

Summary of Product Characteristics

1. Name of the Medicinal Product

Berclomine Baby Drops

2. Qualitative and quantitative composition

Each 0.6 ml of suspension contains 40 mg of simethicone

For a full of excipients see section 6.1.

3. Pharmaceutical Form

Oral drops suspension

4. Clinical Particulars

4.1 Therapeutic Indication (Reference 1.1)

Relieves the discomfort of infant gas frequently caused by air swallowing or certain formulas or foods

4.2 Posology and method of administration (Reference 1.2)

- Shake well before using.
- Find right dose on chart below. If possible, use weight to dose; otherwise, use age.
- Only use the enclosed dropper. Do not use other syringe, dropper, spoon or dosing device when giving this medicine to children.
- Remove cap and insert dropper into the bottle.
- Fill dropper to recommend dosage level and dispense slowly into mouth towards inner cheek.

Age (yr)	Weight (kg)	Dose (mL)
Infants under 2	under 11	0.3
Children over 2	over 11	0.6

- All dosage may be repeated as needed, after meals and at bed time or as directed by a physician.

4.3 Contraindication (Reference 5.1)

Hypersensitivity to simethicone or to components of the product

4.4 Special warning and precautions for use

None known

4.5 Interaction with other medicinal products and other forms of interaction

(Reference 2.1)

Simethicone may result in decreased levothyroxine efficacy. Concomitant use of levothyroxine and simethicone may decrease levothyroxine efficacy by binding to and delaying or preventing levothyroxine absorption, potentially resulting in hypothyroidism. If concurrent use of levothyroxine and simethicone is required, administration of these agents should be separated by at least 4 hours. Consider monitoring TSH levels and/or

other measures of thyroid function when simethicone is initiated or discontinued during levothyroxine treatment.

4.6 Pregnancy and lactation (Reference 3.1)

Pregnancy category C: Use with caution if benefits outweigh risks. Animal studies show risk and human studies not available or neither animal nor human studies done.

Lactation: Not absorbed systemically; not expected to be excreted in milk

4.7 Effects on ability to drive and use machines

None known

4.8 Undesirable effects (Reference 4.1)

Simethicone is apparently nontoxic, and no adverse effects have been reported.

4.9 Overdose (Reference 1.3)

Do not exceed 12 doses per day.

5. Pharmacological Properties

5.1 Pharmacodynamic properties (Reference 4.2)

The clinical use of simethicone is based on its antifoam properties. Silicone antifoams spread on the surface of aqueous liquids, forming a film of low surface tension and thus causing collapse of foam bubbles. Simethicone reportedly allows mucus-surrounded gas bubbles in the GI tract to coalesce and be expelled.

5.2 Pharmacokinetic properties (Reference 4.3)

Simethicone is physiologically inert; it does not appear to be absorbed from the GI tract or to interfere with gastric secretion or absorption of nutrients. Following oral administration, the drug is excreted unchanged in feces.

5.3 Preclinical safety data

None known

6. Pharmaceutical Particulars

6.1 List of excipients

Methylparaben

Propylparaben

Saccharin Sodium

Carmoisine Dye

Strawberry Essence

Citric Acid Anhydrous

Sodium CMC 1800

Xanthan Gum

Purified water

6.2 Incompatibilities

None known

6.3 Shelf life

2 years

6.4 Special precautions for storage

Close the bottle with the original aluminium screw cap

Store below 30°C in well-closed container and protect from light

Do not freeze

6.5 Nature and contents of container

Amber glass type III bottles 15 mL closed with aluminium screw cap with liner packed in printed box 1, 5, 10, 12, 25, 50, 100 bottles with plastic dropper (1.0 mL) 1 piece / box

7. Marketing Authorization Holder

7.1 Distributed by

Polipharm Co., Ltd.

109 Soi Wat Bang Phli Yai Nai, Bangna-Trad Road, Moo 12,

Bang Phli Yai, Bang Phli, Samut Prakan 10540, Thailand

Tel. 0-2316-9419-21

7.2 Manufactured by

Polipharm Co., Ltd.

109 Soi Wat Bang Phli Yai Nai, Bangna-Trad Road, Moo 12,

Bang Phli Yai, Bang Phli, Samut Prakan 10540, Thailand

Tel. 0-2316-9419-21

8. Marketing Authorization Numbers

9. Date of First Authorization/Renewal of the Authorization

10. Date of revision of the text: 22/08/2022