Teetha Teething Granules
Boots Teething Pain Relief

NR 01175/0387

UKPAR

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TEETHA TEETHING GRANULES

BOOTS TEETHING PAIN RELIEF

NR 01175/0387

LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency (MHRA) granted A Nelson & Co Limited a Homeopathic Marketing Authorisation for the homeopathic medicinal products Teetha Teething Granules and Boots Teething Pain Relief (National Rules Scheme authorisation number: 01175/0387) on 30 October 2015. Teetha Teething Granules and Boots Teething Pain Relief are available without prescription from pharmacies and other outlets.

Teetha Teething Granules and Boots Teething Pain Relief are homeopathic medicinal products used within the homeopathic tradition for the symptomatic relief of teething pain and the symptoms associated with teething which are sore and tender gums, flushed cheeks and dribbling.

No new or unexpected safety concerns arose from this application and it was, therefore, decided that a Homeopathic Marketing Authorisation could be granted.
TEETHA TEETHING GRANULES

BOOTS TEETHING PAIN RELIEF

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SCIENTIFIC DISCUSSION

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INTRODUCTION

The MHRA granted A Nelson & Co Limited a Homeopathic Marketing Authorisation for the homeopathic medicinal products Teetha Teething Granules and Boots Teething Pain Relief on 30 October 2015. These products are identical to each other apart from the difference in product name and are on the General Sales List (GSL).

A Product Licence of Right (PLR) was originally granted to A Nelson & Co Limited for this product on 1 September 1972. A Nelson & Co Limited cancelled PLR 01175/5198 on 30 October 2015 following the grant of the Homeopathic Marketing Authorisation.

This Homeopathic Marketing Authorisation application was made under the National Rules Scheme in accordance with arrangements to transfer certain homeopathic products with a PLR to a Homeopathic Marketing Authorisation. No new data were submitted, nor was it necessary for this application, as the data are essentially identical to those of the existing product.
PHARMACEUTICAL ASSESSMENT

HERBAL SUBSTANCE:  

CHAMOMILLA RECUTITA

Scientific/Latin name: Chamomilla recutita
Plant family: Asteraceae

The herbal substance is used as a starting material in the preparation of the homeopathic stock and potencies in the already licensed product. It is, therefore, acceptable.

ACTIVE INGREDIENT (HOMEOPATHIC STOCK):  

CHAMOMILLA RECUTITA 6C

The homeopathic stock and dilutions are all prepared in accordance with the German Homeopathic Pharmacopoeia (GHP) and are acceptable.

HOMEOPATHIC MEDICINAL PRODUCTS: TEETHA TEETHING GRANULES AND BOOTS TEETHING PAIN RELIEF

Description and Composition of the Homeopathic Products
The finished products are fine white to off white granules containing Chamomilla recutita 6C and the excipients lactose, xylitol, maize starch and pregelatinised maize starch.

The formulation is in line with that of the already licensed product. It is, therefore, acceptable.

Manufacture
The manufacturing process is in line with that of the already licensed product and is satisfactory.

Finished Product Specification
The finished product specification is in line with that of the already licensed product and is satisfactory.

Container Closure System
The tablets are stored in paper/polyethylene/aluminium foil/polyethylene sachets packed in a cardboard carton. Pack sizes of 24 sachets have been authorised. This type of packaging has been used to store the already licensed product and is satisfactory.

Stability
The products have a shelf-life of 3 years and the precautions for storage are ‘Do not store above 25ºC’ and ‘Store in the original packaging’. This is in line with the already licensed product and is appropriate.
Summary of Product Characteristics, product labels and Patient Information Leaflets
All product literature is in line with that of the already licensed product, with some details amended in line with other products authorised under the National Rules Scheme.

CONCLUSION
There are no objections to the granting of a Homeopathic Marketing Authorisation from a pharmaceutical point of view.
NON-CLINICAL ASSESSMENT

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

PRODUCT LITERATURE
All product literature is satisfactory from a non-clinical point of view.

CONCLUSION
There are no objections to the granting of a Homeopathic Marketing Authorisation from a non-clinical point of view.
CLINICAL ASSESSMENT

PRODUCT LITERATURE
The product particulars were updated in line with the requirements of the National Rules Scheme. All product literature is medically satisfactory.

CONCLUSION
There are no objections to the granting of a Homeopathic Marketing Authorisation from a clinical point of view.
OVERALL CONCLUSION AND BENEFIT-RISK ASSESSMENT

QUALITY
Teetha Teething Granules and Boots Teething Pain Relief are identical to an already licensed product. They are, therefore, pharmaceutically satisfactory.

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

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

BENEFIT-RISK ASSESSMENT
The quality of the product is acceptable and no new non-clinical or clinical safety concerns have been identified. The benefit: risk balance is acceptable and a Homeopathic Marketing Authorisation should be granted.
SUMMARY OF PRODUCT CHARACTERISTICS

In accordance with Directive 2010/84/EU, the Summaries of Product Characteristics (SmPCs) for products granted Marketing Authorisations at a national level are available on the MHRA website.
In accordance with Directive 2010/84/EU, the Patient Information Leaflets (PILs) for products granted Marketing Authorisations at a national level are available on the MHRA website.
LABELLING

Teetha Teething Granules

Labels:

Carton:
Carton with Braille:
Boots Teething Pain Relief

Labels:

![Teething Pain Relief label](image)

How to give this medicine
For babies aged 1 month old and older: Put the contents of the sachet into the child's mouth every two hours, if you need to. Don't give more than 6 sachets in 24 hours.

Manufactured for The Boots Company
PLC Nottingham NG2 3AA, National
Physicians authorisation holder A Nisam &
Co Limited London SW19 8UD

Carton:

lot: and Exp: to be overprinted by the factory

MHRA PAR; TEETHA TEETHING GRANULES AND BOOTS TEETHING PAIN RELIEF,
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