



Public Assessment Report

National Procedure

Weleda Baby Chamomile Teething Granules

(Chamomilla [*Matricaria recutita*])

NR 00298/0295

Weleda (UK) Ltd

LAY SUMMARY

Weleda Baby Chamomile Teething Granules

(Chamomilla 3X [*Matricaria recutita*] root)

This is a summary of the Public Assessment Report (PAR) for Weleda Baby Chamomile Teething Granules (Chamomilla 3X [*Matricaria recutita*] root).

The Medicines and Healthcare products Regulatory Agency (MHRA) granted Weleda (UK) Ltd a Homeopathic Marketing Authorisation for the homeopathic medicinal product Weleda Baby Chamomile Teething Granules (Homeopathic Marketing Authorisation number: NR 00298/0295) on 11 September 2019. This product is available without prescription and can be bought from pharmacies and other outlets.

Weleda Baby Chamomile Teething Granules is a homeopathic medicinal product used within the homeopathic tradition for the relief of teething pain and other minor symptoms associated with teething in babies and children.

The active ingredient in Weleda Baby Chamomile Teething Granules is Chamomilla 3X (*Matricaria recutita*) root.

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

The full PAR for Weleda Baby Chamomile Teething Granules follows this summary.

This summary was last updated in October 2019.

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I INTRODUCTION

The Medicines and Healthcare products Regulatory Agency (MHRA) granted Weleda (UK) Ltd a Homeopathic Marketing Authorisation for the homeopathic medicinal product Weleda Baby Chamomile Teething Granules (Homeopathic Marketing Authorisation number: NR 00298/0295) on 11 September 2019. This product is on the General Sales List (GSL).

A Product Licence of Right (PLR 00298/5826) was originally granted to Weleda (UK) Ltd for this product on 1 September 1972 under the product name Chamomilla Matricaria root. Weleda (UK) Ltd cancelled PLR 00298/5826 on 11 September 2019 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.

Weleda Baby Chamomile Teething Granules is used within the homeopathic tradition for the relief of teething pain and other minor symptoms associated with teething in babies and children.

II QUALITY ASPECTS

HERBAL SUBSTANCE: *CHAMOMILLA RECUTITA*

Scientific/Latin name: Chamomilla recutita (L) Rauschert

Plant family: Asteraceae

Plant part used: Root

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 3X*

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 product consists of white roughly spherical granules with a translucent appearance. Each level scoop (234 mg) contains Chamomilla 3X (*Matricaria recutita*) root. The product also contains the excipient sucrose.

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 product is presented in a 15 ml soda-lime-silica glass bottle with HDPE Clic-Loc style closure. A polystyrene measuring scoop is included in the pack.

This type of packaging has been used to store the already licensed product and is satisfactory.

Stability

The product has a shelf-life of 3 years and the precautions for storage are 'Do not store above 25°C' and 'Store in the original container'. 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.

III NON-CLINICAL ASPECTS

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.

IV CLINICAL ASPECTS

No new 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 clinical point of view. The product contains sucrose and appropriate warnings have been included on the SmPC, labels and leaflet. The Applicant has updated the labels and leaflets in line with the requirements of the National Rules Scheme and the updated SmPC.

CONCLUSION

There are no objections to the granting of a Homeopathic Marketing Authorisation from a clinical point of view.

V OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

QUALITY

Weleda Baby Chamomile Teething Granules is 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.

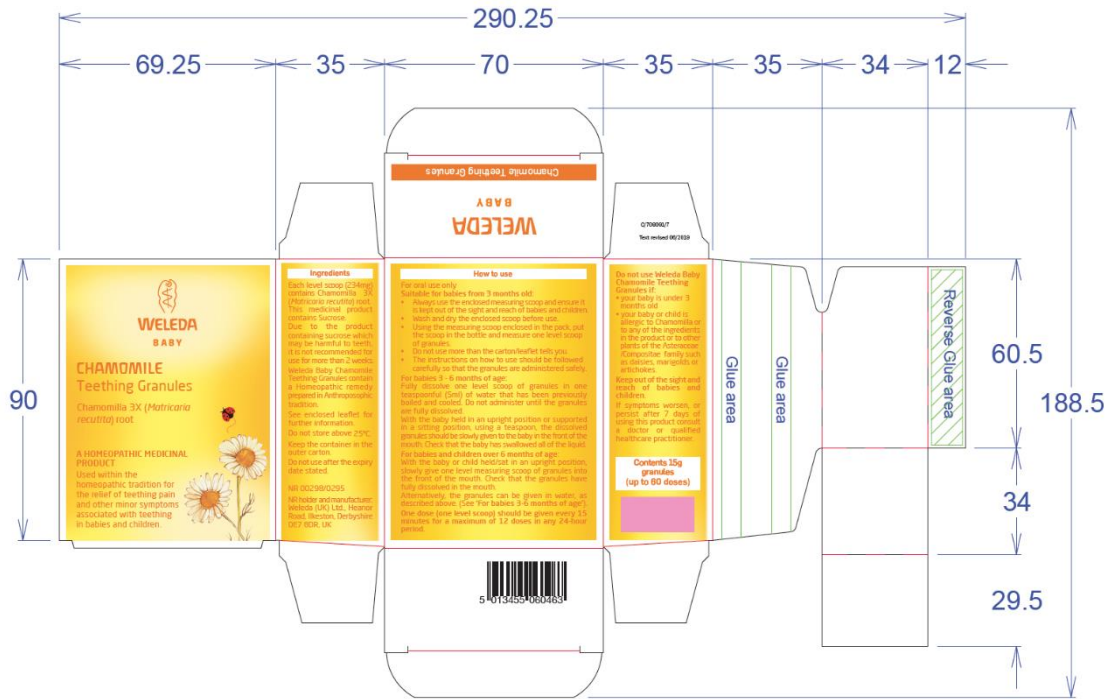
BENEFIT-RISK ASSESSMENT

The quality of the product is acceptable and no new non-clinical or clinical safety concerns have been identified.

The Summary of Product Characteristics (SmPC), Patient Information Leaflet (PIL) and labelling are satisfactory, in line with current guidelines and consistent with the reference product.

In accordance with Directive 2012/84/EU, 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



WELEDA UK LTD
Baby

Chamomile Teething Granules Label
L/708092/11

- Black
- Magenta
- Yellow
- Pantone 158

Please ensure there is 5mm clear of text at each end of label



150%



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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