1. NAME OF THE MEDICINAL PRODUCT

Ashton & Parsons Infants Powder.

Strength:

Each 130mg contains: Tincture of Matricaria 4mg.

Pharmaceutical Form

Oral Powder

2. QUALITATIVE AND QUANTITAVE COMPOSITION

Qualitative Declaration

Tincture of Matricaria 4mg.

Quantitative Declaration

Each 130mg contains: Tincture of Matricaria 4mg.

Excipients see section 6.1

3. PHARMACEUTICAL FORM

Oral Powder

Off – White granular powder free from foreign matter.

4.0 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Are intended for soothing the child, check stomach upsets, relieve restlessness, fretfulness and similar troubles during the teething period and are useful in delayed or unduly prolonged dentition.

4.2 Posology and Method of Administration

For oral administration only

Dosage:

Pack Size: 2.6gx20 Sachet

From 3 - 6 months, one pinch; above six months, two pinches; dry on the tongue, night and morning. When a child is very restless or fretful, the dose can be repeated until improvement.

Pack Size: 6gx20 Sachet

From 3 - 6 months, half a powder; above six months, one powder; dry on the tongue, night and morning. When a child is very restless or fretful, the dose can be repeated every two hours until improvement.

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

Hypersensitivity reactions including urticaria, contact sensitivity, rash; application site reactions including lesions (tongue).

4.7 Effects on Ability to Drive and use Machines

Ashton & Parsons Infants Powder does not affect the ability to drive and use machines.

4.8 Adverse Effects

Hypersensitivity reactions including urticaria, contact sensitivity, rash; application site reactions including lesions (tongue).

The frequency is not known.

4.9 Overdose

Overdosage with this product would cause diarrhea 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

The active of Ashton & Parsons Infants Powder is derived from a herbal preparation, matricaria chamomilla L. flower and as with most herbal preparations it has many constituents mainly Matricaria which contains chamomile which is made up of anthemic acid (anthemidine), anthesterol, anthemene, volatile oil, tannin and matricarin.

5.2 Pharmacokinetic Properties

None Known

5.3 Preclinical safety data

There are no pre-clinical data of relevance to prescriber which are additional to that included in other sections of the summary of product characteristics.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose, Magnesium Stearate.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store in a cool dry place below 30^0C. Protect from light.

6.5 Nature and contents of container

The primary pack is sachet pack made of polypaper and wrapper/insert leaf paper. The secondary pack is unit carton made of chipboard material.

6.6 Special precautions for disposal and other handling

No special requirements

7. MARKETING AUTHPROZATION HOLDER AND MANUFACTURING SITE ADDRESSES

Name: **ASPEN PHARMACARE NIGERIA LIMITED**

Address: **Plot 28, Infinity House, Ilupeju Bypass**

Country: **Nigeria**

Telephone: **+234 90 624 96814**

E-Mail: **info@aspennigeria.com**

Manufacturing Site(s)

Name: **BETA HEALTHCARE INTERNATIONAL LTD**

Address: **Plot No. Nairobi/Block59/135, Mogadishu Road, Industrial Area, Nairobi**

P.O. BOX 42569-00100 Nairobi, Kenya

Country: **KENYA**

Telephone: **+254-20-2652042/89**

E-Mail: info@ke.aspenpharma.com

8. MARKETING AUTHORIZATION NUMBER

NAFDAC REG. No. A7 – 2373L

9. DATE OF FIRST REGISTRATION

Date of First Registration: **25-Jun-2015**

Date of Renewal of Registration: **20-Dec-2025**

10. DATE OF REVISION OF THE TEXT

October 2024

11. DOSIMETRY (IF APPLICABLE)

Not Applicable

12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS (IF APPLICABLE)

Not Applicable