

Use of glucosamine and its derivatives in food supplements

BfR Opinion No. 032/2007, 15 June 2007

Glucosamine is an amino sugar that occurs naturally in the human body. It is a component of connective tissue, cartilage and synovial fluid. Glucosamine is used as a medicinal product to treat degenerative diseases (arthritis) of the knee. In addition numerous glucosamine preparations are on sale on the market as food supplements, frequently in combination with chondroitin sulphate.

Medicinal products require marketing authorisation in the course of which their quality, efficacy and safety must be proven. Food supplements are foods. Unlike medicinal products they do not, in principle, require marketing authorisation. They must be safe and may not be harmful to health. Their ingredients should not have any pharmacological effect. The manufacturer is responsible for compliance with all statutory food provisions. It is the task of the official food control bodies in the federal *Laender* to decide on the classification of glucosamine and its derivatives. This also applies to the question whether glucosamine and its derivatives are substances that can be equated with additives and, therefore, require approval. When it comes to a decision in an individual case, the competent food control authorities of the federal *Laender* examine from which level of glucosamine and its derivatives a product is to be classified as a medicinal product requiring marketing authorisation.

Aside from these classification questions, the Federal Institute for Risk Assessment (BfR) was asked to undertake a health assessment to determine the safety of the glucosamine intakes that are lower than 1250 milligram (mg) per day. The dose of 1250 mg per day was deemed in the case of a medicinal product to be pharmacologically active by the European Medicines Agency (EMA).

BfR comes to the following conclusion: glucosamine sulphate, glucosamine hydrochloride or N-acetyl glucosamine can be used as glucosamine sources. There are differences when it comes to the health assessment of these glucosamine sources. Overall knowledge about the health effects of glucosamine intakes is patchy. BfR only has data that permit a health assessment of glucosamine from the sources glucosamine sulphate and glucosamine hydrochloride. The data currently available do not suffice for the assessment of glucosamine from the source N-acetyl glucosamine.

Regarding the use of glucosamine sulphate and glucosamine hydrochloride at levels which correspond to a glucosamine intake of less than 1250 mg/day, the available data indicate that individuals with limited glucose tolerance, individuals who take coumarin anticoagulants and individuals with a known risk for cardiovascular disease constitute potential risk groups¹. By contrast, the data indicate that no serious health risks are to be expected in the case of healthy and non-pregnant adults. No health assessment of glucosamine for the groups pregnant and breast-feeding women, children and adolescents is possible because of a lack of data.

For precautionary reasons BfR recommends that the above-mentioned groups (consumers who take coumarin anticoagulants, consumers with limited glucose tolerance or with a known risk for cardiovascular disease as well as pregnant and breast-feeding women, children and

¹ On this topic BfR prepared a comprehensive Opinion entitled "Food supplements that contain glucosamine can constitute a health risk for patients who take coumarin anticoagulants as blood coagulation inhibitor" in 2009 (BfR Opinion No. 004/2010, 14 August 2009). The Opinion is available on the Internet on http://www.bfr.bund.de/cm/245/food_supplements_that_contain_glucosamine_can_constitute_a_health_risk.pdf

adolescents) be protected through corresponding indications on the labels of glucosamine-containing supplements.

Furthermore, glucosamine, which is produced from the shell of crustaceans, could prove problematic when it is inadequately processed for individuals with a shellfish allergy. BfR, therefore, believes that the label of glucosamine produced from the shells of crustaceans should carry an indication of the source from which it comes.

The full version of the BfR Opinion in German is available on http://www.bfr.bund.de/cm/208/verwendung_von_glucosamin_und_dessen_verbindungen_in_nahrungsergaenzungsmitteln.pdf