- Dyspepsia
- Meteorism
- Colic
- Pain and cramps
- Antifoaming action

Medical device II CE 0426

PJ PHARMA

Quality Assurance ISO 9001 - ISO 13485

BREVETTO Farma Impresa PATENT Russia - USA - Europe

MADE IN ITALY

INFANT COLIC AND FUSSINESS

DESCRIPTION

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

The single dose consists in 20 drops

Single dose: 20 drops = 40 mg of Simethicone

DOSAGE

Infants: 1 dose 1-2 times/day
Children: 1 dose 1-3 times/day
Adults: 1-2 doses 2-4 times/day

THERAPEUTIC INDICATIONS

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

PRESENTATION

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

INGREDIENTS

Simethicone in olive oil, vitamin E and coenzyme Q.

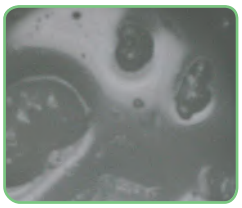
REGULATORY STATUS

- Class IIa
- Free sale certificate
- CE certificate n° 190-01-01-DM
- Certificate of origin
- ISO 13485 certificate
- US FDA registration

NO ALCOOL ETHANOL · SUGAR FREE · GLUTEN FREE · NO PRESERVATIVES · OMEO BIMBO · NO ARTIFICIAL FLAVORS

PLUS

BETTER DISPERSION OF SIMETHICONE

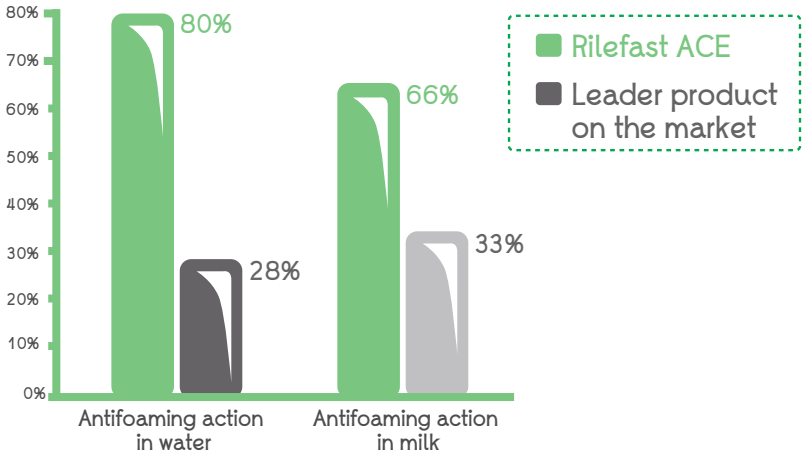


Leader product on the market

Rilefast ACE suspension

TIGE of Rilefast ACE for simplifies administration

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 ACE presents enhanced anti-foam activity both in aqueous and oily (emulsions) administration media.

CLINICAL TEST

RISK ANALYSIS - according to UNI CEI EN ISO 14971
BIOCOMPATIBILITY – according to UNI EN ISO 10993:
- 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 HYPERENSIVITY TEST (GPMT) - according to UNI EN ISO 10993-10:2010

CLINICAL EVALUATION – according to MEDDEV 2.7.1:2016
STABILITY-according to ICH Guidelines / European Pharmacopoeia:
- ACCELERATED STABILITY STUDY
- LONG TERM
- PAO

CHALLENGE TEST according to FU

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