NUROFEN FOR CHILDREN 3 MONTHS TO 9 YEARS ORANGE FLAVOUR 100 MG/5 ML ORAL SUSPENSION (PL 00063/0705)

UKPAR

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LAY SUMMARY
Nurofen for Children 3 months to 9 years Orange Flavour 100mg/5ml Oral Suspension (ibuprofen)

This is a summary of the public assessment report (PAR) for Nurofen for Children 3 months to 9 years Orange Flavour 100mg/5ml Oral Suspension (PL 00063/0705). It explains how Nurofen for Children 3 months to 9 years Orange Flavour 100mg/5ml Oral Suspension 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 Nurofen for Children 3 months to 9 years Orange Flavour 100mg/5ml Oral Suspension.

For practical information about using Nurofen for Children 3 months to 9 years Orange Flavour 100mg/5ml Oral Suspension, patients should read the package leaflet or contact their doctor or pharmacist.

What is Nurofen for Children 3 months to 9 years Orange Flavour 100mg/5ml Oral Suspension and what is it used for?
This medicine contains the active ingredient ibuprofen. It is used to help bring down a high temperature (fever and post-immunisation fever), relieve the symptoms of cold and flu and relieve pain from headaches, sore throats, minor aches and sprains, teething and toothache.

How is Nurofen for Children 3 months to 9 years Orange Flavour 100mg/5ml Oral Suspension used?
This medicine can be obtained without a prescription.

How does Nurofen for Children 3 months to 9 years Orange Flavour 100mg/5ml Oral Suspension work?
This medicine contains the active ingredient ibuprofen which is a non-steroidal-anti-inflammatory (NSAID) painkiller.

How has Nurofen for Children 3 months to 9 years Orange Flavour 100mg/5ml Oral Suspension been studied?
This application is identical to the previously granted application for Nurofen for Children Orange Baby/Nurofen for Children Orange/Nurofen for Children 3 months to 9 years Orange 100mg/5ml Oral Suspension (PL 00063/0668; Reckitt Benckiser Healthcare (UK) Limited), which was granted a licence on 16 August 2011 following a change of ownership from PL 00327/0158 (Crookes Healthcare Limited). This application was, in turn, identical to the previously granted application for Nurofen for children 2% w/v (PL 00327/0085; Crookes Healthcare Limited) which was granted a marketing authorisation on 11 March 1998.

The company referred to data provided by Reckitt Benckiser Healthcare (UK) Limited for the grant of the licence for Nurofen for Children Orange Baby/Nurofen for Children Orange/Nurofen for Children 3 months to 9 years Orange 100mg/5ml Oral Suspension (PL 00063/0668) as a basis for the grant of an identical licence for Nurofen for Children 3 months to 9 years Orange Flavour 100mg/5ml Oral Suspension (PL 00063/0705).

What are the benefits and risks of Nurofen for Children 3 months to 9 years Orange Flavour 100mg/5ml Oral Suspension?

As Nurofen for Children 3 months to 9 years Orange Flavour 100mg/5ml Oral Suspension (PL 00063/0705) is considered identical to Nurofen for Children Orange Baby/Nurofen for Children Orange/Nurofen for Children 3 months to 9 years Orange 100mg/5ml Oral Suspension (PL 00063/0668), its benefits and risks are taken as being the same as for Nurofen for Children Orange Baby/Nurofen for Children Orange/Nurofen for Children 3 months to 9 years Orange 100mg/5ml Oral Suspension (PL 00063/0668).

Why is Nurofen for Children 3 months to 9 years Orange Flavour 100mg/5ml Oral Suspension approved?

No new or unexpected safety concerns arose from this duplicate application of Nurofen for Children Orange Baby/Nurofen for Children Orange/Nurofen for Children 3 months to 9 years Orange 100mg/5ml Oral Suspension (PL 00063/0668). Therefore, the view was that, as for Nurofen for Children Orange Baby/Nurofen for Children Orange/Nurofen for Children 3 months to 9 years Orange 100mg/5ml Oral Suspension (PL 00063/0668), the benefit outweighs the identified risk.

What measures are being taken to ensure the safe and effective use Nurofen for Children 3 months to 9 years Orange Flavour 100mg/5ml Oral Suspension?

Safety information has been included in the Summary of Product Characteristics and the package leaflet for Nurofen for Children 3 months to 9 years Orange Flavour 100mg/5ml Oral Suspension, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Nurofen for Children 3 months to 9 years Orange Flavour 100mg/5ml Oral Suspension

A Marketing Authorisation was granted for Nurofen for Children 3 months to 9 years Orange Flavour 100mg/5ml Oral Suspension on 24 October 2013. For more information about treatment with Nurofen for Children 3 months to 9 years Orange Flavour 100mg/5ml Oral Suspension, read the package leaflet or contact your doctor or pharmacist.

