

Instructions for use

formoline
L112



Please read this entire leaflet carefully before taking **formoline L112**.



Composition

Active ingredients:

Specification L112 of β -1,4 polymer of D-glucosamine and N-acetyl-D-glucosamine from the shells of crustaceans.

Excipients:

Cellulose from plants, vitamin C, tartaric acid, tableting excipients

Additional information:

Does not contain preservatives and colouring agents. Gelatine, lactose and cholesterol free, also to be recommended for diabetics (no carbohydrate exchange value).

formoline L112 is a product of natural origin. Variations in colour and taste may therefore occur and do not affect its efficacy.



Recommendations for use

■ For weight loss:

Twice daily 2 tablets each

Take **formoline L112** with the two meals that have the highest fat content towards the end of the meal for best effect.

■ For weight maintenance:

Twice daily 1 tablet each

Take **formoline L112** with the two meals that have the highest fat content towards the end of the meal for best effect.

Take **formoline L112** unchewed and together with a preferably low-calorie beverage (at least 250 ml) to achieve optimum effect and ensure best possible transportation of the tablets into the stomach. Since **formoline L112** is a fibre-rich product we recommend sufficient intake of fluids of at least 2 litres per day.

In order to stabilise your weight for the long term after weight reduction you may continue to take 1 tablet of **formoline L112** with each of the two main meals.

For losing weight and for weight maintenance with **formoline L112** a fat and calorie conscious diet (60 – 80 g fat per day) as well as physical exercise is recommended. It is recommended to consult your physician before you change your diet on a long-term basis.

To ensure the uptake of the fat-soluble vitamins A, D, E and K as well as of the essential fatty acids we recommend to take **formoline L112** only with 2 out of 3 main meals. In addition to that, you should eat at least one meal per day containing beneficial oils and fats that provide the body with the fat-soluble vitamins and essential fatty acids it needs. A multi-vitamin supplement may also help to meet the body's vitamin requirements.



Indications

Lipid adsorbent to

- support the treatment of overweight
- support long-term weight control
- lower cholesterol intake from diet



Duration of use

formoline L112 is suitable for long-term use.



Mechanism of action

formoline L112 - Reduces calorie intake from dietary fats.

The main ingredient in **formoline L112** is the fibre polyglucosamine (L112). It is of natural origin and can bind large quantities of nutritional fats in the digestive tract due to its very high fat-binding capacity. This reduces the absorption of nutritional fats from the intestine. The main ingredient of **formoline L112** is not digestible and is excreted naturally together with the bound fats. In addition, the indigestible and expanded fibre materials of **formoline L112** are slightly filling.

formoline L112 mostly affects excess weight that is caused by high-fat food such as fatty meat, sausage, butter, cheese, crisps, nuts, cake or ice cream. Other nutrients such as sugar, carbohydrates, protein or alcohol are not bound by **formoline L112**; these calories should be reduced because otherwise they are completely available for the body.

Taking **formoline L112** with vitamin-rich meals (salad, vegetable) containing beneficial oils or omega-3 fatty acid (salmon, etc.) is not recommended because the fat-soluble vitamins and essential fatty acids may be partially bound.



The basis for weight loss

Successful and permanent weight loss requires patience and time as noticeable weight loss does not occur from one day to the next. Depending on the desired weight it may take weeks or even months. In order to lose 1 kg of body fat the body needs to either burn approximately an additional 7,000 kilocalories, or reduce the caloric intake by this amount. This amount of energy is contained, for example, in 778 g of pure fat.

A daily surplus of just 40 kilocalories (for example in 7 g = 14 peanuts, 8 g = 1 piece of milk chocolate or 11 g Gouda, 45% fat in dry matter) leads to a weight gain of approximately 2 kg per year. If energy intake and use

remain this imbalanced over the course of several years, your body will have gained 20 kg of excess weight after 10 years. However, those who manage to constantly maintain their weight over a longer period of time have achieved a lot. To do that, **formoline L112** provides effective help with weight maintenance.

