

# Safety evaluation of excessive intake of Proteoglycan Complex 80 from salmon nasal cartilage —a randomized, double-blind, placebo-controlled, parallel-group study—

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## Abstract

**Objective** In the current study, we aimed to evaluate the safety of excessive intake of a dietary supplement containing Proteoglycan complex 80, derived from salmon nasal cartilage.

**Methods** This randomized, double-blind, placebo-controlled, parallel-group study enrolled 30 participants (39.5±9.7 years [mean±standard deviation]) who ingested a dietary supplement containing 200 mg of Proteoglycan complex 80 or placebo for four weeks. General blood and urine biomarkers for health and medical conditions were analyzed at 0, 2, 4, and 6 weeks.

**Results** There were no clinically relevant changes related to the test supplement. Furthermore, there were no side effects related to the intake of Proteoglycan complex 80.

**Conclusion** Our findings demonstrated the safety of excessive intake of the dietary supplement containing Proteoglycan complex 80 derived from salmon nasal cartilage.

**Keywords** : Proteoglycan complex 80, excessive intake, safety evaluation

## I Introduction

“The New Health Frontier Strategy,” prepared and issued by the Japanese Government in 2007, recommends addressing locomotor disorders by promoting preventive measures against conditions requiring care.<sup>1)</sup> According to “Graphically Represented Status of Household 2014 - Based on the Results of the Comprehensive Survey of Living Conditions (2013),” by the Ministry of Health, Labour and Welfare (MHLW), leading causes for conditions that require care include “joint diseases” and “fracture and fall”, which collectively account for 29.4 and 10% in females and males, respectively.<sup>2)</sup> As gonarthrosis (knee osteoarthritis) is a joint disease mainly observed in older individuals, the number of patients with subjective symptoms is estimated at approximately 10 million, and the number of potential patients (determined based on X-ray diagnosis) is estimated at approximately 30 million.<sup>3)</sup> X-ray diagnosis should be performed based on grades of the Kellgren-Lawrence

(KL) classification, and ≥Grade II symptoms are diagnosed as knee osteoarthritis.<sup>4)</sup> Locomotor disorders (or motor system diseases), including knee osteoarthritis, impair physical activity due to pain, resulting in excessive weight gain and decreasing muscle mass/strength. Additionally, affected individuals tend to be confined indoors or experience psychiatric adverse effects owing to infrequent outdoor activities, leading to a decline in general vital functions. Finally, these disorders often require long-term care and impose a considerable economic burden; hence, efforts to prevent the development of locomotor disorders, such as knee osteoarthritis, must be implemented. To prevent locomotor disorders, the Japanese official “Physical Activity Guidelines for Health 2013” recommends promoting physical activities suitable for respective life stages and increasing physical activity to decrease the risk of locomotive syndrome.<sup>5)</sup> However, older individuals often experience difficulties in performing physical exercise owing to pain or uncomfortable feeling in the locomotorium.