Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Boots Paracetamol 3 Months Plus 120mg/5ml Suspension

(Paracetamol)

PL 00014/0660

UK Public Assessment Report

The Boots Company plc

LAY SUMMARY

Boots Paracetamol 3 Months Plus 120mg/5ml Suspension

(Paracetamol)

The product may be referred to as 'Paracetamol 3 Months Plus Suspension' in this report.

This is a summary of the Public Assessment Report (PAR) for Boots Paracetamol 3 Months Plus 120mg/5ml Suspension (PL 00014/0660), formerly known as Boots Paracetamol Pain Relief 3 months + 120mg/5ml Suspension. It explains how the application for Paracetamol 3 Months Plus Suspension was assessed and its authorisation recommended, as well as the conditions of use. It is not intended to provide practical advice on how to use Paracetamol 3 Months Plus Suspension.

For practical information about using Paracetamol 3 Months Plus Suspension, patients should read the package leaflet or contact their doctor or pharmacist.

What is Paracetamol 3 Months Plus Suspension and what is it used for?

This medicine is the same as Boots Pain Relief Paracetamol 120mg/5ml Suspension (PL 00014/0617), which is already authorised in the UK. Boots Pain Relief Paracetamol 120mg/5ml Suspension may be referred to as Boots Pain Relief Paracetamol Suspension in the remainder of this report. The licence holder (The Boots Company plc) for Pain Relief Paracetamol Suspension (PL 00014/0617) has agreed that its own scientific data can be used as a basis for the grant of an identical licence for Paracetamol 3 Months Plus Suspension (PL 00014/0660) (informed consent).

Paracetamol 3 Months Plus Suspension is used to relieve mild to moderate pain including toothache, teething pain, headache and other pains. It can also be used to relieve the symptoms of colds and flu and to reduce fever, including fever after vaccination at 2 months of age.

How does Paracetamol 3 Months Plus Suspension work?

The active ingredient in Paracetamol 3 Months Plus Suspension is paracetamol, which belongs to a group of medicines called analgesic and antipyretics, which act to relieve pain and reduce fever.

How is Paracetamol 3 Months Plus Suspension used?

Paracetamol 3 Months Plus Suspension is available as an oral suspension containing 120 mg of paracetamol per 5ml of oral suspension. The product is taken orally (by mouth).

The caregiver should check the cap seal is not broken before first use. If the cap seal is broken, the medicine should not be given.

This medicine should not be given with any other paracetamol-containing product.

The caregiver should check the tables on the back of the package leaflet to see how much of the medicine should be given to give his/her child. The patient should never be given more than that which is shown in the table.

It is important that the bottle is shaken for at least 10 seconds before use.

The caregiver should always use the syringe supplied with the pack and follow the instructions for its use provided in the package leaflet. The syringe can be used to measure 2.5 ml or 5 ml by drawing the liquid to the correct mark on the syringe.

Children aged 3 months - 6 years:

Child's age	**How much**	**How often (in 24 hours)**
3 months up to 6 months	2.5 ml	4 times
6 months up to 2 years	5 ml	4 times
2 years up to 4 years	7.5 ml	4 times
4 years up to 6 years	10 ml	4 times
Do not give more than 4 times in any 24 hours. **Leave at least 4 hours between doses.**		

The patient should not be given more than the amount recommended above. The medicine should not be given to a child for more than three days, without speaking to the doctor or pharmacist.

It symptoms do not go away, the caregiver should contact a doctor.

Other Uses

Babies over 2 months in age **For the relief of fever after vaccination at 2, 3 and 4 months** 2.5ml. This dose may be given up to 4 times a day at the time of vaccination. The patient should not be given more than 4 doses in any 24 hour period. At least 4 hours should be left between doses. If the baby still needs this medicine 2 days after receiving the vaccine, the caregiver should contact a doctor or pharmacist.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

Paracetamol 3 Months Plus Suspension can be obtained without a prescription, at pharmacies under the supervision of a pharmacist.

What benefits of Paracetamol 3 Months Plus Suspension have been shown in studies?

The application for Paracetamol 3 Months Plus Suspension (PL 00014/0660) is considered to be identical to the previously authorised licence for Pain Relief Paracetamol Suspension (PL 00014/0617), with the same benefits and risks. So, no new studies have been provided for Paracetamol 3 Months Plus Suspension (PL 00014/0660). However, reference is made to the studies for Pain Relief Paracetamol Suspension (PL 00014/0617).