The formula for successful weight loss in overweight individuals has to be: a healthy diet with reduced fat intake (60 – 80 grams of fat/day) in combination with lots of exercise and **formoline L112** to support weight loss. Especially during the initial phase of implementing dietary changes, **formoline L112** promotes motivation through ease of use and weight loss goals that are easier to achieve.

Action	Average consumption (too much fat)	Weight loss through reduced intake*	Weight loss with formoline L112 (fat-conscious)
Daily fat consumption	120 g and more	40 g	60 – 80 g

*Recommendation from nutritional scientists for weight loss

To lose weight without **formoline L112** a low fat diet (about 40 g of fat daily) has proven to be successful. Many people find it very difficult to adjust from a fat-rich diet (daily intake of 120 g and more) to a low-fat diet. This is why most often long-term successes in losing weight cannot be achieved. With **formoline L112** it is possible to successfully lose weight with a fat-conscious diet but without dieting stress.

Frequent dieting over prolonged periods of time may lead to insufficient intake of vitamins (vitamin C, B vitamins), minerals (iron, calcium) as well as trace elements (iodine and fluorine). Taking additional vitamins and mineral supplements when dieting may prevent possible deficiencies.



Contraindications

Only take **formoline L112** after consulting with your physician in the event of:

- long-term intake of drugs
- serious gastro-intestinal diseases (ulcerative colitis, Crohn's disease, diverticulitis, short bowel syndrome, gastric ulcer, strong irritable colon, reflux treated with drugs, etc.) and after surgery in the gastro-intestinal tract
- chronic digestive problems (constipation, colonic inertia, etc.)
- growing children and teenagers
- anyone over the age of 80 years
- long-term intake of drugs to reduce colonic inertia

formoline L112 should not be taken by the following persons:

- infants and children up to the age of three years
- individuals suffering from underweight (BMI < 18.5)
- persons with a known allergy to crustaceans or one of the ingredients

Use during pregnancy and while breast-feeding

During pregnancy or while breast feeding a treatment of excess weight should not be attempted or only under medical supervision. Best possible nutrient supply is essential for foetal development and to provide the baby with optimal breast milk.



Interactions and side effects

Due to the high fat binding capacity of **formoline L112**, not only dietary fats but also (fat-soluble) active pharmaceutical ingredients (e. g. hormone preparations, oral contraceptives, antiepileptic drugs, anticoagulant drugs) or fat-soluble vitamins (vitamin A, D, E, K) can be bound. In this case, it is recommended to let at least 4 hours pass between taking **formoline L112** and these substances. **formoline L112** may reduce the availability of fat-soluble (lipophilic) agents.

The intake of **formoline L112** may lead to temporary changes in stool consistency. In very rare instances digestive problems (constipation, flatulence, feeling of fullness) have been observed with inadequate fluid intake. Constipation may lead to short-term weight gain.

Allergic reactions to one of the ingredients or with an existing allergy to house dust mites are possible in very rare cases (symptoms may include in isolate cases: diarrhoea, vomiting, nausea, skin rash, swelling, itching, sweating, tingling, shivering, dizziness, headache).

However, **formoline L112** may generally be termed as being very well tolerated.

It is recommended to stop using **formoline L112** and to consult a physician or pharmacist, if necessary, should one of the interactions and side effects occur that are described above.



Further instructions

formoline L112 is a medical device which is certified by an authorized notified body throughout the entire EU and is registered in its country of origin under registration number, "DE/CA64/Certmedica/001". Quality and efficacy of the active ingredient is strictly controlled prior to manufacture.

It is recommended to leave the **formoline L112** tablets in their blister until use.

Store **formoline L112** at room temperature.

With increased room temperature store in a cool and dry place, for example in a refrigerator with automatic defrosting.



Precautions



Please observe the expiry date.

Manufactured in Germany

Information as of: 2015-03

Packaging size: 16, 20, 40, 48, 60, 80, 96, 100, 144, 160 tablets



Manufacturer:
Certmedica International GmbH
Magnolienweg 17
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Medical device

formoline
L112

CE 0481

For further information regarding the use of the product or on the issue of losing weight please visit our website:
www.L112.com