

Package Leaflet: Information for the User  
**Kentera® 3.9mg/24h Transdermal patch**  
(oxybutynin)

Your medicine is known by the above name, but will be referred to as Kentera® throughout this leaflet.

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**

1. What Kentera® is and what it is used for
2. What you need to know before you use Kentera®
3. How to use Kentera®
4. Possible side effects
5. How to store Kentera®
6. Contents of the pack and other information

**1. WHAT KENTERA® IS AND WHAT IT IS USED FOR**

Kentera® is used in adults to control the symptoms of urge incontinence and/or increased urinary frequency and urgency.

Kentera® works by allowing the bladder to expand and accommodate more urine.

**2. WHAT YOU NEED TO KNOW BEFORE YOU USE KENTERA®**

**Do not use Kentera® if you:**

- are allergic to oxybutynin or any of the other ingredients of this medicine (listed in section 6)
- have a rare condition called myasthenia gravis that makes the muscles in the body become weak and tire easily
- experience incomplete bladder emptying during urination, the use of oxybutynin may increase this problem. You should discuss this problem with your doctor before using Kentera®
- have digestion problems caused by reduced emptying of the stomach after a meal, you should consult your doctor before using Kentera®
- have glaucoma or a family history of glaucoma, tell your doctor.

**Warnings and precautions**

Talk to your doctor or pharmacist before using Kentera® if you have any of the following:

- liver problems
- kidney problems
- difficulty urinating
- intestinal blockage
- bloody stools
- generalized muscle weakness
- painful swallowing.

Since treatment with oxybutynin may cause decreased perspiration, there is an increased risk of fever and heat stroke if you are exposed to high environmental temperatures.

**Children and adolescents**

Kentera® is not recommended for use in children or adolescents.

**Other medicines and Kentera®**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Applying the Kentera® patch at the same time as taking other medicines that have similar side effects such as dry mouth, constipation and drowsiness, may increase how often and how severe these side effects are experienced.

Oxybutynin may slow the digestive tract and thereby influence the adsorption of other oral medicines, or the use of this medicine together with other medicines may increase the effect of oxybutynin. Especially:

- ketoconazole, itraconazole or fluconazole (used for the treatment of fungal infections)
- erythromycin a macrolide antibiotic (used to treat bacterial infections)

- levodopa or amantadine (used to treat Parkinson's disease)
- antihistamines (used in the treatment of allergies such as hay fever)
- phenothiazines or clozapine (used to treat mental illness)
- tricyclic antidepressants (used to treat depression)
- dipyridamole (used to treat blood clotting problems)
- atropine and other anticholinergic medicines (used for treatment in stomach disorders such as irritable bowel syndrome).

**Kentera® with food, drink and alcohol**

Oxybutynin may cause drowsiness or blurred vision. Drowsiness may be increased by consumption of alcohol.

**Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Kentera® should not be used during pregnancy unless clearly necessary.

When oxybutynin is used during breast-feeding, a small amount is excreted in the mother's milk. Use of oxybutynin while breast-feeding is therefore not recommended.

**Driving and using machines**

Because Kentera® may produce drowsiness, somnolence, or blurred vision, patients should be advised to exercise caution when driving or using machinery.

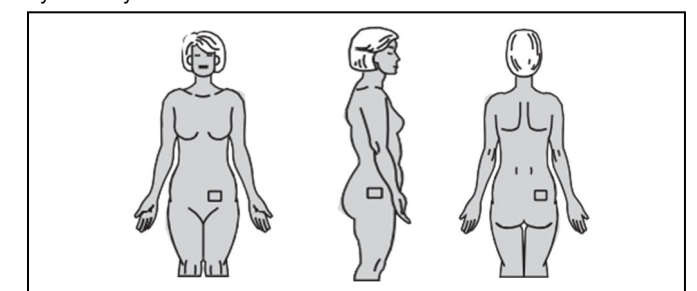
**3. HOW TO USE KENTERA®**

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Apply a new Kentera® patch twice weekly (every 3 to 4 days) according to the instructions for use. Change the patch on the same two days every week, for example, every Sunday and Wednesday or Monday and Thursday. Printed on the inside flap of your Kentera® package, you will find a Kentera® calendar checklist that will help you to remember your dosing schedule. Mark the schedule you plan to follow and remember always to change your patch on the same two days of the week you have chosen on your calendar. Make sure to wear only one patch at a time and wear your patch continuously, until it is time to apply a new one.

