is one 2.5 ml spoonful three times a day. This medicine should not be given to babies aged 3 to 6 months for more than 24 hours.

Doses should usually be given every 6 – 8 hours, preferably with or after food.

This medicine should not be given more often than every 4 hours and the recommended dose should not be exceeded in 24 hours.

For post-immunisation fever in babies and children 3 months and over weighing more than 5 kg, one 2.5ml spoonful may be given followed by one further 2.5ml spoonful 6 hours later if necessary. No more than 2 doses should be given in 24 hours. If fever is not reduced, a doctor should be consulted.

For further information on how Ibuprofen oral suspension is used, refer to the Patient Information Leaflet (PIL) and Summary of Product Characteristics (SmPC) available on the Medicines and Healthcare products Regulatory Agency (MHRA) website.

This medicine can be obtained without a prescription.

The patient/carer should always use the medicine exactly as their doctor/pharmacist has told them. The patient/carer should check with their doctor or pharmacist if they are not sure.

What benefits of Ibuprofen oral suspension have been shown in studies?
Ibuprofen oral suspension is considered identical to the previously authorised product with the same benefits and risks. No new studies have been provided for Ibuprofen oral suspension, however, reference is made to the studies for Ibuprofen 100 mg/ 5 ml oral suspension (PL 20395/0259).

What are the possible side effects of Ibuprofen oral suspension?
Ibuprofen 100 mg/5 ml oral suspension is considered to be identical to the previously authorised product with the same benefits and risks.

For the full list of all side effects reported with this medicine, see Section 4 of the PIL or the SmPC available on the MHRA website.

Why was Ibuprofen oral suspension approved?
The MHRA decided that the benefits of Ibuprofen 100 mg/5 ml oral suspension are greater than the risks and recommended that this medicine is approved for use.

What measures are being taken to ensure the safe and effective use of Ibuprofen oral suspension?

A Risk Management Plan (RMP) has been developed to ensure that Ibuprofen oral suspension is used as safely as possible. Based on this plan, safety information has been included in the SmPC and PIL, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored and reviewed continuously.

Other information about Ibuprofen oral suspension

A Marketing Authorisation was granted in the UK on 19 March 2021.

The full PAR for Ibuprofen oral suspension follows this summary.

This summary was last updated in April 2021.

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I. INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the Medicines and Healthcare products Regulatory Agency (MHRA) considered that the application for Ibuprofen 100 mg/5 ml oral suspension/Tesco Health Ibuprofen 100 mg/5 ml Oral Suspension/Bells Healthcare Children's Pain and Fever Relief 100 mg/5 ml Oral Suspension (PL 20395/0329) could be approved.

The product is approved for the following indications:
For the fast and effective reduction of fever, including post immunisation pyrexia and the fast and effective relief of the symptoms of colds and influenza and mild to moderate pain, such as a sore throat, teething pain, toothache, headache, minor aches and sprains.

The name of the active substance is ibuprofen. Ibuprofen is a proprionic acid derivative non-steroidal anti-inflammatory drug (NSAID) which has analgesic, antipyretic and anti-inflammatory properties. Ibuprofen inhibits prostaglandin synthesis, furthermore, ibuprofen reversibly inhibits platelet aggregation. Ibuprofen has been shown to have an onset of both analgesic and antipyretic action within 30 minutes.

This is a national abridged application submitted under Regulation 56 of The Human Medicines Regulation 2012, as amended (previously Article 10c of Directive 2001/83/EC, as amended; an informed consent application). The application cross-refers to the reference product Ibuprofen 100 mg/ 5 ml oral suspension (PL 20395/0259), currently held by Relonchem Limited, which was originally granted in the UK to the Marketing Authorisation Holder Cipla (EU) Limited on 02 September 2011 (PL 36390/0042).

No new non-clinical or clinical data have been supplied and none are required for this informed consent application.

Suitable justification has been provided for non-submission of an Environmental Risk Assessment (ERA). As the application is for an identical version of an already authorised product, no increase in environmental exposure is anticipated and no ERA is required.

The MHRA has been assured that acceptable standards of Good Manufacturing Practice (GMP) are in place for this product at all sites responsible for the manufacture, assembly and batch release of this product.

A Risk Management Plan (RMP) and a summary of the pharmacovigilance system have been provided with this application and are satisfactory.

A Marketing Authorisation was granted on 19 March 2021.

II. EXPERT REPORT

The applicant cross-refers to the data for Ibuprofen 100 mg/ 5 ml oral suspension (PL 20395/0259; Relonchem Limited), to which this application is claimed to be identical. This is acceptable.

III. ASSESSOR'S COMMENTS ON THE PRODUCT INFORMATION SUMMARY OF PRODUCT CHARACTERITICS (SmPC)

The SmPC is in line with that Ibuprofen 100 mg/ 5 ml oral suspension (PL 20395/0259, dated 01/2020).

