

INSTRUCTIONS FOR USE

Please read this entire leaflet carefully before you start taking formoline L112.

THE BASIS FOR WEIGHT LOSS

Successful and permanent weight loss requires perseverance and time, as noticeable weight loss does not occur overnight. Generally, excess weight is gained gradually over the years. In order to lose 1 kg (2.2 lb) of body fat, the body must either burn approximately 7,000 kcal *more*, or take in this amount less through food and drink. This amount of energy is contained, for example, in 778 g (1 lb 12 oz) pure fat.

Successful weight loss requires restricted calorie intake combined with increased physical activity. formoline L112 supports weight loss target achievement.

The formula for successful weight loss in overweight individuals is based on the following: a healthy diet that focuses on a modified-fat intake (60-80 g or 2-3 oz daily) in combination with a high level of physical activity, along with formoline L112 to support weight loss. Due to its high fat binding capacity, formoline L112 can bind substantial amounts of dietary fats, thereby inducing weight loss by reducing energy intake. formoline L112 enhances motivation, particularly at the beginning of dietary adjustment. See the table below for details.

Going on a low-fat diet (about 40 g or 1½ oz of fat daily) is a proven method of losing weight without utilising a fat-adsorbing agent. Most people find it very difficult to adjust from a diet high in fat (daily intake of 120 g or 4½ oz of fat or more) to a low-fat diet, which is why almost no long-term successes have been achieved. formoline L112, along with a healthy, modified-fat diet,* enables you to lose weight successfully, without dieting stress.

Frequent dieting over prolonged periods of time may contribute to vitamin and mineral depletion: vitamin C, B-vitamins, iron, calcium, iodine and fluorine. It is therefore advisable for all people following a weight loss programme to take additional vitamin and mineral supplements.

For weight maintenance *after* weight loss, 1 tablet formoline L112 twice daily can be taken with two main meals. In order to maintain your weight, you should continue to eat a healthy, nutritionally balanced, reduced-fat diet.

INDICATIONS

formoline L112 Weight Management Tablets help to reduce excess weight. They can assist long-term weight control in conjunction with a healthy, modified-fat diet,* and lower LDL cholesterol.

Recommendations for use

formoline L112 Weight Management Tablets should be taken as part of a healthy balanced diet.

- > For weight reduction: take 2 tablets, twice daily.
- > For weight maintenance: take 1 tablet, twice daily, with 2 main meals.

Do not exceed maximum recommended dosage (2 tablets, twice daily).

Take tablet/tablets with at least 250 ml/half a pint of water (*to ensure the best possible uptake and transport of the tablets through the stomach*). We recommend that you drink 2-3 litres/4-5 pints of water daily (*as formoline L112 is a dietary fibre*).

The body needs adequate nutrients, including fat-soluble vitamins such as A, D, E and K, and essential fatty acids. To meet these requirements, you should only take formoline L112 Weight Management Tablets with **2 main meals each day**. We recommended that you eat a third meal containing beneficial oils and fats to provide your body with the fat-soluble vitamins and essential fatty acids it needs. Multivitamin supplements may also be required. For optimum weight loss, combine formoline L112 with a healthy, balanced diet (with reduced calorie intake and fat content).

DURATION OF USE

formoline L112 Weight Management Tablets are suitable for long-term use.

MECHANISM OF ACTION

formoline L112 Weight Management Tablets reduce calorie intake from dietary fats.

The active ingredient in formoline L112 is *polyglucosamine (L112)*, a naturally sourced fibre with an extremely high fat-binding capacity. L112 can bind to (or adsorb) a substantial amount of dietary fats from food in the digestive tract. The active ingredient is not digestible and is excreted naturally, together with the bound fats, significantly reducing the calories your body can process from the food you have eaten. Furthermore, the indigestible and expanded fibre materials induce a feeling of being full. **formoline L112 can only affect weight loss if excess weight is caused by high-fat food such as fatty meat, sausages, butter, crisps, nuts and ice cream. Carbohydrates, e.g. from sweet, sugary food/drinks and alcoholic drinks, are not bound by formoline L112 and will be metabolised normally.**

formoline L112 has been shown to reduce elevated serum cholesterol and LDL cholesterol levels. HDL cholesterol (the so-called 'good' cholesterol) can be raised, and elevated triglyceride levels can be reduced.

