formoline L112 is generally considered as being very well tolerated. In very rare cases, undesirable effects (less than 1 in 10,000 users) such as constipation, flatulence or an allergic reaction were reported. These complaints were only temporary and disappeared soon. Constipation is usually induced by inadequate fluid intake accompanied by an increased consumption of dietary fibre. formoline L112 can therefore be regarded as well-tolerated product for weight management.

4.3 Tolerability
formoline L112 will only work effectively as a lipid adsorbent if the meal contains a relevant amount of fat. formoline L112 is not suitable for people who follow a low-fat diet. Other food components such as sugar, carbohydrates, protein or alcohol cannot be bound by formoline L112; they will either be converted into energy or eventually be stored as body fat.

5. Discussion
In summary, we can conclude that formoline L112 is an effective and safe product to support the management of weight loss and weight control. formoline L112 is very well-tolerated and suitable for long-term use.[5][6]

Decreased adsorption of lipids resulting from taking formoline L112 leads to a reduction in energy intake and therefore contributes to a clinically relevant weight loss.

An improvement in the overall health status (e.g. metabolic syndrome) can be seen in overweight people. [5]

The beneficial effect of lipid adsorption of polyglucosamine, specifically for L112 was documented.[7][8]

When taken in accordance with the recommendations mentioned in the leaflet, formoline L112 in combination with a conscious diet containing 60 - 80 g of fat daily is able to lead to notable weight loss success in overweight people.

Long-term weight reduction requires a change in diet via an awareness of the fat and caloric conscious diet of the foods consumed, hand-in-hand with a level of physical activity which is appropriate for the respective individual.

The dietary recommendations for formoline L112 correspond to the nutritional guidelines for a healthy diet as recommended by nutritional associations with the objective of achieving sensible eating habits over the long-term.[8]
formoline L112 helps individuals to gradually learn to eat a healthy, sensible diet and to maintain this behaviour over the long-term.[6][7]

It will enable to counteract the yo-yo effect. All diets that radically deprive the body of its nutrient stores over a long period of time will lower the basal metabolic rate. This can eventually result in undesirable rapid weight gain at the end of such radical dietary modifications.[10]

Used as an aid to lose weight, formoline L112 can help to achieve a significant and long-term weight loss. This success will motivate and improve patient compliance.[6][7]

4.4 Tolerability
Guideline based use and efficacy of the lipid binder formoline L112 in the treatment of overweight and obesity

Scientific information
formoline L112 – The medical device for weight loss and weight control

1. Preliminary remarks
1.1 Product safety
formoline L112 is a class III medical device registered in its country of origin under registration number DE/CA64/Certmedica/001. It has received certification from a notified body and can be marketed in the entire EU. The efficacy and quality of the main substance are strictly examined prior to manufacturing. Independent experts authorised by a notified body carried out evaluations of the stated intended purpose, and officially confirmed the performance of the medical device during the EC design examination.

1.2 Composition
The main substance of formoline L112 is an indigestible fibre of natural origin (β-1,4 polymer of D-glucosamine and N-acetyl-D-glucosamin) the specification L112.
formoline L112 does not contain any flavour enhancers, preservatives or colorants and is free of gelatine, gluten, lactose and cholesterol. L112 is also recommended for diabetics.

1.3 Indications
Lipid adsorbent to support
■ Treatment of overweight
■ Weight control
■ Lower cholesterol intake from diet

2. Mechanism of action of polyglucosamine L112
2.1 Main substance
Polyglucosamine, the main substance in L112, is known to be an effective gastrointestinal lipid adsorbent. It has been proven that polyglucosamine fibres can adsorb and bind therapeutically relevant quantities of fat.

Polyglucosamine L112 acts in multiple ways in the digestive tract; the individual mechanisms of action complement each other’s activity synergistically in the management of weight loss and therefore the metabolic syndrome.

