

simethicone +
active charcoal

KEBENE[®]
plus

20 double film-coated tablets, with modified release, for oral intake

1. Utilisation, composition and destination for the use of the medical device

1.1 Description and utilisation method

KEBENE[®] plus is a medical device in the form of a tablet, useful for the amelioration of irritation symptoms related to intestinal aerophagia and meteorism. It is indicated for the treatment of symptoms related to gastric bloating (aerophagia) or intestinal bloating (meteorism) due to gases accumulation. The device minimises the pain and the cramps that are in relation to aerophagia and meteorism and prevents flatulence and eructation.

1.2 Composition

Each tablet contains the following:

50 mg simethicone

30 mg charcoal

Excipients: maltodextrin, household sugar, microcrystalline cellulose, hydroxipropylmethyl-cellulose, polyvinylpyrrolidone, colloidal silica, sodium croscarmellose, polyvinylpolypyrrolidone, behenate glyceryl, silica dioxide, vegetal magnesium stearate.

1.3 Action mechanism

The effectiveness of the device is due to the antifoaming action of simethicone, combined with the gas absorption process exercised by the charcoal: the activity is based exclusively on the mechanic phenomenon. The double layered film coated tablets releases approximately 50% of its ingredients in the gastric environment during a period of time of 15 minutes, its desegregation in the intestinal environment being complete during a period of one hour. The components are not absorbed in the gastro-intestinal tract and do not influence the absorption of nutritive substances.

2. Presentation of the content

The box contains 20 double layered film coated tablets, packed in a blister.

3. Dose, administration route and administration time

Adults: 4 tablets per day, preferably 2 tablets after the main meal.

Extract the tablet from the blister taking care not to tore it and swallow the tablet with one glass of water.

4. Known adverse reactions

If the recommended dose is administered, a brownish colouring of the faeces can be noticed, due to the presence of the charcoal. The phenomenon is absolutely normal and does not have any pathologic significance.

No long- and medium-term reactions were observed.

The product does not negatively influence the sensorial capacities (the level of attention, ability to drive vehicles or carry out activities).

5. Storage conditions

Store the tablets in their blister, in a dry place, apart from direct solar light or sources of heat; take out the tablets from the blister only when you use them.

Do not store at temperatures exceeding 25°C.

6. Warnings and precautions

Do not use the product for children under 14. Keep away from children.

Do not ingest the tablets while laying down.

Do not use the product after the expire date written on the box and blister.

Do not use the tablets in case the packaging material is deteriorated.

Each tablet is a single use tablet and must be extracted from the blister right before its use; do not try to reuse the partially used tablets (tablets that were previously broken) or the tablets already extracted from the blister. This improper utilisation manner could lead to the contamination of the product.

Do not exceed the recommended dose.

Do not use the product in case of known gastric or intestinal lesions.

Do not use the product in case of intestinal blockage.

Do not take the product while using other medical devices with oral administration or with other medicines: the absorption effect of the active charcoal and the effect of simethicone could have a negative effect upon their effectiveness.

Discuss with your physician prior to taking **KEBENE® plus** in case you take also treatments with other medicine. Simethicone could obstruct the effect of certain agents used in diagnose, for example, guaiaac gum.

The product can be used, normally, during a period of maximum 30 days. If the symptoms persist, seek medical advice.

7. Advices against the use of the medicine

The use of the product is not recommended in case of hypersensitivity to any of the product's ingredients.

There are no sufficient data to support the use of the product during pregnancy and breast-feeding; consequently, the use of the product during pregnancy and breast-feeding can be performed only in case of real need and following the examination of a physician.

8. Disposal

When the product is consumed or expired, dispose it together with its related packaging material in the environment in an adequate manner, in compliance with the current regulations in force.

Manufacturer:



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Distributor:

Terapia SA - 124, Fabricii St., Cluj Napoca, Romania

Text revision date: June 2018

