



**IDEAL FOR INFANTS  
AND CHILDREN**

**ALSO AVAILABLE  
OIL-BASED  
VERSION**



- **Dyspepsia**
- **Meteorism**
- **Pain and cramps**
- **Colic**

Medical device II CE<sub>0426</sub>



**MADE IN ITALY**

# INFANT COLIC AND FUSSINESS

## DESCRIPTION

The Secol formulation consists of simethicone suspension in water and is indicated in prevention and treatment of dyspeptic disorders, gastroenteric meteorism, aerophagia and gas colic in infants and children.



**Infants:** 1 dose 1-2 times/day  
**Children:** 1 dose 1-3 times/day



## THERAPEUTIC INDICATIONS

- Dyspeptic disorders
- Gastroenteric meteorism
- Aerophagia
- Gaseous colic

## PRESENTATION

Secol is supplied in four sales formats: 20ml; 30ml; 50ml; 100ml. Every package is equipped with a rubber teat dropper that simplifies administration.

## INGREDIENTS

Simethicone in aqueous solution. Preservatives: sodium benzoate, potassium sorbate; Sweetener: saccharin sodium; strawberry flavor.

## REGULATORY STATUS

- Class IIb
- MDR CE certified
- ISO 13485 certificate

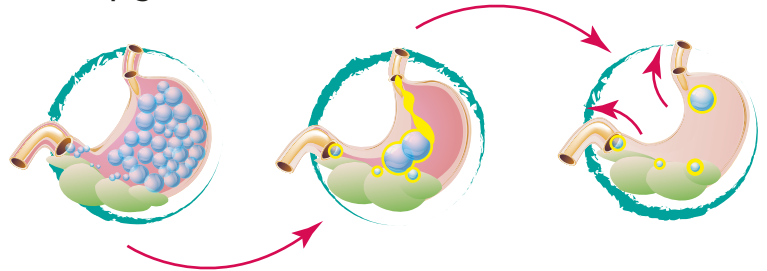
**LACTOSE FREE**

**SUGAR FREE**

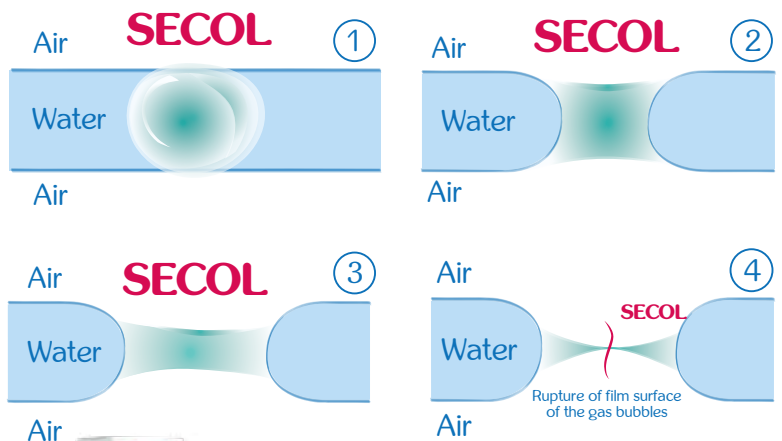
**GLUTEN FREE**

## + PLUS

Secol is useful to relieve symptoms of extra gas caused by air swallowing or certain foods/infant formulas. It helps break up gas bubbles in the GUT.



## MECHANISM OF ANTIFOAMING ACTION OF SECOL



## CLINICAL TEST

- CYTOTOXICITY for DIRECT CONTACT - according to UNI EN ISO 10993-5:2009
- ACUTE ORAL TOXICITY EVALUATION – according to OECD 420:2011
- ORAL MUCOSA IRRITATION TEST - according to UNI EN ISO 10993-10:2010
- DELAYED HYPERSENSIVITY TEST (GPMT) - according to UNI EN ISO 10993-10:2010
- CLINICAL STUDY

# CLINICAL TRIAL

*Secol drops: a product based on Simethicone*



## CLINICAL TRIAL ENDPOINTS



**Infant Colic**



**Meteorism**

## MULTICENTER STUDY



Infants under 6 month



20 Drops/ 2 times for 14 days

## EVALUATION OF METEORISM AND INFANT COLIC

*Through*

***GIQLI Questionnaire***

## THERAPEUTIC PROTOCOL

*Baseline Evaluation according to including criteria*

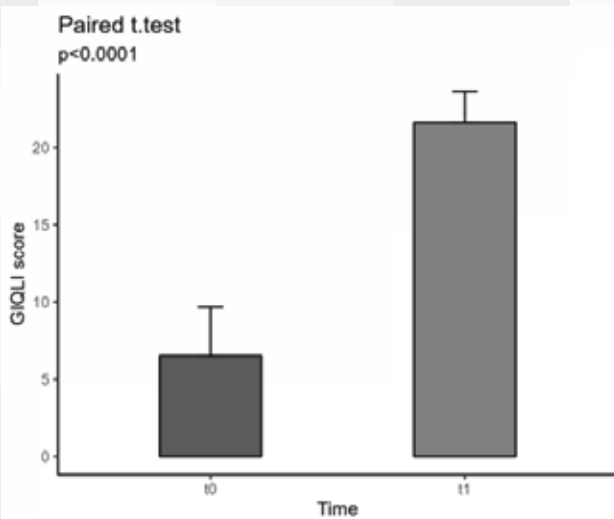


*Treatment of Meteorism and Infant Colic*



*Follow-up Evaluation*

## RESULTS OF THE TRIAL



Overall improvement of symptoms before and after treatment

Figure 1. GIQLI Questionnaire overall scores, before (T0) and after (T1) the treatment

*After 2 weeks of treatment in infants under 6 month*



**Pain (-95)%**



**Bloating (-100)%**



**Aerophagia (-95)%**



**Burping (-95)%**

