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EPAR summary for the public

Emselex

darifenacin

This is a summary of the European public assessment report (EPAR) for Emselex. 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 Emselex.

What is Emselex?

Emselex is a medicine that contains the active substance darifenacin. It is available as prolonged-release tablets (7.5 mg and 15 mg). 'Prolonged-release' means that darifenacin is released slowly from the tablet over a few hours.

What is Emselex used for?

Emselex is used in adults with overactive bladder syndrome. It is used to treat the urge incontinence (sudden lack of control over urination), increased urinary frequency (need to urinate frequently) and urgency (sudden urge to pass urine) that are associated with the syndrome.

The medicine can only be obtained with a prescription.

How is Emselex used?

The recommended starting dose of Emselex is 7.5 mg once a day. For patients requiring greater symptom relief, the dose may be increased to 15 mg. The tablets should be swallowed whole with some liquid, and not chewed, divided or crushed.

How does Emselex work?

The active substance in Emselex, darifenacin, is an anticholinergic medicine. It blocks a receptor called the 'muscarinic M3 receptor'. In the bladder, this causes the muscles that push urine out of the bladder

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to relax. This leads to an increase in the capacity of the bladder and changes in the way the bladder contracts, resulting in fewer bladder contractions. This helps Emselex to prevent unwanted urination.

How has Emselex been studied?

Emselex has been studied in four main studies in a total of 2,078 male and female patients with symptoms of overactive bladder. Emselex was used at various doses (from 3.75 mg to 30 mg a day) and compared with placebo (a dummy treatment) or with tolterodine (another medicine used in this condition). The main measure of effectiveness was the change in the number of incontinence episodes per week.

What benefit has Emselex shown during the studies?

When the results from all four studies were combined, Emselex was more effective in reducing the number of incontinence episodes than placebo. At the start of the studies, the patients had around 16 incontinence episodes per week. After 12 weeks of treatment, patients receiving Emselex 7.5 mg or 15 mg had 8.8 (68%) or 10.6 (77%) fewer episodes of incontinence per week, respectively, and patients receiving placebo had 7 or 7.5 (54 or 58%) fewer episodes per week.

What is the risk associated with Emselex?

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

Emselex must not be used in people who are hypersensitive (allergic) to darifenacin or any of the other ingredients. It must not be used in patients with:

- urinary retention (difficulty 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 causing muscle weakness);
- severe liver problems;
- severe ulcerative colitis (severe inflammation of the gut causing ulcers and bleeding);
- toxic megacolon (a very serious complication of colitis).

Emselex must not be taken by patients who are also taking medicines that could affect the way that Emselex is broken down in the body, such as protease inhibitors (used to treat HIV infection, such as ritonavir), or ketoconazole or itraconazole (used to treat fungal infections).

Why has Emselex been approved?

The CHMP concluded that Emselex showed an effectiveness similar to that of other anticholinergic medicines used in overactive bladder syndrome. The Committee decided that Emselex's benefits are greater than its risks and recommended that it be given marketing authorisation.

Other information about Emselex

The European Commission granted a marketing authorisation valid throughout the European Union for Emselex on 22 October 2004.

The full EPAR for Emselex 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 Emselex, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 04-2013.