Weight Loss Programmes	Low-fat diet*	Modified-fat diet*	Average consumption (high-fat diet)	Weight loss without L112 (low-fat diet)*	Weight loss with L112 (modified-fat diet)
Daily Fat Consumption	40g (1½ oz)	60 - 80g (2 to 3oz) Women 76g Men 100g	120g or more (4½ oz)	40g (1½ oz)	60 - 80g (2 to 3oz)

*Recommendation COMA

COMPOSITION

Active ingredients

β -1,4-polymer of D-glucosamine and N-acetyl-D-glucosamine (from crustacean shells), specification L112.

Excipients

Cellulose from plants, vitamin C, tartaric acid, silicon dioxide, magnesium stearate (vegetable origin).

Additional information

Contains no gelatine, gluten, lactose, milk protein, cholesterol, flavour enhancers, colours or preservatives. Suitable for diabetics (no carbohydrate exchange value). formoline L112 is a product of natural origin. Variations in colour and taste may occur but do not affect its efficacy.

CONTRAINDICATIONS

- > In case of persistent gastrointestinal problems (e.g. constipation, after intestinal surgery), metabolic disorders or long-term medication (e.g. hormone preparations such as the **contraceptive pill** or medication to manage bowel functions), **formoline L112 should only be taken after medical consultation.**
- > Do not take formoline L112 if you are prone to allergies or allergic to crustaceans or any of the other ingredients.
- > Do not take formoline L112 if you are underweight (BMI < 18.5).
- > Should only be given to growing children and teenagers after medical consultation.
- > Not suitable for infants and children (up to the age of three).
- > A weight control regime for anyone over the age of 80 years should be undertaken only on the advice of your GP/doctor.
- > Please consult your doctor when treating elevated cholesterol and LDL levels, before taking formoline L112.

Pregnancy and breast-feeding

During pregnancy and breast-feeding, weight loss and dietary measures should only be initiated under close medical supervision as an adequate supply of fats is essential for foetal growth and development, and for milk production.

LIMITATIONS ON USE

- > You should consult your doctor before you change your diet on a long-term basis.
- > Do not take fat-soluble medicines (**including the contraceptive pill**) or vitamins within 4 hours of taking formoline L112 weight management tablets. If you are taking medicines long-term, seek advice from your doctor or health professional.
- > Discontinue use if you experience persistent or chronic constipation, and consult your doctor or healthcare professional.

Interactions and side effects

Due to the high fat binding capacity of formoline L112, all fats and fat-like substances can be bound, including vitamin A or steroids found in oral contraceptives – 'the pill' – and in menopausal discomfort treatments. formoline L112 may also impair the availability of fat-soluble (lipophilic) substances. Therefore, avoid concomitant use of medicines or vitamins for at least 4 hours.

The use of formoline L112 may lead to temporary changes in stool consistency and, in rare instances, digestive problems (e.g. constipation, flatulence, feelings of fullness) may be observed by inadequate fluid intake. Constipation may lead to short-term weight gain.

Doses of above the recommended daily dosage have not been shown to provide additional benefit, but may increase the tendency towards constipation.

In very rare cases, allergic reactions to one of the ingredients are possible. In individual cases, symptoms of allergy may include diarrhoea, vomiting, nausea, skin rash, itching, sweating, tingling, shivering, dizziness and headache. However, formoline L112 is generally accepted as being well tolerated.

A NOTE ON PRODUCT QUALITY

formoline L112 is a medical device certified Europe-wide by a Notified Body and registered in the country of origin under the registration number 'DE/CA66/Certmedica/001'.

The quality and efficacy of the active ingredients are strictly controlled prior to manufacture.

For further information about our product or information on more weight loss topics, please visit our Web site: www.L112.com

Precautions

- > Please observe the expiry date.
- > Storage: store tablets at room temperature.

Manufactured in Germany

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