**Where to apply**

Apply the patch to a clean, dry, smooth area of skin on your abdomen, hips or buttocks. Avoid placing the patch in the waistline area to prevent tight clothing from rubbing against the patch. Do not expose the patch to the sun. Place the patch underneath your clothing. Rotate application sites with each new application. Do not apply a patch to the same place on your body for at least 1 week.



abdomen

hips

buttocks

**How to apply**

Each patch is individually sealed in a protective sachet. Please read all the information below before you begin to apply Kentera®.

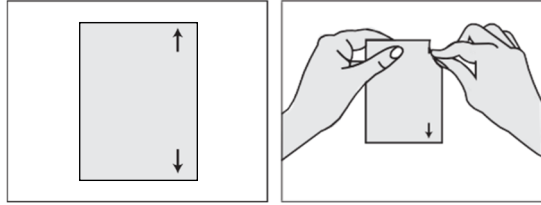
**To apply Kentera®:**

**Step 1: Choose a spot for the patch that is:**

- Freshly washed, but dry and cool (wait a few minutes after taking a hot bath or shower).
- Free of body powder, lotion, and oil.
- Free of cuts, rashes or any other skin irritation.

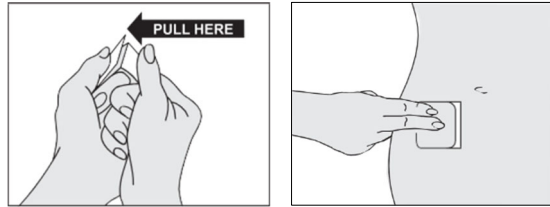
### Step 2: Open the sachet that contains the patch.

- Tear open along arrows marked on the right side of the sachet as shown in drawing below.
- Do not cut the sachet with scissors, which might damage the patch inside.
- Pull the patch out.
- Do not cut or divide the patch, do not use damaged patches.
- Apply immediately to your skin; do not keep or store the patch outside the sealed sachet.



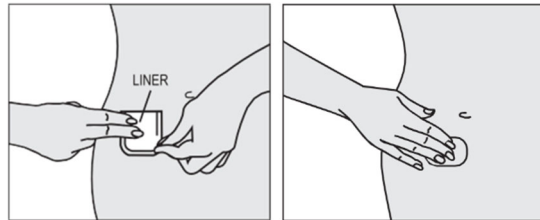
### Step 3: Apply one half of the patch to your skin.

- Gently bend the patch and remove the first piece of protective liner, which covers the sticky surface of the patch.
- Without touching the sticky surface, firmly press the patch, adhesive face down, onto the part of the abdomen, hips or buttocks you have selected for application.



### Step 4: Apply the second half of the patch to your skin.

- Bend the patch back over itself. Press down on the liner firmly.
- Push the liner forward a little to loosen the edge.
- Grab the loose edge at either corner and peel off the second piece of the liner. Try not to touch the sticky surface of the patch.
- Press the entire patch firmly onto the skin with your fingertips. Press for at least 10 seconds to make sure the patch will stay in place. Be sure all of it sticks to your skin, even around the edges.
- Discard the protective liners.



### Bathing, showering, swimming and exercise:

You should wear each patch all the time until you apply a new one. Baths, showers, swimming and exercise should not affect the patch as long as you do not rub the patch as you wash. Avoid soaking in a hot bath for a long period of time, which can make the patch come off.

### If the patch comes off:

If the patch starts to lift off your skin, apply a little bit of pressure using your fingertips. The patch is designed to re-stick. Very rarely will the patch come off completely. If it does, try putting the same patch back on the same spot. If it sticks firmly all over, leave it on. If not, take it off and put a new patch on a new spot. No matter what day this happens, continue with the twice-a-week schedule that you have marked on your patch box.

### If you forget to change the patch after 3-4 days:

As soon as you remember, remove the old patch and apply a new one to a new spot on your abdomen, hips or buttocks. No matter what day this happens, continue with the same twice-a-week schedule for your next patch, even if it means changing the new patch before 3 to 4 days have elapsed.

