JOHNSON & JOHNSON CONSUMER INC.
SUMMARY CLINICAL REPORT

PROTOCOL TITLE:	A Non-Interventional Clinical Study to Assess the Risk and Performance Aspects of Olynth Saline/Ectomed Nasal Drops/Spray Based Upon Previous Usage
PROTOCOL NUMBER:	CCSURA003229
VERSION & DATE:	Final Version 16 June 2022
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The principles of the International Council for Harmonisation (ICH) Guidelines for Good Clinical Practice (GCP E6 (R2)) will be applied to this study.

1. STUDY SYNOPSIS

The principles of the International Council for Harmonisation (ICH) Guidelines for Good Clinical Practice (GCP E6 (R2)) were applied to this study.

INTRODUCTION	European Union (EU) Medical Device Regulation 2017/745 requires active surveillance of marketed medical devices via post-marketing clinical follow-up (PMCF) studies. Olynth Saline Nasal drops and Olynth Saline Nasal spray have been marketed for over 10 years and Olynth Ectomed Nasal spray has been marketed by Johnson & Johnson since 2014 in the EU. Olynth Saline Nasal drops/spray are intended for children and adults and used for the purposes of gentle cleaning and moisturizing nasal mucosa and for supportive treatment in case of a blocked nose. Olynth Ectomed Nasal spray is intended for children from 6 years of age and adults and used for treating a blocked nose and dry and irritated nasal mucous membranes. They are all class IIa Medical Devices, with a physical mode of action from the rinsing and soothing of nasal mucous membranes. Olynth Saline Nasal Spray is a preservative-free, non-medicated, isotonic nasal solution containing 0.8% sodium chloride and minerals. Olynth Saline Nasal Spray is used for treating blocked, dry, or irritated nasal passages caused by cold and flu, sinusitis, allergy including hay fever and post-nasal surgery. It works by rinsing and restoring moisture to the nasal passages/mucosa. Olynth Saline Nasal Drops are a preserved, buffered salt solution intended to cleanse and moisturize the nasal mucosa with the intent of reducing congestion. Olynth Ectomed Nasal Spray contains ectoin and a hypertonic saline solution intended to rinse and soothe the irritated nasal mucosa to treat a blocked nose or dry and irritated nasal passages associated with the common cold. A review of the safety parameters in the clinical trials demonstrates a favorable safety profile [1, 2, 3, 4] and this has been supported by the post-market surveillance data. Since the launch of Olynth Saline Nasal drops/spray and Olynth Ectomed Nasal spray, adverse events and product quality complaints have been collected via the Consumer Care Centre (CCC). These reactive data require consumers to contact the company following product use. The required proactive data collection amongst consumers of the nasal drops/sprays is currently missing in the available data. The Risk Assessment Documents (RAD) and Clinical Evaluation Reports (CER) were used to formulate the questions that are in the survey to ensure all relevant safety and performance parameters are considered.
OBJECTIVE	The objective of this study is to proactively collect customer feedback on the performance aspects and risk factors of Olynth Nasal Saline Drops/Spray and Olynth Ectomed Nasal Spray.

STUDY DESIGN	This was a virtual, non-interventional clinical study, with subjects being recruited via Research Vendor database and completing a single internet survey.
SUBJECT INFORMATION	Subjects in Germany aged 18 years or older who met the eligibility criteria. Subjects of age 18 years or older who have personally used or administered Olynth Nasal Saline Drops/ Olynth Ectomed Nasal Spray to a child. The complete eligibility criteria for this study were followed as defined in the study protocol referenced in Attachment 1 of this report.
INVESTIGATIONAL STUDY MATERIALS	Not applicable – this study included subjects who had used Olynth Nasal Saline Drops/Spray or Olynth Ectomed Nasal Spray once within the past 6 months. Note: "used" means "on self or someone else in the household."
DOSE AND MODE OF APPLICATION	Not applicable as this was a non-interventional consumer study.
METHODOLOGY	Eligible subjects were recruited using an online consumer panel. Eligibility was established through a two-phase unprompted screening process: Either provision of a photograph of Olynth Nasal Drops/Spray or Olynth Ectomed Nasal Spray to prove purchase. OR Correct selection of Olynth Nasal Drops/Spray or Olynth Ectomed Nasal Spray from a pictorial brand board of the Olynth® range. Once eligibility had been established, subjects were provided with a unique Subject ID and instructions on how to access the survey in the electronic Patient Reported Outcomes (ePRO) system. Subjects were consented and then they provided their survey responses via the ePRO system.
MEASUREMENT AND/OR EVALUATION SCHEDULE	Not applicable.
SAMPLE SIZE	84 subjects An additional 10 to 20% of subjects will be enrolled, considering the possibility of dropouts during the study due to various reasons.

INSTITUTIONAL REVIEW BOARD (IRB)/INDEPENDENT ETHICS COMMITTEE (IEC) INFORMATION	This study was reviewed and approved by the following IRB/IEC: • IMDEC (International Medical & Dental Ethics) Commission, Schiller Str. 34, 79102 Freiburg , Germany • Final approval date: 3 April 2021
SAFETY AND ADVERSE EVENTS	All Adverse Events and Serious Adverse Events (AEs/SAEs) were collected based upon prior usage of the Olynth Nasal Drops/Spray and Olynth Ectomed Nasal Spray. The safety conclusions based upon prior usage in this study population are presented in this summary clinical study report.
MONITORING, QUALITY CONTROL, AND QUALITY ASSURANCE	The study monitoring was conducted as per the Sponsor´s requirements. The Study Site is subject to quality assurance audits performed by the Sponsor and/or to inspection by appropriate regulatory authorities.
CONCLUSION	The performance aspects of the Olynth nasal spray products (saline nasal spray, saline nasal drops, Ectomed nasal spray) with regard to improvement of the nasal passages are supported. The safety aspects of the device are in line with those stated in the Risk Assessment Document which can be found in the Technical File.