

PACKAGE LEAFLET: INFORMATION FOR THE USER

Kentera 3.9 mg / 24 hours transdermal patch Oxybutynin

Read all of this leaflet carefully before you start using Kentera.

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

In this leaflet:

1. What Kentera is and what it is used for
2. Before you use Kentera
3. How to use Kentera
4. Possible side effects
5. How to store Kentera
6. Further 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. BEFORE YOU USE KENTERA

Do not use Kentera:

- If you are hypersensitive (allergic) to oxybutynin or any of the ingredients of Kentera.
- If you have a rare condition called myasthenia gravis that makes the muscles in the body become weak and tire easily.
- If you 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.
- If you have digestion problems caused by reduced emptying of the stomach after a meal you should consult your doctor before using Kentera.
- If you have glaucoma or a family history of glaucoma, tell your doctor.

Take special care with 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.

Kentera is not recommended for use in children or adolescents.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken 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).
- Biperiden, levodopa, or amantadine (used to treat Parkinson's disease).
- Antihistamines (used in the treatment of allergies such as hayfever).
- 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).

Using Kentera with food and drink

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

Pregnancy and breast-feeding

Ask your doctor for advice before taking any 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

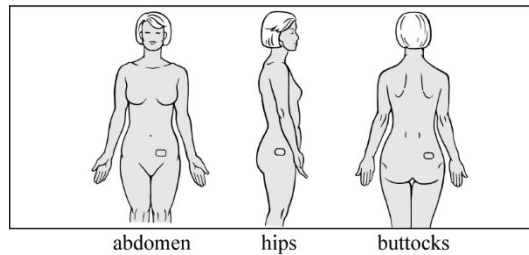
Always use Kentera exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.

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.



How to apply

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

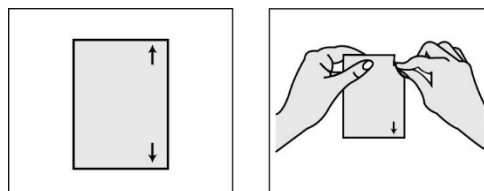
To apply Kentera:

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.

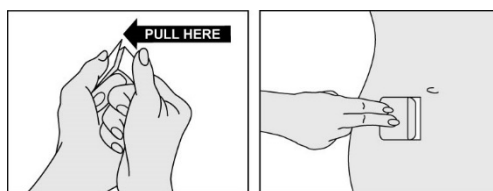
Step 2: Open the sachet that contains the patch.

- 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.
- Apply immediately to your skin; do not keep or store the patch outside the sealed sachet.



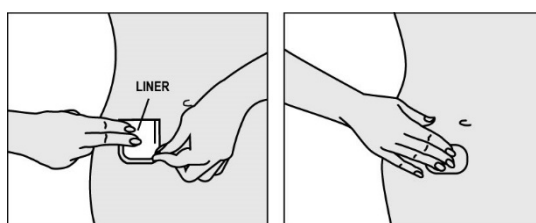
Step 3: Apply one half of the patch to your skin.

- 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 don't 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.

Talk to your doctor or pharmacist if you have any questions on the use of this medical product.

4. POSSIBLE SIDE EFFECTS

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

The frequency of possible side effects listed below is defined using the following convention:

- Very common (affects more than 1 user in 10)
- Common (affects 1 to 10 users in 100)
- Uncommon (affects 1 to 10 users in 1,000)
- Rare (affects 1 to 10 users in 10,000)
- Very rare (affects less than 1 user in 10,000)
- Not known (frequency cannot be estimated from the available data)

Very common side effect:

- itching around the site of patch application

Common side effects:

- 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:

- upper respiratory tract or fungal infections
- anxiety

- confusion
- nervousness
- agitation
- difficulty in sleeping
- palpitations
 - hot flushes
 - back pain
 - urinary retention
 - difficulty urinating
 - common cold
 - accidental injury

Rare side effects

- panic reaction
- mental confusion
- 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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Ireland

HPRA Pharmacovigilance
 Earlsfort Terrace
 IRL - Dublin 2
 Tel: +353 1 6764971
 Fax: +353 1 6762517
 Website: www.hpra.ie
 e-mail: medsafety@hpra.ie

United Kingdom

Yellow Card Scheme
 Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

5. STORING KENTERA

Keep out of the reach and sight of children.

