Eroxon Clinical Trial Data

Introduction

The efficacy of Eroxon® has been demonstrated in two Phase 3 clinical trials in approximately 300 Eroxon® users with mild, moderate, and severe erectile dysfunction (ED), which investigated improvement in their erectile function compared with baseline. These trials provided the basis of the EU CE mark and UKCA regulatory approvals, meaning that Eroxon® is approved as a Class 2 medical device in the EU and UK for the treatment of ED and is available without a doctor's prescription.

The clinical data was rigorously reviewed as part of the European MDR regulatory approval process for CE marking. The trials also formed the foundation of Eroxon®'s regulatory application to the US FDA for marketing authorisation in the US.

First Phase 3 Trial with Eroxon® (FM 57)

A 12-week multi-centre trial of 250 men with ED using Eroxon® in nine European countries. Participants were monitored for four weeks before using the treatment to establish the extent of their ED, which was measured using three internationally recognised and fully validated measures and represent the 'gold standard' of measured outcomes in ED trials. They are the International Index of Erectile Function – Erectile Function ("IIEF-EF") scale and the Sexual Encounter Profile ("SEP") questions 2 and 3.

IIEF-EF Domain

1. How often did you get an erection?
2. How often were erections hard enough to penetrate?
3. How often were you able to penetrate?
4. How often were you able to maintain erection after penetration?
5. How difficult to maintain erection to complete intercourse?
6. How do you rate your confidence to get and keep erection[1]?

Each question scored on a 0-5 point scale depending on answer. Aggregate score out of maximum of 30 determines patient's ED severity:

No ED	Mild ED	Moderate ED	Severe ED
26-30	17-25	11-16	6-10

Baseline measured by minimum of four intercourse attempts pre-treatment
Measured again at after 4, 8 and 12 weeks treatment (minimum of four intercourse attempts every 4 weeks)

SEP2

Were you able to insert your penis?

Answer is binary YES/NO
% Improvement over baseline

SEP3

Did your erection last long enough for intercourse?

Answer is binary YES/NO
% Improvement over baseline

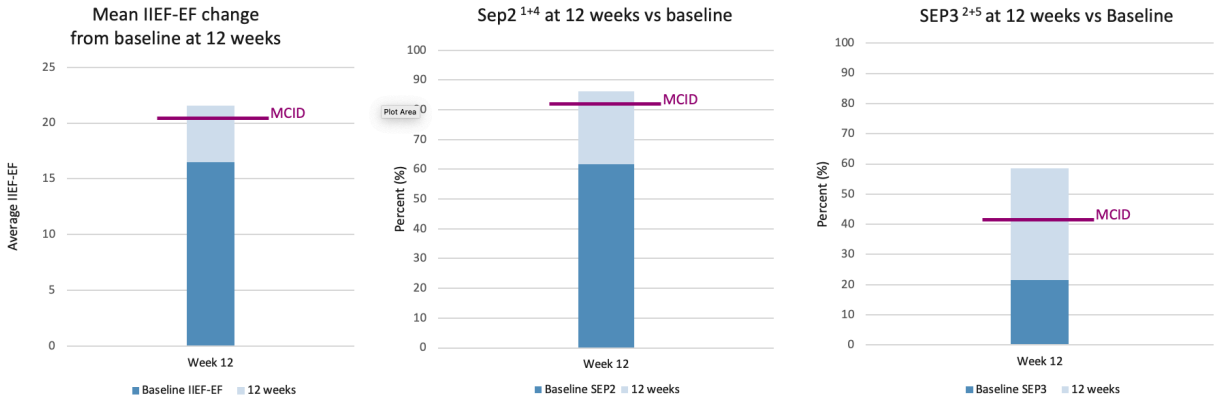
Over the 12-week period of using Eroxon®, ED levels were assessed – while also examining factors like safety and speed of action – and compared to the subjects' baseline.

Over the course of the study 63% of men using Eroxon® met or exceeded the Minimal Clinically Important Difference (MCID) (Rosen et al 2011) with a slight improvement over time. 60% of product uses led to an erection within 10 minutes of application.

