Ashton and Parsons Infants’ Powders

THR 16853/0076

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TABLE OF CONTENTS

Lay summary Page 2
Scientific discussion Page 3
Steps taken for assessment Page 10
Summary of Product Characteristics Page 11
Product Information Leaflet Page 14
Labelling Page 15
ASHTON AND PARSONS INFANTS’ POWDERS

THR 16853/0076

LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency (MHRA) granted Alliance Pharmaceuticals Limited a Traditional Herbal Registration Certificate for the traditional herbal medicinal product Ashton and Parsons Infants’ Powders (Traditional Herbal Registration number: THR 16853/0076) on 8 November 2012. Ashton and Parsons Infants’ Powders is available without prescription and can be bought from pharmacies and other outlets.

Ashton and Parsons Infants’ Powders is a traditional herbal medicinal product used for the symptomatic relief of teething pain and the symptoms associated with teething, which are sore and tender gums, flushed cheeks and dribbling, based on traditional use only.

This registration is based exclusively upon evidence of the use of Matricaria flower as a traditional herbal medicine and not upon data generated from clinical trials. There is no requirement under the Traditional Herbal Registration scheme to prove scientifically that the product works.

No new or unexpected safety concerns arose from this application and it was, therefore, decided that a Traditional Herbal Registration Certificate could be granted.
ASHTON AND PARSONS INFANTS’ POWDERS

THR 16853/0076

SCIEnTIFIC DISCUSSION

TABLE OF CONTENTS

Introduction Page 4
Pharmaceutical assessment Page 5
Preclinical assessment Page 7
Clinical assessment Page 8
Overall conclusions and risk assessment Page 9
INTRODUCTION

The MHRA granted a Traditional Herbal Registration Certificate for the traditional herbal medicinal product Ashton and Parsons Infants’ Powders (THR 16853/0076) to Alliance Pharmaceuticals Limited on 8 November 2012. This product is on the general sales list (GSL).

A product licence of right (PLR) was originally granted to Beecham Group Plc for this product. The PLR was reviewed and a product licence (PL 00079/5001R) was granted to Beecham Group Plc on 22 July 1988. The product licence was transferred to Seton Products Limited on 30 August 1997 (PL 11314/0110), to SSL International plc on 31 January 2006 (PL 17905/0070) and to Alliance Pharmaceuticals Limited on 9 January 2012 (PL 16853/0125). PL 16853/0125 was cancelled on 12 November 2012.

This THR application was made under Article 16.c of Directive 2001/83 EC in accordance with arrangements to transfer certain herbal products with a Marketing Authorisation to a THR (according to MHRA Guidance dated January 2009). The application falls within the simplified THR application Category A, as no significant changes have been made to the formulation of the product. 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: MATRICARIA FLOWER

Scientific name of the plant: Matricaria recutita L.
Plant family: Asteraceae
Synonyms of the herbal substance: Chamomile

The herbal substance complies with the Ph Eur monograph and is, therefore, acceptable.

HERBAL PREPARATION: MATRICARIA FLOWER TINCTURE

Drug extract ratio (DER): 1:4-5
Extraction solvent: Ethanol 70% v/v

The herbal preparation specification is in line with that applied to the herbal preparation used in the already licensed product. It is, therefore, acceptable.

HERBAL PRODUCT: ASHTON AND PARSONS INFANTS’ POWDERS

Description and Composition of the Herbal Product
Ashton and Parsons Infants’ Powders is a fine, white, crystalline, oral powder. Each sachet contains 0.002 ml of Matricaria flower tincture. The only other product ingredient is lactose. The formulation is identical to 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
Ashton and Parsons Infants’ Powders is contained in a wrapper made of glazed paper. The product is sold in boxes containing 20 wrappers. This type of packaging has been used to store the already licensed product and is satisfactory.

Stability
The product shelf-life of 36 months for product stored in unopened wrappers was applied to the already licensed product and is appropriate.
Summary of Product Characteristics, product labels and Patient Information Leaflet
All product literature is in line with that of the already licensed product, with some details amended in line with other products registered under the THR scheme.

A package leaflet has been submitted to the MHRA along with results of consultations with target patient groups ("user testing"), in accordance with Article 59 of Council Directive 2001/83/EC. 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.

ASSESSOR’S OVERALL CONCLUSION
It is recommended that a Traditional Herbal Registration can be granted.
PRECLINICAL ASSESSMENT

INTRODUCTION
No new preclinical data have been supplied with this application and none is required for an application of this type.

Assurance has been given that the results of genotoxicity testing will be provided by the renewal date of the Traditional Herbal Registration.

PRODUCT LITERATURE
All product literature is satisfactory from a preclinical point of view.

ASSESSOR'S OVERALL CONCLUSION
It is recommended that a Traditional Herbal Registration can be granted.
CLINICAL ASSESSMENT

INTRODUCTION
The clinical particulars for Ashton and Parsons Infants’ Powders are identical to those for the already licensed product. This is satisfactory.

PRODUCT LITERATURE
All product literature is medically satisfactory.

ASSESSOR’S OVERALL CONCLUSION
It is recommended that a Traditional Herbal Registration can be granted.
OVERALL CONCLUSION AND BENEFIT-RISK ASSESSMENT

QUALITY
Ashton and Parsons Infants’ Powders is identical to an already licensed product. It is, therefore, pharmaceutically satisfactory.

PRECLINICAL
No new preclinical data were submitted and none are required for an application of this type. The results of genotoxicity testing will be provided before the THR is renewed.