Do not use Kentera after the date shown on the sachet and the carton.

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.

6. FURTHER 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 cm² contains 36 mg of oxybutynin.

The other ingredients are: Each patch contains triacetin, and acrylic adhesive solution. The oxybutynin, triacetin and acrylic adhesive are coated on clear 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 2, 8, and 24 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.

Marketing Authorisation Holder

Teva B.V.
Swensweg 5
2031 GA Haarlem
The Netherlands

Manufacturer

Teva Pharmaceuticals Europe B.V.
Swensweg 5
2031 GA Haarlem
The Netherlands

Merckle GmbH
Ludwig-Merckle-Straße 3
89143 Blaubeuren
Germany

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

België/Belgique/Belgien Eurocept BV Tél/Tel: +31 (0) 35 528 8377	Lietuva UAB Teva Baltics Tel: +370 5 266 02 03
България Actavis EAD Tel: +359 2 489 95 85	Luxembourg/Luxemburg Eurocept BV Tél/Tel: +31 (0) 35 528 8377
Česká republika Teva Pharmaceuticals CR, s.r.o. Tel: +420 251 007 111	Magyarország Teva Gyógyszergyár Zrt. Tel: (+36) 1 288 6400
Danmark Recordati AB Sverige Tlf: +46 8 545 80 230 infoNordic@recordati.com	Malta V.J. Salomone Pharma Ltd Tel: +35 621 220 174

Deutschland Recordati Pharma GmbH Tel: +49 (0) 731 7047 0	Nederland Eurocept BV Tel: +31 (0) 35 528 8377
Eesti UAB Teva Baltics Eesti filiaal Tel: +372 661 0801	Norge Recordati AB Sverige Tlf: +46 8 545 80 230 infoNordic@recordati.com
Ελλάδα Recordati Hellas Pharmaceuticals A.E. Τηλ: +30 210-6773822	Österreich Haemo- Pharma Consult GmbH Tel: +43 (0) 2689 3116 0
España Laboratorios Gebro Pharma, S.A. Tel: +34 93 205 86 86	Polska Teva Pharmaceuticals Polska Sp. z o.o. Tel: +48 22 345 93 00
France Teva Santé Tél: +33 1 55 91 78 00	Portugal Jaba Recordati S.A. Tel: +351 21 4329 500
Hrvatska Pliva Hrvatska d.o.o. Tel: + 385 1 37 20 000	România Teva Pharmaceuticals S.R.L. Tel: +4021 230 65 24
Ireland Recordati Ireland Ltd. Tel: +353 (0) 21 4379400	Slovenija Pliva Ljubljana d.o.o. Tel: +386 1 58 90 390
Ísland Actavis Pharmaceuticals Iceland ehf. Sími: + 354 550 3300	Slovenská republika Herbacos Recordati s.r.o. Česká republika Tel: +420 466 741 915
Italia Innova Pharma S.p.A. Tel: +39 02 48787.1	Suomi/Finland Recordati AB Ruotsi/Sverige Puh/Tel: +46 8 545 80 230 infoNordic@recordati.com
Κύπρος Recordati Hellas Pharmaceuticals A.E. Ελλάδα Τηλ: +30 210-6773822	Sverige Recordati AB Tel: +46 8 545 80 230 infoNordic@recordati.com
Latvija UAB Teva Baltics filiāle Latvijā Tel: +371 67 323 666	United Kingdom Orion Pharma (UK) Ltd Tel: +44 (0) 1635 520300

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Detailed information on this medicine is available on the European Medicines Agency (EMA) web site: <http://www.ema.europa.eu>