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EPAR summary for the public

Kentera

oxybutynin

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

What is Kentera?

Kentera is a medicine that contains the active substance oxybutynin. It is available as a transdermal patch (a patch that delivers a medicine across the skin) and as a gel in a sachet or a metering pump.

What is Kentera used for?

Kentera is used to treat urge incontinence (sudden lack of control over urination), increased urinary frequency (need to urinate frequently) and urgency (sudden urge to pass urine) in adults with an overactive bladder (when the bladder muscles contract suddenly).

The medicine can only be obtained with a prescription.

How is Kentera used?

For the transdermal patches, one patch is used twice a week (every three to four days). The patch should be applied to dry, intact skin on the abdomen (tummy), hip, or buttock immediately after it is removed from the protective sachet. A new application site should be chosen for each new patch so that the same area of skin is not used more than once within a week.

For the gel, the recommended daily dose is 4 mg of oxybutynin once a day, which corresponds to one gram of gel delivered using a metering pump or to the content of one sachet. The gel is applied to dry, intact skin on the abdomen, upper arm, shoulders or thighs. Different application sites should be chosen, so that the same area of skin is not used on consecutive days.

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How does Kentera work?

The active substance in Kentera, oxybutynin, is an anticholinergic medicine. It blocks some receptors in the body called muscarinic M1 and M3 receptors. In the bladder, this causes the muscles that push urine out of the bladder to relax. This leads to an increase in the amount of urine that the bladder can hold, and to changes in the way the bladder muscles contract as the bladder fills up. This helps Kentera to prevent unwanted urination. Oxybutynin has been available as a tablet for the treatment of overactive bladder since the 1970s.

How has Kentera been studied?

Kentera transdermal patches were studied in a total of 881 patients, mostly elderly women, with overactive bladders in two main studies. In one study, they were compared with placebo (a dummy treatment) in 520 patients. In the other, they were compared with tolterodine capsules (another medicine used to treat urge incontinence) in 361 patients. The main measure of effectiveness was the number of incontinence episodes over either three or seven days.

Kentera gel was compared with placebo in one main study in 789 patients with overactive bladders. The main measure of effectiveness was the change in the number of daily incontinence episodes after 12 weeks of treatment.

What benefit has Kentera shown during the studies?

Kentera was more effective than placebo. After 12 weeks, the average number of incontinence episodes per week had decreased by 19 (about three per day) with Kentera patches, compared with a decrease of 15 episodes with placebo. Kentera patches were as effective as tolterodine, with both treatments decreasing the number of episodes by about three per day.

In the study on the gel, after 12 weeks the average number of daily incontinence episodes, which was initially at 5.4, was reduced by 2.7 episodes per day in patients receiving Kentera gel compared with a drop on average of 2 episodes per day in patients receiving placebo.

What is the risk associated with Kentera?

The most common side effects with Kentera patches (seen in more than 1 patient in 10) are application site reactions (including itching around the site of patch application). The most commonly reported side effect with Kentera gel is dry mouth (seen in between 1 and 10 patients in 100). For the full list of all side effects reported with Kentera, see the package leaflet.

Kentera should not be used in people who may be hypersensitive (allergic) to oxybutynin or any of the other ingredients. It must not be used in patients with urinary retention (difficulty in passing urine), severe gastro-intestinal conditions (problems with the stomach and gut), uncontrolled narrow-angle glaucoma (increased eye pressure even with treatment) or myasthenia gravis (a disease of the nerves and muscles causing muscle weakness), or in patients at risk of these conditions.

Why has Kentera been approved?

The CHMP had first evaluated Kentera transdermal patches and concluded that their effectiveness was similar to that of the oxybutynin tablets already on the market and that the benefits outweighed the risks. The Committee recommended that the Kentera patch be given marketing authorisation.

During its assessment of the application for Kentera gel, the CHMP concluded that its effectiveness was similar to that of the previously approved patches. The Committee therefore decided that the benefits of Kentera gel also outweighed its risks and recommended the approval of the new formulation.

Other information about Kentera

The European Commission granted a marketing authorisation valid throughout the European Union for Kentera on 15 June 2004.

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

This summary was last updated in 06-2011.