

Utilisation instructions
Please read carefully this Patient Information Leaflet prior to using this product.
- Keep this Patient Information Leaflet in case you must read it again
- Seek medical attention if the symptoms persist or if no improvement occurs

The content of this Patient Information Leaflet including instructions:
1. What is Kebene extra 240 mg soft capsules and what is it used for?
2. How you should use Kebene extra 240 mg soft capsules
3. Advises against use
4. Warnings and precautions
5. Possible adverse reactions
6. How should Kebene extra 240 mg soft capsules be kept
7. Additional information.

Kebene extra 240 mg soft capsules contains: 240 mg simethicone
Excipients: gelatine, glycerol, yellow quinoline

1. What is Kebene extra 240 mg soft capsules and what is it used for
Kebene extra 240 mg soft capsules contains a high dose of simethicone, which increases the efficiency of this product leading to a better amelioration of discomfort associated to severe flatulence. Simethicone is a stable mixture of silicone polymer and silica dioxide having antifoaming properties and intestinal gases reduction properties. The recommended dose of simethicone acts only at the surface and is inactive in the organism from a chemical view-point. Simethicone is not absorbed into the organism at the level of the gastro-intestinal tract, does not cause a modification of the pH at the level of the digestive system or upon digestion and does not interfere with the intestinal absorption. It is discharged into the body in an unmodified form. Simethicone reduces the superficial tension of the mucus and gas bubbles in the intestine and, in this way, helps breaking the gas bubbles, facilitating in this manner the elimination of the gastro-intestinal gas in excess. Kebene extra 240 mg soft capsules is used for the amelioration of the symptoms caused by the accumulation of gases in the stomach and intestine during the entire development of the digestive process, during which fermentation occurs. These symptoms include bloating, flatulence and eructation, one of the causes of their occurrence being the unhealthy nourishing habits.
Kebene extra 240 mg soft capsules is also used as adjuvant prior to the diagnosis investigations at the level of the abdominal cavity in which imagistic techniques are used, such as: radiology, ultrasonography and endoscopy. This medicine contributes to the discharge of gases and air from the gastro-intestinal tract, improving in this manner the quality of images and eliminating difficulties in settling a diagnosis.

2. How you should use Kebene extra 240 mg soft capsules
The medical device, presented as gelatinous capsules, must be administered as oral intake.
Symptoms associated with the excess of gases in the gastro-intestinal tract: bloating, flatulence and eructation.
Persons ages 18 and above 18: 2-3 capsules during a period of 24 hours.
Preparation for diagnostic investigations
The day before performing the test: 1 capsule in the evening, During the day the test is performed: 1 capsule in the morning, prior to having breakfast.
The capsules can be administered prior, during or after the meals and must be accompanied by an adequate quantity of liquid (approximately 1 glass of water).
If you forget to take a dose, you must not take a double dose to compensate the forgotten dose.
The recommended dose must not be exceeded.
The product must not be used after the expiration date.

3. Advises against use
You must not take Kebene extra 240 mg soft capsules if you are allergic to simethicone or to any other excipient of this product.

4. Warnings and precautions
You must seek medical attention in case you use this product during pregnancy or breast-feeding.
If the symptoms persist, become more severe or you experience new gastro-intestinal symptoms, you must discuss with your physician in order to settle the cause and receive adequate treatment.
It was noticed that simethicone does not cause any important medication interaction; however, due to the possibility that medication interactions might occur, it is not recommended to take Kebene extra 240 mg soft capsules during treatment with medicines.

5. Possible adverse reactions
No adverse reactions were reported in relation to the utilisation of this product. Some users could occasionally experience gastric pains, diarrhoea, constipation. Any adverse reactions that occurred as a result of using this product must be reported to the producer.

6. How should Kebene extra 240 mg soft capsules be kept
The product should be kept in its original packaging material, at temperatures below 25° C, in a place in which it shall not be at sight; the product should be kept away from children's reach.

7. Additional information
Kebene extra 240 mg soft capsules is available in boxes containing 15 or 30 soft capsules.

Information on package:



Number of lot


Used until



Medical device


Maximum temperature


See the instructions of use


Manufacturer

Distributor:
Terapia SA
124, Fabricii St.,
Cluj Napoca, Romania

Manufacturer:
NTC S.r.l.
3, Via Luigi Razza
20124 Milano, Italy

Review date: July 2017