Clinical response of Nuberol Forte® (Paracetamol 650 mg + Orphenadrine 50 mg) for pain management with musculoskeletal conditions in routine Pakistani practice (NFORTE-EFFECT)

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ABSTRACT

Background: Musculoskeletal pain is the most common complaint presented to the health practitioner. It is well known that untreated or under-treated pain can have a significant negative impact on an individual's quality of life (QoL).

Objectives: This study was conducted across 10 sites in six (6) major cities of Pakistan, to evaluate the tolerability, safety, and the clinical response of Nuberol Forte® (Paracetamol 650 mg + Orphenadrine 50 mg) to musculoskeletal pain in routine Pakistani practice and its impact on improving the patient's QoL.

Design & Methods: This NFORT-EFFECT observational, prospective multicenter study was conducted in compliance with Good Clinical Practice guidelines and local regulatory requirements. The study sponsor was "The Searle Company Limited, Pakistan. To maintain the GCP compliances, the sponsor assigned the CRO for the site and data management. Ethical approval was obtained from an independent ethics committee. The IEC reviewed the progress of the study. Written informed consent was obtained from the study participants, and their confidentiality was maintained throughout the study. A total of 399 patients with known prescreened musculoskeletal conditions and pain who attended the study sites were recruited, as per the inclusion/exclusion criteria (clinicaltrials.gov ID# NCT04765787). The recruited patients were then prescribed Paracetamol (650 mg) and Orphenadrine (50 mg) combination (Nuberol Forte®) for 7 to 14 days as per the investigator's discretion based on the pain intensity. After the initial screening (visit 1), a follow-up visit was conducted after 1-2 weeks of the treatment (visit 2).

Study Endpoints: The primary objective was to assess the pain management response of Nuberol Forte treatment and the overall safety of the drug. The Visual Analogue Scale (VAS) scale was used to measure pain severity. Secondary to pain, the patients' health-related quality of life (HRQoL) was also assessed using the Muscle, Joint Measure (MJM) scale. The safety was monitored on the first dose by the patients. These assessments were done on each study visit.

Results: Out of 399 enrolled patients, 49.4% were males, and 50.6% were females with a mean age of 47.24 ± 14.20 years. Most patients were presented with Knee Osteoarthritis (OA), i.e., 148(38%), followed by backache 70(18.2%). A significant reduction in the mean pain score was observed after the treatment with the combination of Paracetamol and Orphenadrine ($p<0.05$). Furthermore, an overall improvement in the patient's QoL was also observed. During the study, only ten patients reported mild adverse events (AEs).

Conclusion: The combination of Paracetamol and Orphenadrine (Nuberol Forte®) exhibited effective pain management among patients with musculoskeletal conditions and also improved their QoL.

Keywords: Musculoskeletal Pain, Orphenadrine/Paracetamol Combination, Pain Management, Quality of Life, Effectiveness, Safety, Pakistani Population