### How to remove

When changing the patch, remove the old patch slowly. Fold it in half (sticky sides together) and throw it away to keep out of the reach of children and pets. Mild redness may be present at the application site. This redness should disappear within several hours after removal of the patch. If irritation persists, please contact your doctor.

Gently washing the application site with warm water and a mild soap should remove any adhesive that remains on your skin after removal of the patch. A small amount of baby oil may also be used to remove any excess residue. Rings of adhesive that become soiled may require a medical adhesive removal pad that should be available from your pharmacist. Alcohol or other strong solvents may cause skin irritation and should not be used.

After use the patch still contains substantial quantities of active ingredients. Remaining active ingredients of the patch may have harmful effects if reaching the aquatic environment. Hence, after removal, the used patch should be folded in half, adhesive side inwards so that the release membrane is not exposed, placed in the original sachet and then discarded safely out of reach of children. Any used or unused patches should be discarded according to local requirements or returned to the pharmacy. Used patches should not be flushed down the toilet nor placed in liquid waste disposal systems.

### If you use more Kentera® than you should

The patient should not apply more than one patch at a time.

### If you forget to use Kentera®

Apply a Kentera® patch as soon as you realise your patch is missing, or you have missed a scheduled day of application.

### If you stop using Kentera®

Your urge incontinence may return and you may have increased urinary frequency if you decide to stop using the patch. Continue to use Kentera® as long as your doctor tells you to.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## 4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Very common** side effect (may affect more than 1 in 10 people):

- itching around the site of patch application.

**Common** side effects (may affect up to 1 in 10 people):

- redness or rash at the site of patch application
- dry mouth
- constipation
- diarrhoea
- upset stomach
- stomach pain
- headache or sleepiness
- urinary tract infections
- blurred vision
- dizziness.

**Uncommon** side effects (may affect up to 1 in 100 people):

- upper respiratory tract or fungal infections
- anxiety
- confusion
- nervousness
- agitation
- difficulty in sleeping
- a forceful heartbeat that may be rapid or irregular (palpitations)
- hot flushes
- back pain
- inability to completely empty the bladder (urinary retention)
- difficulty urinating
- common cold
- accidental injury.

**Rare** side effects (may affect up to 1 in 1,000 people):

- panic reaction
- mental confusion
- seeing, hearing or feeling things that are not there (hallucinations)
- disorientation
- memory impairment
- loss of memory
- abnormal tiredness
- poor concentration.

### Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects, you can help provide more information on the safety of this medicine.

## 5. HOW TO STORE KENTERA®

- **Keep out of the sight and reach of children.**
- Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.
- Do not refrigerate or freeze.
- The used patches should be folded in half, adhesive side inwards so that the release membrane is not exposed, placed in the original sachet and then discarded safely out of the reach of children. Any used or unused patches should be discarded according to local requirements or returned to the pharmacy. Used patches should not be flushed down the toilet nor placed in liquid waste disposal systems.
- If your medicine shows any signs of deterioration or discoloration, consult a pharmacist who will advise you what to do.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

## 6. CONTENTS OF THE PACK AND OTHER INFORMATION

### What Kentera® contains

The active substance is oxybutynin. Each transdermal patch releases 3.9 mg of oxybutynin per 24 hours. Each patch of 39 cm<sup>2</sup> contains 36 mg of oxybutynin.

The other ingredients are: Each patch contains triacetin, and acrylic adhesive solution (containing 2-ethylhexyl acrylate; N-vinyl pyrrolidone and hexamethyleneglycol dimethacrylate polymer domains). The oxybutynin, triacetin and acrylic adhesive are coated on clear polyester/ethylene-vinyl acetate film (PET/EVA) backing film and covered with a siliconised polyester release liner.

### What Kentera® looks like and contents of the pack

Kentera® is a transdermal patch and it is packaged in cartons containing 8 patches. Each patch consists of a clear backing film that has the pharmaceutical ingredients coated on the side containing the protective backing film. The backing film is to be removed prior to patch application.

Manufactured by Merckle GmbH, Ludwig-Merckle-Strasse 3, 89143 Blaubeuren, Germany.

Procured from within the EU and repackaged by the Product Licence Holder Beachcourse Ltd., Unit 2-3, Townsend Industrial Estate, Waxlow Road, London, NW10 7NU.

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**POM**

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Tel: 020 8896 9054 for help.  
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