The full PAR for Nurofen for Children 3 months to 9 years Orange Flavour 100mg/5ml Oral Suspension follows this summary.

This summary was last updated in November 2013.

NUROFEN FOR CHILDREN 3 MONTHS TO 9 YEARS ORANGE FLAVOUR 100 MG/5 ML ORAL SUSPENSION (PL 00063/0705)

SCIENTIFIC DISCUSSION

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INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the UK granted a Marketing Authorisation to Reckitt Benckiser Healthcare (UK) Limited for the medicinal product Nurofen for Children 3 months to 9 years Orange Flavour 100mg/5ml Oral Suspension on 24 October 2013.

This product is a general sales list medicine (legal status GSL). It is indicated for the reduction of fever, including post immunisation pyrexia, for the 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.

This application was submitted as an abridged simple application according to Article 10c of Directive 2001/83/EC, as amended, cross-referring to Nurofen for Children Orange Baby/Nurofen for Children Orange/Nurofen for Children 3 months to 9 years Orange 100mg/5ml Oral Suspension (PL 00063/0668; Reckitt Benckiser Healthcare (UK) Limited). The reference product was granted a licence on 16 August 2011 following a change of ownership from PL 00327/0158 (Crookes Healthcare Limited). This product was granted a licence on 05 August 2004 via an abridged simple application, cross referring to Nurofen for children 2% w/v (PL 00327/0085), which was originally granted a licence to the same Marketing Authorisation Holder (Crookes Healthcare Limited) on 11 March 1998.

This product contains the active substance ibuprofen, which is a proprionic acid derivative non-steroidal anti-inflammatory drug (NSAID). Ibuprofen has analgesic, antipyretic and anti-inflammatory properties.

PHARMACEUTICAL ASSESSMENT

LICENCE NO:	PL 00063/0705
PROPRIETARY NAME:	Nurofen for Children 3 months to 9 years Orange Flavour 100mg/5ml Oral Suspension
ACTIVE(S):	Ibuprofen
COMPANY NAME:	Reckitt Benckiser Healthcare (UK) Limited
E.C. ARTICLE:	Article 10c
LEGAL STATUS:	GSL

1. INTRODUCTION

This is a simple, piggyback application for Nurofen for Children 3 months to 9 years Orange Flavour 100mg/5ml Oral Suspension, submitted under Article 10c of Directive 2001/83/EC, as amended. The proposed MA holder is Reckitt Benckiser Healthcare (UK) Limited, 103-105 Bath Road, Slough, Berkshire, SL1 3UH, United Kingdom.

The application cross-refers to Nurofen for Children Orange Baby/Nurofen for Children Orange/Nurofen for Children 3 months to 9 years Orange 100mg/5ml Oral Suspension (PL 00063/0668), which was originally granted to Reckitt Benckiser Healthcare (UK) Limited on 16 August 2011, following a change of ownership from PL 00327/0158 (Crookes Healthcare Limited). This product cross referred to Nurofen for Children 2% w/v (PL 00327/0085), which was originally granted a licence to Crookes Healthcare Limited on 11 March 1998.

The current application is considered valid.

2. MARKETING AUTHORISATION APPLICATION FORM

2.1 **Name(s)**

The proposed name of the product is Nurofen for Children 3 months to 9 years Orange Flavour 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

5 ml of the oral suspension contains 100 mg ibuprofen (equivalent to 2% w/v).

The finished product is packaged in an Amber-coloured polyethylene terephthalate (PET) bottle with a child-resistant closure, fitted with a low density polyethylene (LDPE) liner. The bottle contains 100 ml of product. Either a double-ended spoon with measures of 2.5 ml and 5 ml or a syringe composed of a polypropylene barrel and a polyethylene piston with measures of 2.5 ml and 5 ml will be provided.

The proposed shelf-life (3 years) and storage conditions (Store below 25°C) are consistent with the details registered for the cross-reference product.

2.3 Legal status

On approval, the product will be available as a general sales list medicine (GSL).

2.4 Marketing authorisation holder/Contact Persons/Company

Reckitt Benckiser Healthcare (UK) Limited, 103-105 Bath Road, Slough, Berkshire, SL1 3UH, United Kingdom.

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

2.5 Manufacturers

The proposed manufacturing sites are consistent with those registered for the cross-reference product and evidence of Good Manufacturing Practice (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.

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 these products. This is consistent with the cross-reference product.

2.11 Bioequivalence

No bioequivalence data are required to support this informed consent application, as the proposed product is manufactured to the same formula utilising the same process as the reference product Nurofen for Children Orange Baby/Nurofen for Children Orange/Nurofen for Children 3 months to 9 years Orange 100mg/5ml Oral Suspension (PL 00063/0668).

