KEBENE Pro Baby oral droplets Suspension for functional gastrointestinal disorder

KEBENE Pro Baby instant suspension is a product made up of the following:

- 1 bottle of 20 ml with dropper provided with pump containing an emulsion of Simethicone in aqueous solution.
  Preserving agents: sodium benzoate, sweeteners: sodium saccharine, strawberry flavour
- 1 sachet with 2 g of Saccharomyces Boulardii, maltodextrins.

Therapeutic indications:

KEBENE Pro Baby is a medical device indicated in case of: dyspeptic disorders, gastrointestinal meteorism, aerophagia and gaseous colic in new born babies, children and adults.

As a result of the association between simethicone (active ingredient) and probiotic (active adjuvant), KEBENE Pro Baby instant suspension has the role to protect and regenerate the intestinal biological barrier (intestinal flora) and in the same time to reduce the superficial tension of gastric air bubbles in order to help release the above mentioned symptoms.

The main activity is exercised by Simethicone (activated methylpolysiloxane), inert chemical polymer of methyl siloxane. The chemical and physical property of simethicone is to reduce the superficial tension, so that the gas bubbles from the intestinal tract would connect forming a free gas, which can be easily eliminated. As such, it ameliorates all unpleasant symptoms (pain, cramps, tension feeling, eructation, flatulence), related to bloating, characteristic for many of the gastro-intestinal tract diseases.

This activity is also supported by Saccharomyces Boulardii that acts as a temporary flora, protecting the intestinal system and allowing the system to function correctly through re-settling the micro-flora. When you interrupt the treatment, this component shall be eliminated in a few days.

Posology and administration

Unique dose: 20 droplets containing 40 mg of Simethicone.

Adults: 20-40 droplets, eventually diluted in a liquid, preferable after meals, 2-4 times per day or depending on the physician's advice.

Children: 20 droplets, eventually diluted in a liquid, preferable after meals, 1-3 times per day or depending on the physician's advice.

New born babies: 20 droplets, eventually diluted in a liquid, preferable after meals, 1-2 times per day or depending on the physician's advice.

Instructions for use

Instant suspension: in order to ensure maximum stability and quality of the product, Saccharomyces Boulardii powder is stored in a protected environment in a sachet and is diluted in the simethicone liquid only when the product is used. Mix well prior to using the product in order to obtain a homogenous suspension. Close the bottle correctly after use. Mark the date of reconstituted the suspension on the side of the box, in the blank space provided in this respect.

Storage conditions: The product should be stored at room temperature. Keep the product adequately sealed and protected from sources of heat. Once the product was reconstituted, it shall be stored in the refrigerator for improving its probiotic activity. In any case, the product should not be used more than 14 days following the reconstitution.

Warnings:

- The product can be presented in two different stages. After the mixing, it should be presented as homogenous emulsion.

- Do not use the product after more than 14 days from the reconstitution.
- After reconstitution and agitation of the product the potential present of suspension masses does not affect the functionality and quality of the product.
- Keep away from use of children.
- Do not exceed the recommended dose.
- Do not use the product after the expiration date; the expiration date refers to the intact product and to the product adequately stored.
- Do not use the product if the packaging material is not intact.
- All components comprising the product, including the dropper must be intact.
- Do not use the sachet individually, but only to reconstitute the product.
- After a short period of treatment (7 days) with no significant results, seek medical attention,
- In case of adverse reactions, interrupt the use of the product and discuss with your physician in order to settle the adequate treatment.
- Do not use the product in case you suspect intestinal perforation or ileus.
- During use, if the dropper is dirty, clean it adequately prior to reintroducing it into the bottle in order to avoid a potential contamination.

It is important that you inform your physician or the pharmacist with respect to any adverse reactions that are not listed in this patient information leaflet.

Advices against use: Do not use the product in case of hypersensitivity reactions to the product's components.

Interactions and incompatibilities

There are no known or reported interactions with other medicines or incompatibilities with other pharmaceutical products.

In case of therapy with medicines based on Levotiroxine, discuss with your physician prior to using the product.

During pregnancy and breast-feeding

Pregnancy: no adequate data exist with respect to the use of KEBENE Pro Baby by pregnant women; as such, this product must not be used except when there is a real need for using it and after the physician's assessment.

Breast-feeding: It is not known if Simethicone is excreted in the mother's milk; as such, this product must not be used except when there is a real need for using it and after the physician's assessment.

Driving vehicles and use of machines

No effects upon the ability to drive vehicles and use machinery were reported.

Adverse reactions and over-dosage

Usually, Simethicone does not have secondary effects when administered according to the instructions on the package or according to your physician's recommendations; in any case, some persons could report less frequent adverse reactions, such as:

- Nausea, vomiting, diarrhoea, pain at the level of the abdomen and ileum

And rare cases of allergic reactions such as:

- Cutaneous eruptions, palpebral oedema and lips oedema, throat swallowing with breathing difficulties (angioedema)

In such a case, immediately consult the physician.

No adverse reactions were reported in case of over-dosage.

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