What are the possible side effects from Paracetamol 3 Months Plus Suspension?

Like all medicines, Paracetamol 3 Months Plus Suspension can cause side effects, although not everybody gets them.

For the full list of all side effects reported with Paracetamol Pain Relief Suspension, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Paracetamol 3 Months Plus Suspension approved?

No new or unexpected safety concerns arose from this application. The MHRA, therefore, considered that the benefits of Paracetamol 3 Months Plus Suspension outweigh their risks; and the grant of a Marketing Authorisation was recommended.

What measures are being taken to ensure the safe and effective use of Paracetamol 3 Months Plus Suspension?

Safety information has been included in the Summary of Product Characteristics and the package leaflet for Paracetamol 3 Months Plus Suspension, 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/reviewed continuously.

Other information about Paracetamol 3 Months Plus Suspension

A Marketing Authorisation was granted in the UK to The Boots Company plc on 06 March 2008.

The full PAR for Paracetamol 3 Months Plus Suspension follows this summary.

For more information about treatment with Paracetamol 3 Months Plus Suspension, read the package leaflet, or contact your doctor or pharmacist.

This summary was last updated in May 2016.

Boots Paracetamol 3 Months Plus 120mg/5ml Suspension

(paracetamol)

PL 00014/0660

SCIENTIFIC DISCUSSION

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INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the MHRA granted The Boots Company plc a Marketing Authorisation for the medicinal product Boots Paracetamol 3 Months Plus 120mg/5ml Suspension (PL 00014/0660), formerly known as Boots Paracetamol Pain Relief 3 months + 120mg/5ml Suspension, on 06 March 2008. The product may be referred to as 'Paracetamol 3 Months Plus Suspension' in this report. The product is a Pharmacy (P) medicine available from pharmacies. The suspension is indicated for the treatment of mild to moderate pain and to reduce fever in many conditions including headache, toothache, teething, feverishness, colds and influenza, and following vaccination.

The application was submitted as a simple abridged (informed consent) application according to Article 10c of Directive 2001/83/EC (as amended), cross-referring to Boots Pain Relief Paracetamol 120mg/5ml Suspension (PL 00014/0617, The Boots Company plc), approved on 27 November 2000. Boots Pain Relief Paracetamol 120mg/5ml Suspension had been approved as a generic medicinal product of Calpol Infant Suspension (PL 00003/5067R) granted to The Wellcome Foundation Limited on 19 February 1982, and transferred to McNeil Products Limited (PL 15513/0004) on 28April 1997.

Paracetamol 3 Months Plus Suspension contains the active ingredient paracetamol, which is a peripherally acting analgesic with antipyretic activity.

No new data were submitted nor was it necessary for this simple abridged (informed consent) application, as the data are 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.

PHARMACEUTICAL ASSESSMENT

LICENCE NUMBER:	PL 00014/0660
PROPRIETARY NAME:	Boots Paracetamol 3 Months Plus 120mg/5ml Suspension
ACTIVE INGREDIENT/S:	Paracetamol
COMPANY NAME:	The Boots Company plc
E.C. ARTICLE:	Article 10c of Directive 2001/83/EC, as amended
LEGAL STATUS:	P

1. INTRODUCTION

This is an informed consent application, submitted under Article 10c of Directive 2001/83/EC (as amended) for Boots Paracetamol 3 Months Plus 120mg/5ml Suspension.

The reference product is Boots Pain Relief Paracetamol 120mg/5ml Suspension (PL 00014/0617), held by The Boots Company plc. The application is considered valid.

2. MARKETING AUTHORISATION APPLICATION FORM

2.1 Name(s)

The proposed name of the product is Boots Paracetamol 3 Months Plus 120mg/5ml Suspension (formerly Boots Paracetamol Pain Relief 3 months + 120mg/5ml 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 paracetamol. Each 5ml dose of solution contains 120mg of paracetamol. The container closure system is amber PET bottles, of size 120ml, 130ml, 140ml, 150ml, 200ml, 240ml, 250ml, or 300ml, that are fitted with polypropylene child resistant closures. The MAH have stated that not all pack sizes will be marketed.