The MCID is an outcome measure that would be noticeable to a person using the product and be of clinical relevance. An overall MCID of a 4-unit change over baseline using the IIEF-EF is used by leading experts in ED and regulatory authorities as a threshold for success in ED clinical studies. The 4-unit change is an average with a change of 2 for mild, 5 for moderate and 7 for severe erectile dysfunction.

The speed of onset was significantly faster than on demand oral PDE5i's, which typically start to work within 30-60 minutes.

The changes in the three primary outcome measures (IIEF, SEP 2 and SEP 3) with administration of Eroxon® are shown in the graphs below.



At 12 weeks, men using Eroxon® showed significant improvement from baseline across all measures, and all severity levels. The percentage of men achieving or exceeding the MCID was as follows: 61% for mild ED, 59% for moderate ED and 80% for severe ED.

Reported side effects were minimal: 3% of men reported headache, 1% of men and 0.4% of their female partners reported a mild 'localised burning sensation'.[1]

Adverse Events with Eroxon® in FM 57

Adverse Events Men	Eroxon®
Headache	3%
Back pain	0%
Non cardiac chest pain	0%
Nausea	0%
Dyspepsia	0%
Myalgia	0%
Flushing	0%
Pain in limb	0%
Local side effects[1]	1%

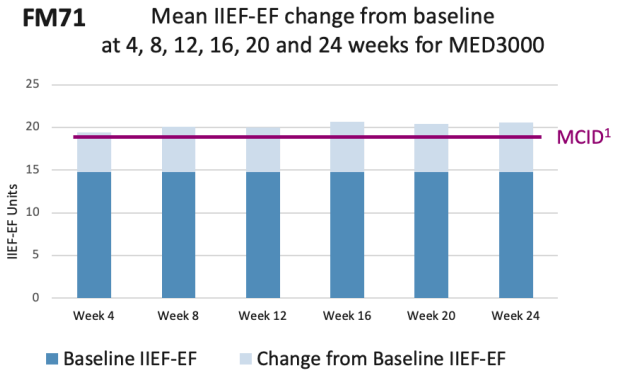
[1] FM 57 data on file

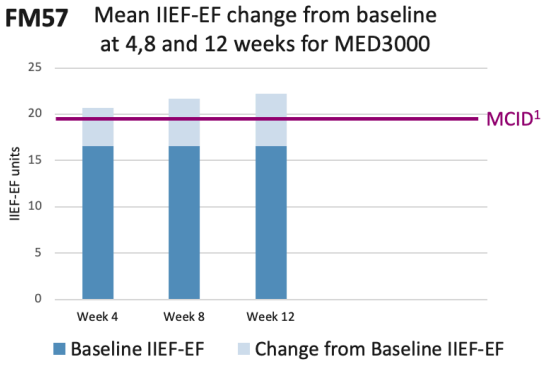
Second Phase 3 Trial with Eroxon® (FM 71)

A 24-week trial in 96 subjects with half on Eroxon® and half on a comparator product. Trial FM 71 was primarily designed to meet the recommendations of the US Food and Drug Administration (FDA) and was conducted in three European countries and the US to confirm efficacy beyond 12 weeks and included a head-to-head comparison with a comparator product (a well-known US prescription oral medication). Efficacy, safety and onset of action were assessed at various time points and at 24 weeks.

The study met its primary endpoint of exceeding the IIEF-EF MCID of four unit change at 24 weeks and the secondary endpoint of speed of onset. The results, presented at the European Society for Sexual Medicine (ESSM) Congress in 2023 demonstrated that Eroxon® was clinically effective in 61% of patients with ED at 24 weeks, with 55% of those with mild ED, 51% of men with moderate ED and 87% with severe ED achieving this clinical goal. Efficacy increased marginally over the course of the trial and the side-effects were extremely low. Overall, and assessing the data against the comparator product there was an excellent benefit to risk profile for Eroxon especially in the context of non-prescription use.

Results for FM71 and FM57 were broadly equivalent for efficacy (exceeding the MCID), helping men get an erection within 10 minutes, and with an excellent safety profile.





MED3000 = Eroxon®

Adverse Events with Eroxon® in FM 71

Adverse Events - Men	MED3000 subjects	MED3000 Total AE's
Headache	2 (4%)	2
Back pain	0 (0%)	0
Non cardiac chest pain	0 (0%)	0
Nausea	2 (4%)	2
Local side effects	1 (2%)	1