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ORIGINAL ARTICLES

DUROS® Technology Delivers Peptides and Proteins at Consistent Rate Continuously for 3 to 12 Months

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Abstract

Background:
DUROS® delivery technology consists of sterile, nonbiodegradable, single-use devices for continuous, subcutaneous administration of therapeutic molecules at steady rates. DUROS delivery technology is capable of delivering a wide range of therapeutic molecules for durations ranging from 3 to 12 months. Administration of therapy via DUROS devices may facilitate patient compliance with treatment since the DUROS device does not require self-injections. Consistent delivery of drug levels within a targeted therapeutic window achievable with DUROS delivery technology avoids exposure to high initial drug concentrations that can result from bolus injections and that may be associated with certain adverse drug effects.

Methods:
Several approaches have been taken to assess the suitability of DUROS devices for delivery of the therapeutic molecules leuprolide acetate, glucagon-like peptide-1 (GLP-1), and omega interferon (omega IFN). Testing includes determining protein stability and measuring *in vitro* protein release rates.

Results:
Three peptides or proteins were formulated into either a solution (leuprolide) or Intarcia's proprietary DUROS suspension formulation (GLP-1, omega IFN) and filled into DUROS devices. The devices demonstrated reliable start-up and continuous steady drug delivery in *in vitro* studies. Stability of the molecules was maintained for 3 years at 37°C (leuprolide), 2 years at 30°C (omega IFN), or 6 months at 37°C (GLP-1). Patients in clinical studies of a 1-year DUROS device found the device to be comfortable and convenient.

Conclusions:
Multiple studies demonstrated that peptides or proteins remain stable in DUROS devices and that delivery at a steady rate can be achieved over a wide range of delivery rates.

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Abbreviations: (GLP-1) glucagon-like peptide-1, (omega IFN) omega interferon, (RP-HPLC) reversed-phase high-performance liquid chromatography, (SEC) size-exclusion chromatography,

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