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

2.3 Legal status

The product is a Pharmacy (P) medicine, available by supply through pharmacies.

2.4 Marketing Authorisation Holder / Contact Persons / Company

The proposed Marketing Authorisation holder is 'The Boots Company plc, 1 Thane Road West, Nottingham, NG2 3AA'.

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 consistent with that of the cross-reference product.

5. SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

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

6. PATIENT INFORMATION LEAFLET (PIL) / CARTON

No PIL was provided for the initial application for the finished product as all relevant information was included on the labelling. Subsequent to approval of the initial application, the PIL has been prepared in line with the details registered for the cross-reference product.

Colour mock-ups of the labelling have been provided. The labelling is satisfactory and contains all the information that would normally be presented in the PIL. The information presented is consistent with the final SmPC. 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 also included the name of the product in Braille on the outer packaging.

7. CONCLUSIONS

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

NON-CLINICAL ASSESSMENT

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

No new non-clinical data have been supplied with this application and none are required for an application of this type. A non-clinical expert report has been written by a suitably qualified person and is satisfactory.

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 an identical application of Boots Pain Relief Paracetamol 120mg/5ml Suspension (PL 00014/0617), 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 are consistent with that previously assessed for the cross-reference product and as such has been judged to be satisfactory.

NON-CLINICAL

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

EFFICACY

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

Paracetamol is a well-known drug that has been used as an analgesic and anti-pyretic agent for many years. This application is identical to the previously granted application for Boots Pain Relief Paracetamol 120mg/5ml Suspension (PL 00014/0617).

No new or unexpected safety concerns arise from this application.

PRODUCT LITERATURE

The SmPC and PIL are satisfactory, and consistent with those for the cross-reference product. The labelling text complies with statutory requirements and is satisfactory.

RISK BENEFIT ASSESSMENT

The quality of the product is acceptable and no new nonclinical 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 paracetamol is considered to have demonstrated the therapeutic value of the medicinal product. The risk: benefit is therefore considered to be positive.

STEPS TAKEN AFTER THE INITIAL PROCEDURE - SUMMARY

Date submitted	Application type	Scope	Outcome
03 November 2008	Type II	To change the formulation of the product consequentially the shelf life of the product is reduced from 24 to 18 months. Sections 4.4 (Special warnings and precautions for use), 6.1 (List of excipients) and 6.3 (Shelf life) of the Summary of Product Characteristics (SmPC) and the Labelling have been updated	Approved on 24 August 2009
29 October 2015	Type IB	To update Section 4.2 (Posology and method of administration) and 4.4 (Special warnings and precautions for use) of the Summary of Product Characteristics (SmPC) in line with the new advice from the Commission on Human Medicines (CMH) and the Joint Committee on Vaccination & Immunisation (JCVI) for infant paracetamol suspensions. Consequently, the Patient Information Leaflet (PIL) and labelling have been updated.	Approved on 30 March 2016

Annex 1

Our Reference: PL 00014/0660, Application 45
Product: Boots Paracetamol 3 Months Plus 120mg/5ml Suspension
Marketing Authorisation Holder: The Boots Company plc
Active Ingredient(s): Paracetamol

Type of Procedure: National
Submission Type: Variation
Submission Category: Type IB
Submission Complexity: Standard

