After the first 4 weeks of open-label TOCAS + Soli 6 mg treatment, patients were
Exclusion criteria included:

Patients started the open-label extension phase of the study with 4 weeks of TOCAS + Soli 6 mg, taken once daily in the morning.

The NEPTUNE study (a 40-week extension of NEPTUNE) investigated the long-term safety and efficacy of TOCAS 0.4 mg + Soli (either 0.6 or 9 mg) in patients with LUTS associated with BPH who had both voiding and storage symptoms.

### Study design

The NEPTUNE II study was an open-label, 40-week, flexible-dosing, multicentre, phase 3 extension study, following the 12-week, double-blind NEPTUNE study (Figure 1; ClinicalTrials.gov Identifier: NCT01021332).

### Interventions

Patients started the open-label extension phase of the study with 4 weeks of TOCAS + Soli 6 mg at 3-month intervals (i.e. switch between TOCAS + Soli 6 mg and TOCAS + Soli 9 mg).

Patients who received ≥ 1 dose of study medication during the open-label treatment period and who had a total IPSS at baseline plus at least one post-dose total IPSS during the open-label period or a TUS at baseline plus at least one post-dose TUS during the open-label period.

### Safety and tolerability

Five urinary retention episodes occurred in the study, with only 2 cases within the first 10 days of DBC exposure (6 and 22 days), and 3 cases after 90 days of DBC exposure (range 106–347 days).

### Conclusions

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### References


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