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EPAR summary for the public

Toviaz

fesoterodine

This is a summary of the European public assessment report (EPAR) for Toviaz. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Toviaz.

What is Toviaz?

Toviaz is a medicine containing the active substance fesoterodine. It is available as prolonged-release 4 mg tablets and 8 mg tablets. Prolonged-release means that fesoterodine is released slowly from the tablet over a few hours.

What is Toviaz used for?

Toviaz is used in adults with overactive bladder syndrome to treat the symptoms of the disease: increased urinary frequency (need to urinate frequently), urgency (sudden urge to pass urine), and urgency incontinence (sudden lack of control over urination).

The medicine can only be obtained with a prescription.

How is Toviaz used?

The recommended starting dose of Toviaz is 4 mg once a day. The tablets are swallowed whole with a glass of water and must not be chewed. The patient normally gets the full effect of the treatment after two to eight weeks. Based upon individual response, the dose may be increased to 8 mg once daily.

The dose of Toviaz must be adjusted, or the medicine not used at all, in patients with problems with their kidneys or liver, depending on whether they are also receiving 'CYP3A4 inhibitors', a group of medicines that may affect the way Toviaz is broken down in the body. See the summary of product characteristics (also part of the EPAR) for full details.

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How does Toviaz work?

The active substance in Toviaz, fesoterodine, is an anticholinergic medicine. It blocks some receptors in the body, the muscarinic receptors. In the bladder, this causes the muscles that push urine out of the bladder to relax, leading to an increase in the capacity of the bladder and to changes in the way the bladder muscles contract as the bladder fills up. This helps Toviaz to prevent unwanted urination.

How has Toviaz been studied?

The two main studies involved 1,964 patients with overactive bladder syndrome and compared Toviaz (4 or 8 mg a day) with placebo (a dummy treatment). One of the studies also compared Toviaz with tolterodine (another medicine used in overactive bladder syndrome). The main measure of effectiveness was the change in the number of times the patients needed to urinate in a 24-hour period after 12 weeks of treatment.

What benefit has Toviaz shown during the studies?

Toviaz was more effective than placebo and as effective as tolterodine in reducing the number of times the patients urinated in a 24-hour period. Before treatment, patients needed to urinate about 12 times in 24 hours. This number was reduced by 1.74 and 1.86 with the 4 mg dose of Toviaz and by 1.94 with the 8 mg dose. The reductions seen in patients taking placebo and tolterodine were 1.02 and 1.69, respectively.

What is the risk associated with Toviaz?

The most common side effect with Toviaz (seen in more than 1 patient in 10) is dry mouth. For the full list of all side effects reported with Toviaz, see the package leaflet.

Toviaz must not be used in people who are hypersensitive (allergic) to fesoterodine, to any of the other ingredients, to peanut or to soya. Toviaz must also not be used in patients with:

- urinary retention (difficulty in passing urine);
- gastric retention (when the stomach does not empty properly);
- uncontrolled narrow-angle glaucoma (increased eye pressure even with treatment);
- myasthenia gravis (a disease of the nerves causing muscle weakness);
- severe hepatic impairment (severe liver disease);
- severe ulcerative colitis (severe inflammation of the large intestine causing ulceration and bleeding);
- toxic megacolon (a very serious complication of colitis).

Toviaz must not be given to patients with moderate liver or moderate to severe kidney disease at the same time as strong CYP3A4 inhibitor medicines. These include medicines such as ketoconazole and itraconazole (used to treat fungal infections), atazanavir, indinavir, nelfinavir, ritonavir and saquinavir (medicines used in HIV-positive patients), clarithromycin and telithromycin (antibiotics), and nefazodone (used to treat depression).

Why has Toviaz been approved?

The CHMP decided that Toviaz's benefits are greater than its risks and recommended that it be given marketing authorisation.

Other information about Toviaz

The European Commission granted a marketing authorisation valid throughout the European Union for Toviaz on 20 April 2007.

The full EPAR for Toviaz can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports. For more information about treatment with Toviaz, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 02-2012.