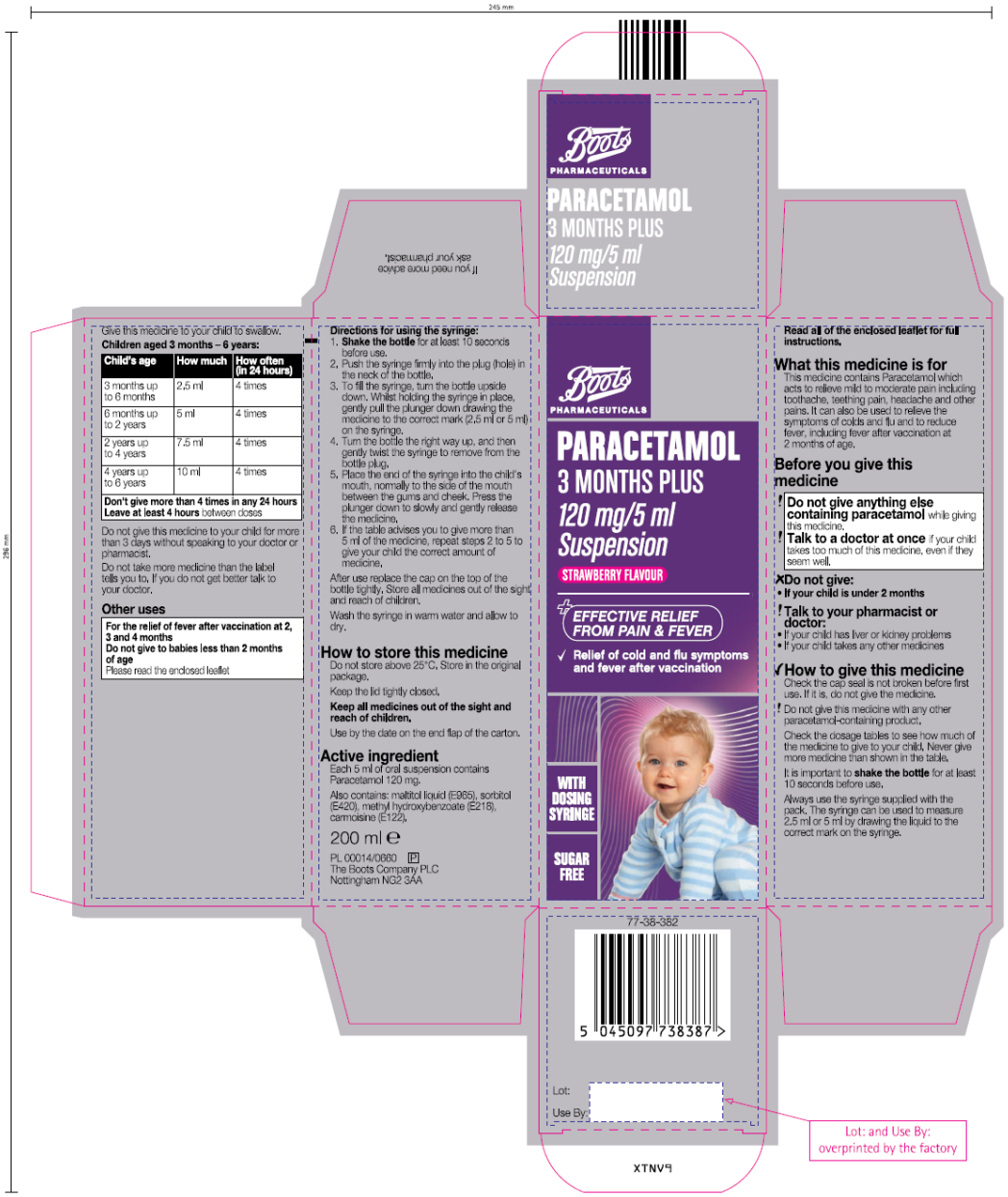
Reason:
To update Section 4.2 (Posology and method of administration) and 4.4 (Special warnings and precautions for use) of the Summary of Product Characteristic (SmPC) in line with the new advice from the Commission on Human Medicines (CMH) and the Joint Committee on Vaccination & Immunisation (JCVI) for infant paracetamol suspensions. Consequently, the Patient Information Leaflet (PIL) and labelling have been updated.

Supporting Evidence
Revised SmPC fragments (sections), and updated labelling and leaflet have been provided

Evaluation
The updated sections of the SmPC and leaflet are acceptable. The updated labelling is acceptable.

Conclusion
The updated sections of the SmPC, the updated labelling and the leaflet are satisfactory and there are no objections to approval.

In accordance with Directive 2010/84/EU the SmPCs and PILs for products granted Marketing Authorisations at a national level are available on the MHRA website. The current labelling is presented below:


245 mm
396 mm
PHARMACEUTICALS
PARACETAMOL
3 MONTHS PLUS
120 mg/5 ml
Suspension
If you need more advice ask your pharmacist.
Give this medicine to your child to swallow.
Children aged 3 months – 6 years:
Child's age | How much | How often (in 24 hours)
3 months up to 6 months | 2.5 ml | 4 times
6 months up to 2 years | 5 ml | 4 times
2 years up to 4 years | 7.5 ml | 4 times
4 years up to 6 years | 10 ml | 4 times
Don't give more than 4 times in any 24 hours
Leave at least 4 hours between doses
Do not give this medicine to your child for more than 3 days without speaking to your doctor or pharmacist.
Do not take more medicine than the label tells you to. If you do not get better talk to your doctor.
Other uses
For the relief of fever after vaccination at 2, 3 and 4 months
Do not give to babies less than 2 months of age
Please read the enclosed leaflet
Directions for using the syringe:
1. Shake the bottle for at least 10 seconds before use.
2. Push the syringe firmly into the plug (hole) in the neck of the bottle.
3. To fill the syringe, turn the bottle upside down. Whilst holding the syringe in place, gently pull the plunger down drawing the medicine to the correct mark (2.5 ml or 5 ml) on the syringe.
4. Turn the bottle the right way up, and then gently twist the syringe to remove from the bottle plug.
5. Place the end of the syringe into the child's mouth, normally to the side of the mouth between the gums and cheek. Press the plunger down to slowly and gently release the medicine.
6. If the table advises you to give more than 5 ml of the medicine, repeat steps 2 to 5 to give your child the correct amount of medicine.
After use replace the cap on the top of the bottle tightly. Store all medicines out of the sight and reach of children.
Wash the syringe in warm water and allow to dry.
How to store this medicine
Do not store above 25°C. Store in the original package.
Keep the lid tightly closed.
Keep all medicines out of the sight and reach of children.
Use by the date on the end flap of the carton.
Active ingredient
Each 5 ml of oral suspension contains Paracetamol 120 mg.
Also contains: maltitol liquid (E965), sorbitol (E420), methyl hydroxybenzoate (E218), carmoisine (E122).
200 ml e
PL 00014/0660
The Boots Company PLC
Nottingham NG2 3AA
PHARMACEUTICALS
PARACETAMOL
3 MONTHS PLUS
120 mg/5 ml
Suspension
STRAWBERRY FLAVOUR
EFFECTIVE RELIEF FROM PAIN & FEVER
✓ Relief of cold and flu symptoms and fever after vaccination
WITH DOSING SYRINGE
SUGAR FREE
Read all of the enclosed leaflet for full instructions.
What this medicine is for
This medicine contains Paracetamol which acts to relieve mild to moderate pain including toothache, teething pain, headache and other pains. It can also be used to relieve the symptoms of colds and flu and to reduce fever, including fever after vaccination at 2 months of age.
Before you give this medicine
! Do not give anything else containing paracetamol while giving this medicine.
! Talk to a doctor at once if your child takes too much of this medicine, even if they seem well.
✗Do not give:
• If your child is under 2 months
! Talk to your pharmacist or doctor:
• If your child has liver or kidney problems
• If your child takes any other medicines
✓How to give this medicine
Check the cap seal is not broken before first use. If it is, do not give the medicine.
! Do not give this medicine with any other paracetamol-containing product.
Check the dosage tables to see how much of the medicine to give to your child. Never give more medicine than shown in the table.
It is important to shake the bottle for at least 10 seconds before use.
Always use the syringe supplied with the pack. The syringe can be used to measure 2.5 ml or 5 ml by drawing the liquid to the correct mark on the syringe.
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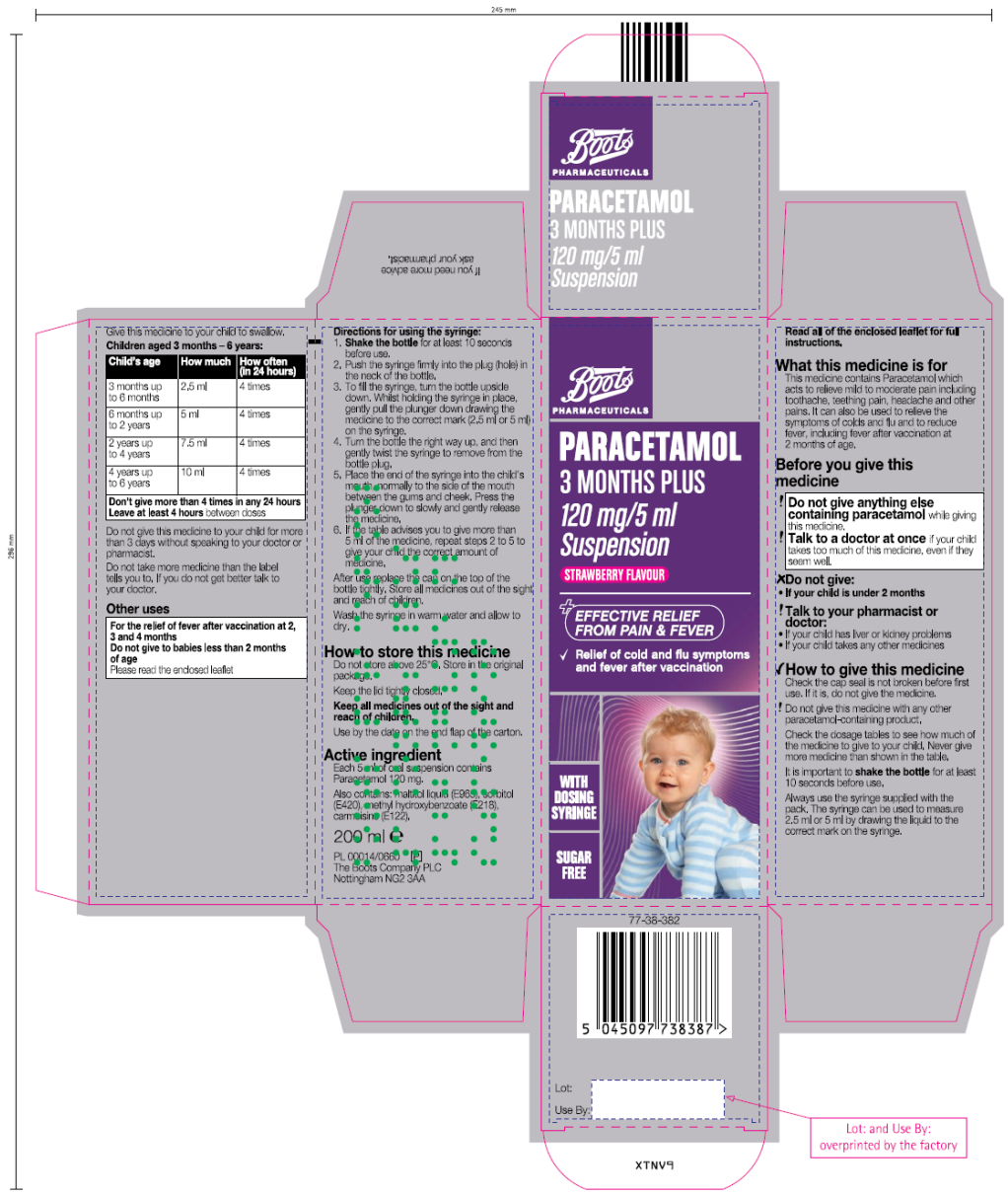