3. EXPERT REPORTS

The applicant has included expert reports in Module 2 of the application. Signed declarations and copies of the experts' CVs are enclosed in Module 1.4 for the quality, non-clinical and clinical experts. All are considered to have sufficient experience for their responsibilities.

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 (SmPC)

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

6. PATIENT INFORMATION LEAFLET (PIL)/LABEL

PIL

The MAH has submitted a text version of the PIL only and has committed to submitting mock-ups to the regulatory authorities for approval before the product is marketed.

The PIL text is in line with the Summary of Product Characteristics (SmPC) and with the details registered for the cross-reference product. The results of consultations with target patient groups ('user testing'), in accordance with Article 59 of Council Directive 2001/83/EC, as amended, for Nurofen for Children Orange Baby (PL 00327/0158) have been provided. 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.

Carton and blister

The MAH has submitted a text version of the labelling only and has committed to submitting mock-ups to the regulatory authorities for approval before the product is marketed.

7. CONCLUSIONS

The data submitted with the application is acceptable. From a quality perspective, a Marketing Authorisation should be granted.

NON-CLINICAL ASSESSMENT

No new non-clinical data have been supplied with this application and none are required for applications of this type.

An Environmental Risk Assessment (ERA) has not been provided. As this product is intended for substitution with a product that is already marketed, no increase in environmental burden is anticipated.

The grant of a Marketing Authorisation is recommended.

CLINICAL ASSESSMENT

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

The Pharmacovigilance System, as described by the applicant, fulfils the requirements and provides adequate evidence that the applicant has the services of a qualified person responsible for pharmacovigilance, and has the necessary means for the

notification of any adverse reaction suspected of occurring either in the Community or in a third country.

Suitable justification has been provided for not submitting a risk management plan for this product.

The grant of a Marketing Authorisation is recommended.

OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT

QUALITY

The data provided for this application is consistent with that previously assessed for the cross-reference product and as such have been judged to be satisfactory. There are no outstanding quality issues that would have a negative impact on the benefit/risk balance.

NON-CLINICAL

No new non-clinical data were submitted and none are required for applications of this type.

EFFICACY

This application is identical to the previously granted application Nurofen for Children Orange Baby/Nurofen for Children Orange/Nurofen for Children 3 months to 9 years Orange 100mg/5ml Oral Suspension (PL 00063/0668) which was granted to Reckitt Benckiser Healthcare (UK) Limited on 16 August 2011. No new clinical pharmacology/efficacy data have been submitted with this application and none are required for applications of this type.

SAFETY

No new safety data have been submitted with this application and none are required for applications of this type.

No new or unexpected safety concerns have arisen from this application.

PRODUCT LITERATURE

The SmPC and text versions of the PIL and labelling are satisfactory and consistent with the reference product.

BENEFIT-RISK ASSESSMENT

The quality of the product is acceptable and no new non-clinical or clinical safety concerns have been identified. Extensive clinical experience with ibuprofen is considered to have demonstrated the therapeutic value of the compound. The benefit/risk is, therefore, considered to be positive.

NUROFEN FOR CHILDREN 3 MONTHS TO 9 YEARS ORANGE FLAVOUR 100 MG/5 ML ORAL SUSPENSION (PL 00063/0705)

STEPS TAKEN FOR ASSESMENT

1	The MHRA received the marketing authorisation applications on 04 July 2012.
2	Following standard checks and communication with the applicant, the MHRA considered the application valid on 13 August 2012.
3	Following assessment of the application, the MHRA requested further information relating to the dossier on 13 August 2012.
4	The applicant responded to the MHRA's requests, providing further information on 27 March 2013.
5	The application was determined on 24 October 2013.

NUROFEN FOR CHILDREN 3 MONTHS TO 9 YEARS ORANGE FLAVOUR 100 MG/5 ML ORAL SUSPENSION (PL 00063/0705)

STEPS TAKEN AFTER AUTHORISATION - SUMMARY

Date submitted	Application type	Scope	Outcome

Summary of Product Characteristics and Patient Information Leaflet

In accordance with Directive 2010/84/EU, the current approved UK versions of the Summary of Product Characteristics (SmPC) and Patient Information Leaflet (PIL) for these products are available on the MHRA website.

Labelling

The following text is the approved label text for Nurofen for Children 3 months to 9 years Orange Flavour 100mg/5ml Oral Suspension (PL 00063/0705). No label mock-ups have been provided for this product. In accordance with medicines legislation, the products shall not be marketed in the UK until approval of the label mock-ups has been obtained.