PATIENT INFORMATION LEAFLET
A leaflet mock-up has been provided which has been aligned with that for Ibuprofen 100 mg/ 5 ml oral suspension (PL 20395/0259, dated 11/2019). The user test bridging report submitted for PL 20395/0259 has been provided.

LABEL
Label mock-ups have been provided.

IV. QUALITY ASPECTS

IV.1 Drug Substance

Drug substance specification
The source of the active substance is in line with the cross-reference product. The proposed drug substance specification is consistent with the details registered for the cross-reference product.

IV.2. Drug Product

Name
The product has been named in line with current requirements.

Strength, pharmaceutical form, route of administration, container and pack sizes
Ibuprofen 100 mg/5 ml oral suspension/Tesco Health Ibuprofen 100 mg/5 ml Oral Suspension/Bells Healthcare Children's Pain and Fever Relief 100 mg/5 ml Oral Suspension is available in an amber-coloured polyethylene terephthalate bottle, sealed with a polypropylene, tamper-evident child resistant cap, fitted with a low-density polyethylene liner, in a pack size of 100 ml.

The appearance of the product is identical to that of the cross-reference product.

The proposed shelf life of the product is 24 months with the recommended storage condition 'Do not store above 25°C. Keep container in the outer carton and protect from light'.

The proposed packaging, shelf life and storage conditions are consistent with the details registered for the reference product.

Legal status
General Sales List (GSL) medicine.

Manufacturers
The proposed manufacturing sites are consistent with the details registered for the cross-reference product and evidence of Good Manufacturing Practice (GMP) compliance has been provided.

Qualitative and quantitative compositions
The composition of the proposed product is consistent with the details registered for the cross-reference product.

Manufacturing process & control of critical steps
The proposed manufacturing processes and process controls are consistent with the details registered for the reference product and the maximum batch size is stated.

Finished product release/shelf life specifications

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

TSE Compliance
None of the excipients used contain material of animal or human origin.

This product does not contain or consist of genetically modified organisms (GMO).

V. NON-CLINICAL ASPECTS
As this application is submitted under Regulation 56 of The Human Medicines Regulation 2012, as amended (previously Article 10c of Directive 2001/83/EC, as amended, as an informed consent application) no new non-clinical data have been supplied and none are required.

VI. CLINICAL ASPECTS
As this application is submitted under Regulation 56 of The Human Medicines Regulation 2012, as amended (previously Article 10c of Directive 2001/83/EC, as amended, as an informed consent application) no new clinical data have been supplied and none are required.

VII. RISK MANAGEMENT PLAN (RMP)
The applicant has submitted an RMP, in accordance with the requirements of Regulation 182 of the Human Medicines Regulation 2012, as amended. The applicant proposes only routine pharmacovigilance and routine risk minimisation measures for all safety concerns. This is acceptable.

VIII. USER CONSULTATION
A user consultation with target patient groups on the Patient Information Leaflet (PIL) has been performed on the basis of a bridging report making reference to Ibuprofen 100 mg/5 ml Oral Suspension (PL 36390/0042; Cipla (EU) Limited) and (for layout) Nizatidine 150 mg and 300 mg Capsules (PL 20395/0303-2; Relonchem Limited). The bridging report submitted by the applicant is acceptable.

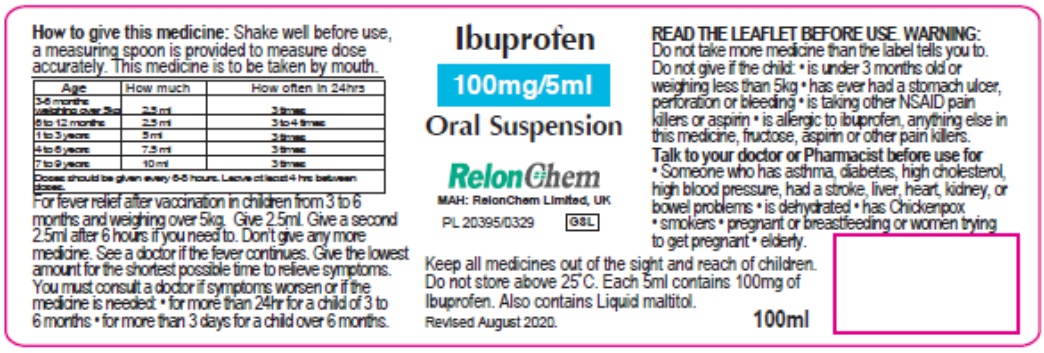
IX. OVERALL CONCLUSION, BENEFIT/RISK AND RECOMMENDATION
The quality of the product is acceptable, and no new non-clinical or clinical safety concerns have been identified. The applicant's product is identical to the cross-reference product. The benefit/risk balance is, therefore, considered to be the same as for the cross-reference product and positive.