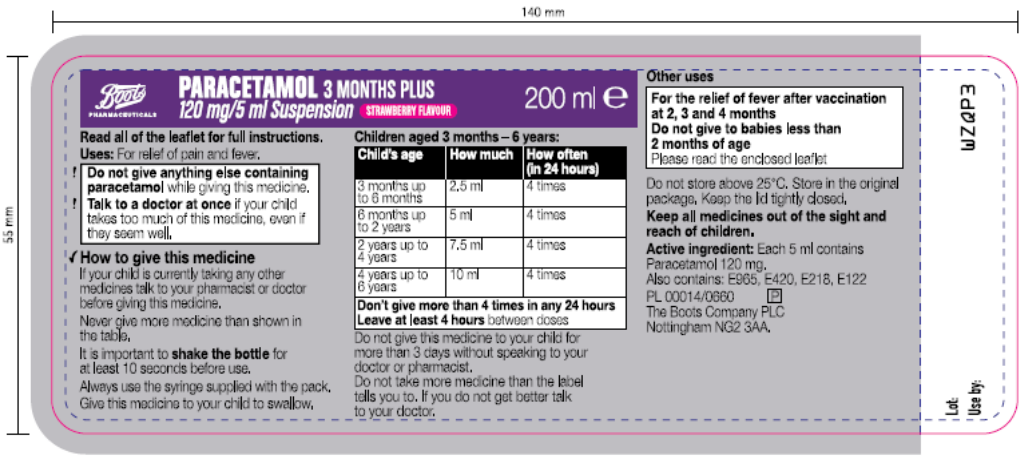

Decision – Approved on 30 March 2016