CARTON, SIDE 1

NUROFEN
for Children
3 months to 9 years
Orange Flavour
100mg / 5ml Oral Suspension

Ibuprofen
3 months to 9 years
FEVER AND PAIN RELIEF
ORANGE FLAVOUR
SUGAR FREE & COLOUR FREE
100ml Oral Suspension

CARTON, SIDE 2

NUROFEN
for Children
3 months to 9 years
Orange Flavour
100mg / 5ml Oral Suspension

NUROFEN FOR CHILDREN 3 MONTHS TO 9 YEARS ORANGE FLAVOUR is an oral ibuprofen suspension for babies and children from 3 months to 9 years.
Each 5ml of oral suspension contains 100mg ibuprofen.
Also contains: Maltitol Liquid, Glycerol
See leaflet for further information.

√ Reduces temperature (including fever caused by immunisation)

√ For the relief of mild to moderate pain such as:

- **teething**
- **toothache**
- **sore throats**
- **headache**
- **minor aches**
- **sprains**

√ Relieves symptoms of cold and flu

CE 0543 The CE mark only covers the syringe.
Reckitt Benckiser Healthcare (UK) Ltd.
Slough, SL1 3UH.

KEEP ALL MEDICINES OUT OF THE REACH AND SIGHT OF CHILDREN

100ml e

CARTON, SIDE 3

DIRECTIONS
For oral and short-term use only. **Shake the bottle well before use.** Use the syringe inside to measure the dose accurately (See leaflet for details). **NOT SUITABLE for children under 3 months of age or weighing less than 5kg.**

READ THE ENCLOSED LEAFLET CAREFULLY BEFORE USE.

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 6hrs later
Do not give more than 2 doses in a 24 hour 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, 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
3 – 6 years	**One 7.5ml (5ml + 2.5ml) dose 3 times** in 24 hours
7 - 9 years	**One 10ml (5ml + 5ml) dose 3 times** in 24 hours
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, consult your doctor.**	

WARNING: DO NOT EXCEED THE STATED DOSE

CARTON, SIDE 4

NUROFEN
for Children
3 months to 9 years
Orange Flavour
100mg / 5ml Oral Suspension

DO NOT GIVE THIS PRODUCT IF YOUR BABY OR 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 with a daily dose above 75mg
- has a fructose intolerance

SPEAK TO YOUR DOCTOR OR PHARMACIST BEFORE GIVING THIS PRODUCT IF CHILD:

- has or had asthma, diabetes, high cholesterol, high blood pressure, a stroke, heart, liver, kidney or bowel problems

If you are an ADULT taking this product:
Speak to a pharmacist or your doctor before taking if you are:

- pregnant
- trying to get pregnant
- elderly
- a smoker

Do not store above 25°C.

PL00063/0705

LABEL FRONT

NUROFEN
for Children
3 months to 9 years Orange Flavour
100mg / 5ml Oral Suspension
Ibuprofen
3 months to 9 years
Relief of fever, symptoms of cold and flu and pain such as teething, toothache, sore throat, headache, rheumatic or muscular pain.

SPEAK TO YOUR DOCTOR OR PHARMACIST BEFORE GIVING THIS PRODUCT IF YOUR BABY OR CHILD:

- has or had asthma, diabetes, high cholesterol, high blood pressure, a stroke, heart, liver, kidney or bowel problems

If you are an ADULT taking this product:
Speak to a pharmacist or your doctor before taking if:

- you are pregnant
- you are trying to get pregnant
- are elderly
- are a smoker

READ THE LEAFLET CAREFULLY BEFORE USE

KEEP ALL MEDICINES OUT OF THE REACH AND SIGHT OF CHILDREN

Lot:
Use By:

Each 5ml of oral suspension contains 100mg ibuprofen. Also contains: Maltitol Liquid, Glycerol. See leaflet for further information.

DO NOT GIVE THIS PRODUCT IF YOUR BABY OR 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 with a daily dose above 75mg
- has a fructose intolerance

Reckitt Benckiser Healthcare (UK) Ltd. SL1 3UH .
PL 00063/0705
Peel here for further information, including Directions.
Do not remove.

100ml e

INSIDE 'PEEL AND REVEAL' LABEL

Directions: For oral and short-term use only. Shake the bottle well before use. NOT SUITABLE for children under 3 months of age or weighing less than 5kg.
Use the syringe provided to measure the dose accurately.

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 6hrs later
Do not give more than 2 doses in a 24 hour period. If the fever is not reduced, consult your doctor.	

WARNING: DO NOT EXCEED THE STATED DOSE

If symptoms persist or worsen consult your doctor.
Do no store above 25°C

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, 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
3 – 6 years	**One 7.5ml (5ml + 2.5ml) dose 3 times** in 24 hours
7 – 9 years	**One 10ml (5ml + 5ml) dose 3 times** in 24 hours
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, consult your doctor.**	