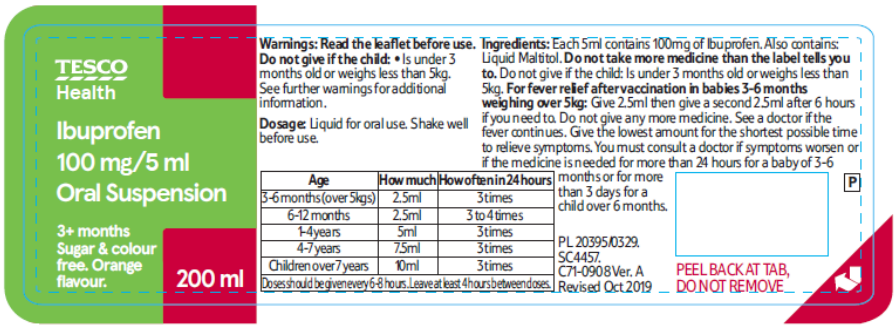
The SmPC, PIL and labelling are satisfactory, in line with current guidelines and consistent with the cross-reference product.

In accordance with Regulation 203(2) of The Human Medicines Regulation 2012, as amended, the current approved UK versions of the SmPCs and PILs for these products are available on the MHRA website.

Representative copies of the labels at the time of UK licensing are provided below.


PHARMACODE AREA
Oral Suspension
100mg/5ml
Ibuprofen
100ml
100ml
Ibuprofen
100mg/5ml
Oral Suspension
For oral use
RelonChem
106 mm
55 mm
Uses: For the reduction of fever (including post immunisation fever) and for the relief of mild to moderate pain such as headache, sore throat, teething pain and toothache, cold and flu symptoms and minor aches and sprains.
Do not give this product if your child:
• is under 3 months old or weighs less than 5kg
• has (or has had two or more episodes of) a stomach ulcer, perforation or bleeding
• is allergic to ibuprofen or any other ingredient of the product, aspirin or other related painkillers
• is taking other NSAID painkillers, or aspirin
• has a fructose intolerance.
Consult a doctor or pharmacist before use for:
• someone who has or had asthma, diabetes, high cholesterol, high blood pressure, a stroke, heart, liver, kidney or bowel problems; is dehydrated; has chicken pox.
• smokers.
• pregnant, breastfeeding or women trying to get pregnant.
• elderly.
You must consult a doctor if symptoms persist or worsen, or if the medicine is needed:
• for more than 24 hours for a child of 3 to 6 months.
• for more than 3 days for a child over 6 months.
Keep all medicines out of sight and reach of children.
Ingredients: Each 5ml contains Ibuprofen 100mg as the active ingredient. Also contains liquid maltitol, E219, E211 and E217. Keep the container in the outer carton to protect from light.
Do not store above 25°C. Store in the original container.
MA Holder:
Relonchem Limited, Cheshire House, Gorsey Lane, Widnes, WA8 0RP.
50 mm
5 055144 200989
PHARMACODE AREA
Directions: For oral and short-term use only. Shake the bottle well before use. A spoon is provided to measure doses 2.5ml or 5ml as required. READ THE ENCLOSED LEAFLET CAREFULLY BEFORE USE.
Not suitable for children under 3 months of age or weighing less than 5kg.
FEVER CAUSED BY IMMUNISATION:
Babies and Children 3 months and over weighing more than 5kg. | One 2.5ml dose if necessary give second 2.5ml dose 6 hours later
Do not give more than 2 doses in a 24 hours period. If the fever is not reduced, consult your doctor.
FEVER, PAIN AND SYMPTOMS OF COLD AND FLU:
3-6 months weighing over 5kg. | One 2.5ml dose 3 times a day.
Do not use for more than 24 hours. If symptoms persist after 24 hours or worsen, consult your doctor.
6-12 months | One 2.5ml dose 3 or 4 times in 24 hours.
1-3 years | One 5ml dose 3 times in 24 hours.
4-6 years | One 7.5ml (5ml +2.5ml) dose 3 times in 24 hours.
7-9 years | Two 5ml spoonful's to be given 3 times a day.
Doses should be given every 6-8 hours. Leave at least 4 hours between doses. For children above 6 months, if symptoms persist after 3 days or worsen, consult your doctor.
Warning: Do not take more medicine than the label tells you to.
Revised August 2020.
GSL
PL 20395/0329