EFFICACY
No clinical efficacy data are required for registration of Traditional Herbal Medicinal Products.

SAFETY
No new or unexpected safety concerns arose from this application.

BENEFIT-RISK ASSESSMENT
The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. The benefit: risk balance is acceptable and a THR should be granted.
ASHTON AND PARSONS INFANTS’ POWDERS

THR 16853/0076

STEPS TAKEN FOR ASSESSMENT

1. The MHRA received the Traditional Herbal Registration application on 19 June 2012.
2. Following standard checks and communication with the applicant the MHRA considered the application valid on 25 July 2012.
3. Following assessment of the application the MHRA requested further information relating to the dossier on 30 July 2012.
4. The applicant responded to the MHRA’s requests, providing further information on the dossier on 18 September 2012.
5. A THR was granted on 8 November 2012.
SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT
Ashton and Parsons Infants’ Powders

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Each sachet contains powder impregnated with 0.002ml of tincture from Matricaria (Matricaria recutita L.) flower (1:4-5). Extraction solvent: Ethanol 70% v/v

Each sachet contains 130mg lactose

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM
Oral powder.
Fine, white, crystalline powder.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications
A traditional herbal medicinal product used for the symptomatic relief of teething pain and the symptoms associated with teething which are sore and tender gums, flushed cheeks and dribbling based on traditional use only.

4.2 Posology and method of administration
For oral short term use only.

Method of administration: Oral use.

This product is only intended for use in teething infants.

Children aged over 6 months: One powder, dry on the tongue, night and morning

Children aged 3-6 months: Half a powder, taken as above

If the child is very restless, the dose may be repeated every 1, 2 or 3 hours if necessary until improvement occurs. The maximum dose is 6 doses in 24 hours.

This product is not recommended for use in babies under 3 months old.

If symptoms worsen or persist after 7 days of using this product, a doctor or qualified healthcare practitioner should be consulted.
4.3 **Contraindications**
Hypersensitivity to the active substance, any members of the Asteraceae/Compositae family or to any of the excipients.

4.4 **Special warnings and precautions for use**
Matricaria may precipitate an allergic reaction or exacerbate existing symptoms in susceptible individuals (e.g. asthmatics).

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 **Interaction with other medicinal products and other forms of interaction**
None known.

4.6 **Fertility, pregnancy and lactation**
The use of this product in pregnancy and lactation is not applicable.

Studies on the effects on fertility have not been performed.

4.7 **Effects on ability to drive and use machines**
None known.

4.8 **Undesirable effects**
Hypersensitivity reactions including urticaria, contact sensitivity, rash; application site reactions including lesions (tongue). The frequency is not known.

If other adverse reactions not mentioned above occur, a doctor or qualified healthcare practitioner should be consulted.

4.9 **Overdose**
Overdosage with this product would cause diarrhoea due to excessive lactose intake.
Treatment would be by withdrawal of the product and supportive measures such as oral rehydration therapy.

5 **PHARMACOLOGICAL PROPERTIES**

5.1 **Pharmacodynamic properties**
Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

5.2 **Pharmacokinetic properties**
Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

5.3 **Preclinical safety data**
Tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.
6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Lactose.

6.2 Incompatibilities
None stated.

6.3 Shelf life
36 months unopened.

6.4 Special precautions for storage
None stated.

6.5 Nature and contents of container
The powder is contained in a wrapper made of glazed paper. 20 wrappers are packed in a boxboard carton.

6.6 Special precautions for disposal
No special requirements.

7 MARKETING AUTHORISATION HOLDER
Alliance Pharmaceuticals Limited
Avonbridge House
Bath Road
Chippenham
Wiltshire
SN15 2BB
UK

8 MARKETING AUTHORISATION NUMBER(S)
THR 16853/0076

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORIZATION
08/11/2012

10 DATE OF REVISION OF THE TEXT
08/11/2012
PRODUCT INFORMATION LEAFLET

All necessary patient information is included on the following product labelling.
Read the carton before use.

For oral use.

Ashton & Parsons®
INFANTS' POWDERS

A herbal product traditionally used in infants for the relief of teething pain and symptoms associated with teething such as sore and tender gums, flushed cheeks and dribbling

Not recommended for use in babies under 3 months. For use in teething infants only. Children 3 - 6 months: half the contents of the wrapper dry on the tongue in the morning and the other half in the evening. The wrapper may be divided in half by empting half the contents onto a teaspoon and retaining the other half in the wrapper.

Children over 6 months: pour the contents of one wrapper dry on the tongue morning and night.
The dose can be repeated every 1, 2 or 3 hours if needed, up to a maximum of 6 doses in 24 hours until improvement. Do not exceed the stated dose.
If symptoms persist for more than 7 days, speak to your doctor.

Ashton & Parsons® INFANTS' POWDERS

Each sachet contains powder impregnated with 0.002ml of the active ingredient tincture of matricaria (Matricaria recutita L.) flower. Also contains lactose. Extraction solvent: Ethanol 70% w/v

THR 16853/0076

Keep out of the sight and reach of children.

THR Holder: Alliance Pharmaceuticals Limited, Newbridge House, Bath Road, Chippenham, Wiltshire, SN15 2BD, UK.

Ashton & Parsons is a registered trademark in the UK of Alliance Pharmaceuticals Limited.

Alliance Pharmaceuticals and associated devices are registered trademarks of Alliance Pharmaceuticals Limited.

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