



Mode of action

Dear users,

With formoline L112 EXTRA, you have purchased a German quality product, which can offer you a well-tolerated method for weight reduction and reduction of high cholesterol, which is suitable for everyday use.

Excess weight and obesity occur as a result of consuming an excess of energy-rich food. A reduced-calorie diet is therefore the basis for combating excess weight. Since one gram of fat contains about double the amount of calories compared to a gram of carbohydrates or a gram of protein, reducing the absorption of dietary fats is an effective way of losing weight and maintaining weight. Many people find it very hard to change from a diet high in fat to a low-fat diet because fat also enhances taste.

The main ingredient in formoline L112 EXTRA is the indigestible dietary fibre polyglucosamine L112. It is of natural origin, and due to its structure, it can bind large quantities of lipids, i.e., fats, fatty acids and cholesterol, in the digestive tract. The bound dietary fats cannot be absorbed, and the calories contained in these fats are therefore not available to the body.

In this way, formoline L112 EXTRA supports you in reducing calorie intake and achieving appropriate nutrition. With formoline L112 EXTRA, it is possible to achieve successful weight loss while on a moderate diet.

A reduction in weight of just 5% has health benefits. Not only do you get closer to your ideal weight, but you also reduce your risk factors for cardiovascular disease. A lower weight also reduces the stress and wear on your joints.

Taking polyglucosamine L112 results in significantly higher and faster weight loss (around 50% higher) than taking a placebo (without active substance) under the same conditions of consuming a moderate diet. This is proven by multiple studies with a placebo control group.

It has been demonstrated, for example, that around half of patients on a light diet and L112 achieved the 5% goal after just three months, and almost all of them (98%) after six months. **Within one year, patients using L112 achieved an average weight loss of more than 12 kg.** Waist circumference decreased by around 13 cm, which equates to 3 dress sizes. Moreover, the blood values that are considered risk factors for cardiovascular disease evolved significantly better than in the control group. In this study, LDL cholesterol, which is seen as critical, fell by 12.9%.

Weight loss and improvement of blood fat levels have a positive effect on your medium and long-term health prognosis. Consistently pursuing the goal of sustainable weight loss pays off.

Good luck!

N.B.: formoline L112 EXTRA primarily influences excessive weight, which is caused by a high fat diet consisting of fatty meats, sausages, butter, cheese, chips, nuts, baked goods or fried foods. High-sugar foods, including high-calorie drinks like soft drinks or alcohol, should only be consumed in small quantities, as the calories they contain are fully available to your body for metabolism. So do not forget to maintain a healthy, balanced, reduced-calorie diet alongside therapy with formoline L112 EXTRA!

Extra tip: Exercise is good for you! Get your body moving with more daily exercise and sport. You will feel better afterwards, and you will have burnt more calories!

Lipid binder

- for weight reduction
- for weight management

With LDL cholesterol-lowering accompanying effect

formoline L112 EXTRA reduces the digestibility of lipids through physical binding, resulting in fewer calories being absorbed. In this way, it helps with losing weight, maintaining weight loss and lowering LDL cholesterol.

Indication

For treatment of excess weight and obesity. formoline L112 EXTRA is intended for adults with a body mass index (BMI) over 25 as part of a reduced calorie diet.

Composition

Polyglucosamine L112 dietary fibre (73%): Specification L112 from β -1,4-polymer from D-glucosamine and N-acetyl-D-glucosamine from crustacean shell

Additives: Ascorbic acid, tartaric acid, tableting aids (magnesium stearate plant-based, cellulose plant-based, sodium sulphate, silicon dioxide)

Recommended dosage

Twice daily 2 tablets

Take formoline L112 EXTRA **at both meal-times with the highest fat content.**

Swallow the tablets whole with plenty of low-calorie liquid (at least 250 ml) to ensure that they are transported to the stomach. Since formoline L112 EXTRA is a high-fibre preparation, please make sure that you drink enough fluids, at least 2 liters daily.

To ensure you get the required amounts of fat-soluble vitamins (A, D, E and K), we recommend taking formoline L112 EXTRA only with 2 of your 3 main meals. This means you should consume at least one meal a day with high-quality oils, which will supply your body with fat-soluble vitamins and essential fatty acids. A multi-vitamin supplement can also meet your body's vitamin requirements.

For weight management, the dose can be reduced to 2 tablets a day.

User

formoline L112 EXTRA is intended for overweight or obese adults who want to reduce their LDL cholesterol and their weight by reducing calorie intake.

Recommended for individuals weighing more than 75 kg

How do I know if I am overweight?