2.2 Lipid adsorption – the primary mechanism of efficacy
The reduced uptake of calories from the dietary fats has been confirmed in an in vivo randomised, double blind placebo-controlled clinical study. The calory intake from dietary fat absorption in the gastrointestinal tract was reduced by 2/3rd with formoline L112. [1] Bound fats were no longer metabolised. The main substance of formoline L112 is indigestible and is excreted naturally together with the bound fats without fatty stools. Taking formoline L112 significantly lowers caloric intake. If the intake of calories is less than the calories burned, then as a matter of this imbalance a weight loss will occur.

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4.4 Tolerability
formoline L112 is generally considered as being very well tolerated. In very rare cases, undesirable effects (less than 1 in 10,000 users) such as constipation, flatulence or an allergic reaction were reported. These complaints were only temporary and disappeared soon. Constipation is usually induced by inadequate fluid intake accompanied by an increased consumption of dietary fibre. formoline L112 can therefore be regarded as well-tolerated product for weight management.

4.5 Limitations on use
formoline L112 can effectively aid weight loss in overweight and obese patients.

Another important factor for successful weight reduction is a healthy diet combined with a moderate level of daily physical activity.

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the positively charged amino groups (NH₂) of the remaining glucosamine (cation) bind the negatively charged acid molecules (COO⁻) of the fatty acids. Other lipophilic substances, like monoglycerides and fatty acids associated with bile salts and phospholipids to form micelles, will be bound by ionic interaction. This very strong attraction leads to a self-stabilising, ordered molecular gel structure. If L112 is taken as recommended along with a fat-containing meal, the resulting polyglucosamine-gel matrix can be optimally distributed.

The extremely efficient process of absorption of the lipids through the intestinal wall of the small intestine is considerably diminished in the presence of polyglucosamine L112. [2][3][4]

After intestinal passage, the lipophilic agglomerate composed of polyglucosamine L112 and the bound fats, is eliminated in the faeces naturally.

2.3. Promote gastric motility – the secondary mechanism of action

If polyglucosamine L112 is taken according to the recommended dosage together with adequate fluid intake, i.e. 2-3 litres a day, the indigestible dietary fibres will swell and enhance intestinal peristalsis and facilitate gastric motility. The formation of a gel with the bound lipids improves the gliding ability of the chyme. As a result, the flow of the digested food is improved and the transit time through the intestinal tract is shortened. Polyglucosamine L112 together with the bound lipids are rapidly excreted. When used in accordance with its intended purpose, polyglucosamine L112 may act as a mild laxative. [4]

3. Directions

3.1. How to take formoline L112

- For weight loss:
  Take 2 tablets formoline L112 twice daily with two main meals with the highest fat content, ideally towards the end of a meal.

- For weight maintenance:
  Take 1 tablet formoline L112 twice daily with two main meals with the highest fat content, ideally towards the end of a meal.

Swallow formoline L112 in whole unchanged together with sufficient liquid (at least 250 ml water) for optimum effect and to ensure best possible passage of the tablets into the stomach. After weight loss and in order to stabilise the weight on a long-term basis, formoline L112 can be continued at a dose of 1 tablet, to be taken with the two main meals.

Due to the high fat binding capacity of formoline L112, not only can it bind to dietary fat but also fat-soluble (lipophilic) active ingredients (e.g. hormonal preparations, oral contraceptive pills) or fat-soluble vitamins (A, D, E, K). It is therefore advisable to take formoline L112 at least 4 hours apart from the aforementioned products. Formoline L112 may interfere with the adsorption of fat-soluble active substances.

To meet the body’s requirements of fat-soluble vitamins A, D, E and K and essential fatty acids, we recommend taking formoline L112 with only two out of three main meals each day. You should eat at least one meal containing beneficial oils and fats to provide your body with the fat-soluble vitamins and essential fatty acids it needs. Multivitamin supplements may be taken additionally.

To support the weight loss with formoline L112, we recommend a healthy, well balanced fat- and calorie-concious diet. As formoline L112 is rich in dietary fibre, we recommend that you drink at least 2 - 3 litres of fluid daily.

