DAR DRUG ASSESSMENT REPORT **04 / 2020**

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TOVEDESO®

DESFESOTERODINE IN SYNDROME OVERACTIVE BLADDER

Making the fesoterodine profitable

IMPORTANT THERAPEUTIC INNOVATION | MODEST THERAPEUTIC INNOVATION | SOME ADDED VALUE IN SPECIFIC SITUATIONS | **NO THERAPEUTIC INNOVATION** | INSUFFICIENT EVIDENCE | + DATA SHEET

WHAT IS IT?

Urinary antispasmodic.

INDICATION

Symptoms of overactive bladder syndrome.

POSOLOGY AND METHOD OF ADMINISTRATION

Recommended initial dose in adults, including the elderly, is 3.5 mg daily. Maximum daily dose 7 mg. Recommended reevaluating the response after 8 weeks of treatment. Administration with or without food.

EFFECTIVENESS

Versus placebo. It uses the fesoterodine data, which shows limited efficacy. Reduction does not reach one over an average of 12 micturitions per 24 hours vs placebo.

RISKS

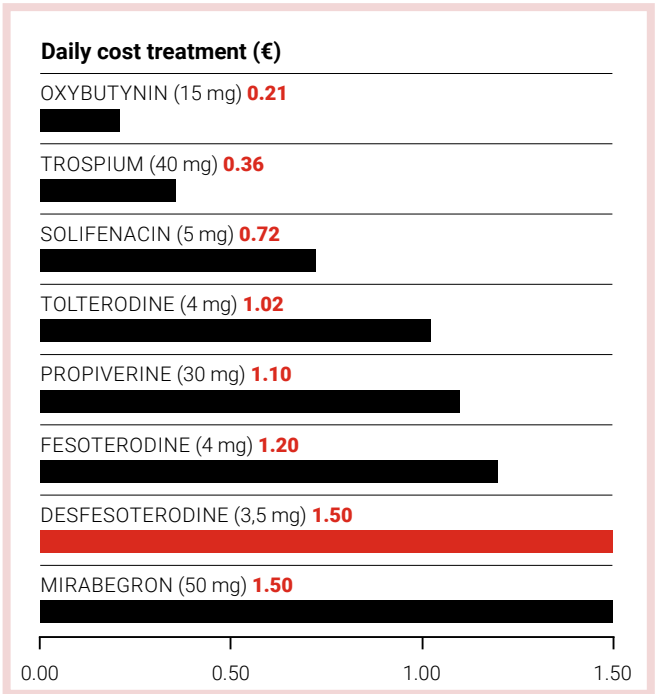
Adverse reactions: Antimuscarinic effects: dry mouth, dry eye, dyspepsia, constipation, urinary retention. **Contraindicated:** Urinary retention. Gastric retention. Narrow angle glaucoma. Myasthenia gravis. Severe hepatic impairment. Concomitant use with potent CYP3A4 inhibitors. Severe ulcerative colitis. Toxic megacolon. Gastroesophageal reflux. Decreased gastrointestinal motility. Autonomic neuropathy. Risk of long QT syndrome and relevant heart diseases (myocardial ischemia, arrhythmia, heart failure).

PLACE IN THERAPEUTICS

Due to the absence of comparative studies and assimilate data of its prodrug fesoterodine, it is considered desfesoterodine does not imply an improvement over other urinary antispasmodics for treatment of overactive bladder syndrome.

PRESENTATIONS

Tovedeso® 3.5 mg prolonged-release tablets, 28 tablets (TEVA PHARMA S.L.U.) € 41.93
Tovedeso® 7 mg prolonged-release tablets, 28 tablets (TEVA PHARMA S.L.U.) € 67.08



REPORT [IN SPANISH]

Servicio Navarro de Salud Osasunbidea

INTERNATIONAL SOCIETY OF DRUG BULLETINS