



**IDEAL FOR INFANTS
AND CHILDREN**

**ALSO AVAILABLE
WATER-BASED
VERSION**



- Dyspepsia
- Meteorism
- Colic

- Pain and cramps
- Antifoaming action

Medical device II CE₀₄₂₆

PJ
PHARMA



BREVETTO

gfi
Farma
Impresa®

PATENT

Russia - USA - Europe

MADE IN ITALY

INFANT COLIC AND FUSSINESS



DESCRIPTION

Rilefast CE is based on simethicone in olive oil. It is indicated to relieve all those symptoms due to an excessive presence of gastro-intestinal gas (pain, cramps, sense of tension, belching, flatulence, etc) in infants and children.

The single dose consists in 20 drops

Single dose:
20 drops
=
40 mg
of Simethicone



Adults: 1/2 dose, 2-4 times daily.
Children: 1 dose, 1-3 times daily.
Infants: 1 dose, 1-2 times daily.

THERAPEUTIC INDICATIONS

- Dyspeptic disorders
- Gastroenteric meteorism
- Aerophagia
- Gaseous colic
- Diarrheic dysbiosis

PRESENTATION

Rilefast Ce Drops is supplied in different packages:
10ml; 20ml; 30ml; 50ml; 100ml.

INGREDIENTS

Simethicone in olive oil, vitamin E and coenzyme Q10.

REGULATORY STATUS

- Class IIb
- MDR CE certified
- ISO 13485 certificate



BETTER DISPERSION OF SIMETHICONE

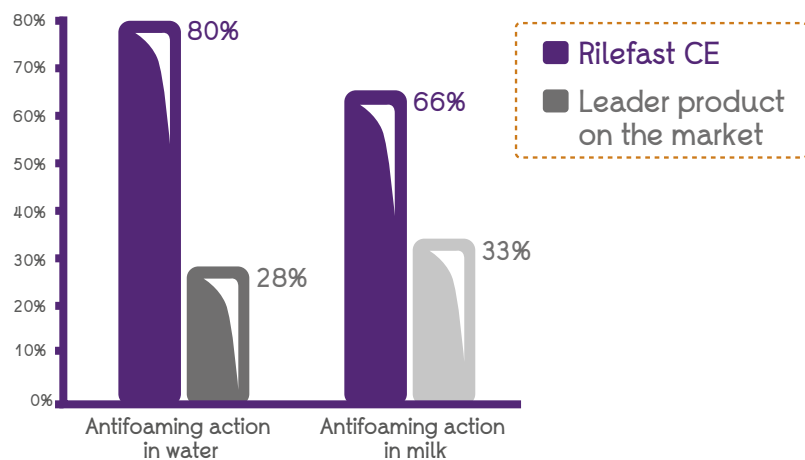


Leader product on the market



Rilefast CE suspension

BETTER ANTIFOAM ACTIVITY



Tests were conducted according to ASTM E2407 – 04 – American Standard Test Methods Int. also dissolving Rilefast ACE in milk.

As showed in the graph, Rilefast CE presents enhanced anti-foam activity both in aqueous and oily (emulsions) administration media.



Bubble-Burster

Increased efficacy compared with classical aqueous emulsions of simethicone

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

Rilefast Ce 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

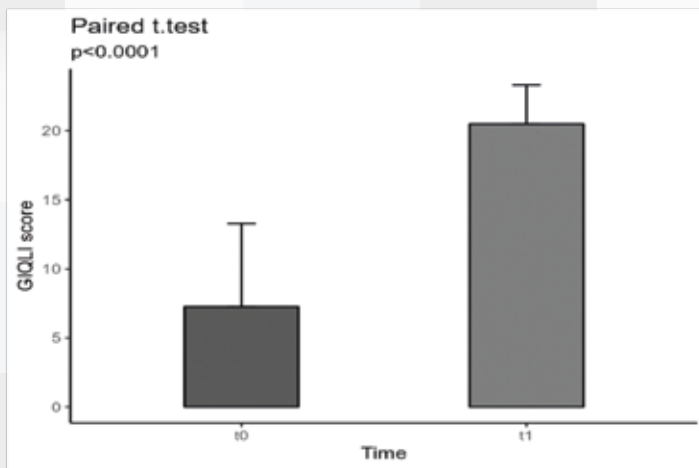


Treatment of Meteorism and Infant Colic



Follow-up Evaluation

RESULTS OF THE TRIAL



Overall Evaluation 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 (-88)%



Bloating (-88)%



Aerophagia (-76)%



Burping (-86)%