How to give this medicine: Shake well before use, a measuring spoon is provided to measure dose accurately. This medicine is to be taken by mouth.
Age | How much | How often in 24hrs
3-6 months weighing over 5kg | 2.5 ml | 3 times
6 to 12 months | 2.5 ml | 3 to 4 times
1 to 3 years | 5 ml | 3 times
4 to 6 years | 7.5 ml | 3 times
7 to 9 years | 10 ml | 3 times
Doses should be given every 6-8 hours. Leave at least 4 hrs between doses.
For fever relief after vaccination in children from 3 to 6 months and weighing over 5kg. Give 2.5ml. Give a second 2.5ml after 6 hours if you need to. Don't give any more medicine. See a doctor if the fever continues. Give the lowest amount for the shortest possible time to relieve symptoms. You must consult a doctor if symptoms worsen or if the medicine is needed: • for more than 24hr for a child of 3 to 6 months • for more than 3 days for a child over 6 months.
Ibuprofen
100mg/5ml
Oral Suspension
RelonChem
MAH: RelonChem Limited, UK
PL 20395/0329
GSL
Keep all medicines out of the sight and reach of children.
Do not store above 25°C. Each 5ml contains 100mg of Ibuprofen. Also contains Liquid maltitol.
Revised August 2020.
READ THE LEAFLET BEFORE USE. WARNING:
Do not take more medicine than the label tells you to.
Do not give if the child: • is under 3 months old or weighing less than 5kg • has ever had a stomach ulcer, perforation or bleeding • is taking other NSAID pain killers or aspirin • is allergic to ibuprofen, anything else in this medicine, fructose, aspirin or other pain killers.
Talk to your doctor or Pharmacist before use for
• Someone who has asthma, diabetes, high cholesterol, high blood pressure, had a stroke, liver, heart, kidney, or bowel problems • is dehydrated • has Chickenpox • smokers • pregnant or breastfeeding or women trying to get pregnant • elderly.
100ml



Further warnings

Do not give if the child:
- Has ever had a stomach ulcer, perforation or bleeding.
- Is taking other NSAID painkillers or aspirin.
- Is allergic to Ibuprofen, anything else in this medicine, fructose, aspirin or other pain killers.

Talk to your doctor or pharmacist before use for:
Someone who has asthma, diabetes, high cholesterol, high blood pressure, had a stroke, liver, heart, kidney or bowel problems, is dehydrated, has chickenpox, smokers, you are pregnant or breast-feeding, are trying to get pregnant or are elderly.

Storage

Keep all medicines out of the sight and reach of children.
Do not store above 25°C.

MAH Holder:
Relonchem Ltd., WA8 0RP, UK.
Produced for: Tesco Stores Ltd., AL7 1GA, UK.
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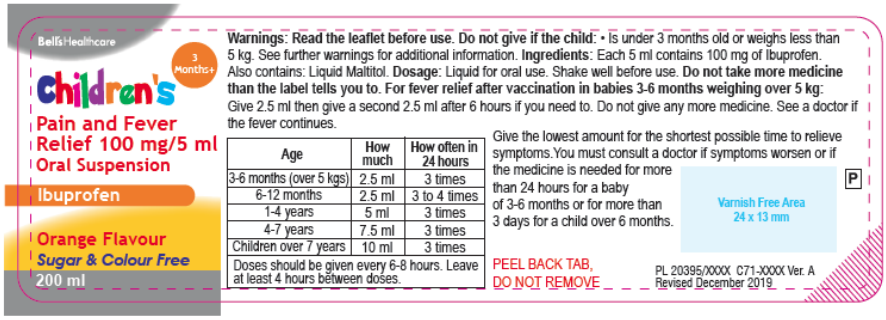
bell's
healthcare
children's pain
and
fever relief
#100 mg/#5 ml
oral suspension



Further Warnings

Do not give if the child:
- Has ever had a stomach ulcer, perforation or bleeding.
- Is taking other NSAID painkillers or aspirin.
- Is allergic to Ibuprofen, anything else in this medicine, fructose, aspirin or other pain killers.

Talk to your doctor or pharmacist before use for:
Someone who has asthma, diabetes, high cholesterol, high blood pressure, had a stroke, liver, heart, kidney or bowel problems, is dehydrated, has chickenpox, smokers, you are pregnant or breast-feeding, are trying to get pregnant or are elderly.

Storage

Keep all medicines out of the sight and reach of children.
Do not store above 25°C.

MA Holder:
Relonchem Limited,
Cheshire House, Gorsey Lane, Widnes, Cheshire,
WA8 0RP, UK.

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Steps taken after the initial procedure with an influence on the Public Assessment Report (non-safety variations of clinical significance).

Please note that only non-safety variations of clinical significance are recorded below and in the annexes to this PAR. The assessment of safety variations where significant changes are made are recorded on the MHRA website or European Medicines Agency (EMA) website. Minor changes to the marketing authorisation are recorded in the current SmPC and/or PIL available on the MHRA website.

Application type	**Scope**	**Product information affected**	**Date of grant**	**Outcome**	**Assessment report attached Y/N**