Adults with a BMI (body mass index) of 25 or more are considered overweight. The calculation formula is as follows:

$$\text{BMI} = (\text{body weight in kg}) / (\text{height in m})^2.$$

You can also use the table below to determine whether your weight is normal, or you are overweight in relation to your height. If you are not overweight, formoline L112 EXTRA is not needed.

Height	Overweight
1,50 m	56,5 kg or more
1,55 m	60,5 kg or more
1,60 m	64,0 kg or more
1,65 m	68,5 kg or more
1,70 m	72,5 kg or more
1,75 m	77,0 kg or more
1,80 m	81,0 kg or more
1,85 m	86,0 kg or more
1,90 m	90,5 kg or more
1,95 m	96,0 kg or more

Contraindications

formoline L112 EXTRA should not be taken by:

- People with a known allergy to crustaceans or one of the ingredients
- People who are underweight (BMI < 18.5 kg/m²)
- Pregnant women or nursing mothers
- People with chronic constipation, intestinal obstruction etc.
- People taking long-term medications that slow down intestinal activity

formoline L112 EXTRA should only be taken in the following cases after consulting with a physician:

- Long-term medication use
- Serious gastrointestinal diseases and after gastrointestinal tract surgery
- Elderly (over 80 years old)

Interactions

Due to the fat binding capacity of formoline L112 EXTRA, it can bind active pharmaceutical ingredients (such as anti-epileptic drugs, anticoagulant drugs,

hormone preparations, contraceptives) or fat-soluble vitamins (A,D,E,K) in addition to dietary fats. The availability of fat-soluble (lipophilic) substances can be reduced. It is recommended to let at least 4 hours pass between taking formoline L112 EXTRA and these substances.

Taking formoline L112 EXTRA with meals that are rich in vitamins (e.g., salad, vegetables) with high-quality oils or Omega-3 fatty acids (salmon etc.) is not recommended because this product can partially bind fat-soluble vitamins and essential fatty acids.

Accidental overdose

Increase the amount you are drinking, as side effects are predominantly observed in the event of insufficient fluid intake. The dietary fibre in formoline L112 EXTRA can also be considered tolerable in higher quantities. As a precaution, stop taking formoline L112 EXTRA and see how your digestion responds.

Side effects

Taking formoline L112 EXTRA can temporarily lead to a change in stool consistency. In very rare cases, digestive problems (constipation, flatulence, bloating) were reported primarily due to not drinking enough fluids.

Allergic reactions to one of the ingredients or if a person has a known allergy to dust mites are possible in very rare cases (the following symptoms could develop: rashes, swelling, itching, nausea, vomiting, diarrhea).

Overall formoline L112 EXTRA can be referred to as very well tolerated.

If side effects or interactions occur, it is recommended that you stop taking formoline L112 EXTRA and consult a physician or pharmacist as necessary.

Reporting serious adverse reactions:

If you notice a serious deterioration in your health while using formoline L112 EXTRA, report this to the manufacturer Certmedica International GmbH, and the competent authority Medical Devices Department, HPRA, Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2, D02 XP77, Ireland

+353 (0)1 676 4971
devicesafety@hpra.ie

<https://www.hpra.ie/safety-information/how-we-monitor-safety/medical-devices/reporting-safety-issues-for-devices>

Duration of use

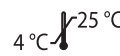
formoline L112 EXTRA can be taken over the long term.

If you cannot detect any weight loss or reduction in your cholesterol value after 12 weeks of using formoline L112 EXTRA, ask your physician or pharmacist for advice.

Storage



Keep out of the reach of children.



4 °C Store between 4 and 25 °C.



Observe the expiry date.



Keep dry

We recommend keeping the formoline L112 EXTRA tablets in the blister packaging until you are ready to ingest them.

Instructions

Dispose of the packaging and tablets not consumed according to the guidelines of your public waste disposal system.

MD Medical device **CE** 0123

With fibre of animal origin

You can find the short report on safety and clinical performance at www.certmedica.com/SSCP.

Further information

The quality and performance of the active ingredient are subject to strict testing.

formoline L112 EXTRA is a class III medical device and is CE certified according to European Regulation (EU) 2017/745 and is registered under the number DE/CA64/00038125.

formoline L112 EXTRA

Available in pharmacies without prescription

formoline L112 EXTRA

Contains 50 % more active substance

Further information: www.L112.com
Made in Germany



Manufacturer:
Certmedica International GmbH
Magnolienweg 17
63741 Aschaffenburg, Germany



Distributor:
Lynch Medical Supplies (LMS) Ltd
Unit C3, M1 Business Park,
Courtclough Co. Dublin, K32 X318

Issuing date of the instructions for use:
2022-08