Calorie-free drinks such as (mineral) water, unsweetened fruit and herbal teas are particularly suitable. In rare cases usually in the first few days, taking formoline L112 may lead to constipation caused by an increased intake of dietary fibre.

3.2. Recommendations for use

One of the causes of overweight and obesity seems to be food high in energy density, especially in the form of dietary fats. Many overweight people consume around 100 - 140 g fat per day [3][4].

As one gram fat contains about twice as much energy as carbohydrates or proteins, limiting the intake of fat is an effective way of losing weight [5]. However, many people find it difficult to adjust and reduce their intake of fat accordingly. The use of formoline L112 as an effective lipid absorbent can bind to substantial amounts of dietary fats from the gastrointestinal tract and therefore restrict energy absorption. [1]

Formoline L112 is ideal for overweight individuals who are either unable or do not wish to follow a radical low-fat diet. It can therefore support successful weight loss for individuals following a fat-controlled diet that contains 60 - 80 g fat per day.

3.3. Contraindications

- formoline L112 should only be taken after consulting your doctor in the event of:
  - Serious gastro-intestinal problems (ulcerative colitis, Croh’s disease, diverticulitis, short bowel syndrome, peptic ulcer, irritable bowel syndrome, medically treated reflux, etc.) and after surgery of the gastrointestinal tract.
  - Chronic digestive problems (constipation, gastrointestinal motility, etc.)
  - Growing children and adolescents
  - Elderly (over 80 years)
  - Long-term medication regimens, particularly medications that reduce bowel movements.

Formoline L112 should not be taken by the following persons:

- Infants and children up to the age of three
- Individuals who are underweight (BMI < 18.5)
- Individuals who are prone to allergies or allergic to crustaceans or any other of the ingredients

Pregnancy and breastfeeding

During pregnancy and breastfeeding, weight loss measures should only be initiated under close medical supervision as an optimum nutrient supply is essential for embryonic growth and development and for breast milk production, the best nourishment for an infant.

4. Clinical studies of weight loss

4.1. Randomised, double-blind placebo-controlled clinical trial in slightly overweight patients with hyperlipidaemia (Cornelli et al. 2008)

In a randomised, double-blind, placebo-controlled study, a total of 60 slightly overweight people (BMI 26 - 30 kg/m²) with hyperlipidaemia received a polyglucosamine preparation or placebo in combination with appropriate physical activity. The results confirmed that taking a polyglucosamine preparation combined with additional physical activity leads to a significant decrease in body weight and has a positive impact on a pre-existing metabolic syndrome (MS). [6]

4.2. Efficacy of polyglucosamine for weight loss – verified by a randomised, double-blind, placebo-controlled clinical trial (Pokhis et al. 2015)

A study involving 115 participants has confirmed that the consumption of formoline L112 leads to a 30 % higher weight loss versus placebo, both groups based on the standard guideline weight management with a hypocaloric diet (-500 kcal) and light physical activity. [7]

The trial participants followed a standard treatment based on a hypocaloric diet and increased daily physical activity and took 2x2 tablets of formoline L112 or a placebo for at least 24 weeks.

By taking formoline L112, the participants lost 30 % more weight versus the standard guideline treatment of a calorie-conscious diet and light physical activity.

A weight loss of 5 % of the initial weight had already been achieved by 52 % of participants in the formoline L112 group after only 8 weeks on average. In the placebo group, this was the case for only 20 % of the participants.

This study involving 64 participants has proven that the active substance polyglucosamine L112 is significantly more effective in supporting weight loss than Orlistat (60 mg). With formoline L112, the participants lost an average of 6.7 kg over a period of three months. [7][8]

This weight loss in the formoline L112 group was around 30 % more successful than the placebo group. This advantage is also maintained for 3 months and 6 months after treatment.

4.3. A randomised, double-blind, placebo-controlled clinical trial of polyglucosamine in the treatment of overweight and obesity (Stoll et al. 2016)

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