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.

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
- palpitations
- hot flushes
- back pain
- urinary retention
- difficulty urinating
- common cold
- accidental injury

If any of the side effects get serious, or if you notice any side effects not listed in the leaflet, please tell your doctor.

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 and Manufacturer

Nicobrand Limited
189 Castleroe Road
Coleraine
Northern Ireland
BT51 3RP

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

<table>
<thead>
<tr>
<th>België/Belgique/Belgien</th>
<th>Luxemburg/Luxemburg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eurocept BV</td>
<td>Eurocept BV</td>
</tr>
<tr>
<td>Tél/Tel: +31 (0) 35 528 8377</td>
<td>Tél/Tel: +31 (0) 35 528 8377</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>България</th>
<th>Magyarország</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nicobrand Limited</td>
<td>Nicobrand Limited</td>
</tr>
<tr>
<td>Великобритания (Обединеното краалство)</td>
<td>Nagy-Britannia</td>
</tr>
<tr>
<td>Тел.: +44 (0) 28 7086 8733</td>
<td>Тел.: +44 (0) 28 7086 8733</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Česká republika</th>
<th>Malta</th>
</tr>
</thead>
<tbody>
<tr>
<td>Herbacos Recordati s.r.o.</td>
<td>Nicobrand Limited</td>
</tr>
<tr>
<td>Tel: +420 466 741 915</td>
<td>Ir-Renju Unit</td>
</tr>
<tr>
<td>Tel: +44 (0) 28 7086 8733</td>
<td>Tel: +44 (0) 28 7086 8733</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Danmark</th>
<th>Nederland</th>
</tr>
</thead>
<tbody>
<tr>
<td>Orion Pharma A/S</td>
<td>Eurocept BV</td>
</tr>
<tr>
<td>Tlf: +45 49 12 66 00</td>
<td>Tél/Tel: +31 (0) 35 528 8377</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Deutschland</th>
<th>Norge</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recordati Pharma GmbH</td>
<td>Orion Pharma AS</td>
</tr>
<tr>
<td>Tel: +49 (0) 731 7047 0</td>
<td>Tlf: +47 40 00 42 10</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Eesti</th>
<th>Österreich</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nicobrand Limited</td>
<td>Haemo- Pharma Consult GmbH</td>
</tr>
<tr>
<td>Ühendkuningriik</td>
<td>Tel: +43 (0) 2689 3116 0</td>
</tr>
<tr>
<td>Tel: +44 (0) 28 7086 8733</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Elláda</th>
<th>Polska</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recordati Hellas Pharmaceuticals A.E.</td>
<td>Nicobrand Limited</td>
</tr>
<tr>
<td>Τηλ.: +30 210-6773822</td>
<td>Wielka Brytania</td>
</tr>
<tr>
<td>Tel.: +44 (0) 28 7086 8733</td>
<td>Tel.: +44 (0) 28 7086 8733</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>España</th>
<th>Portugal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laboratorios Gebro Pharma, S.A.</td>
<td>Jaba Recordati S.A.</td>
</tr>
<tr>
<td>Tel: +34 93 205 86 86</td>
<td>Tel: +351 21 4329 500</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Malta</th>
<th>Nederland</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nicobrand Limited</td>
<td>Eurocept BV</td>
</tr>
<tr>
<td>Ir-Renju Unit</td>
<td>Tél/Tel: +31 (0) 35 528 8377</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Polska</th>
<th>Portugal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nicobrand Limited</td>
<td>Jaba Recordati S.A.</td>
</tr>
<tr>
<td>Wielka Brytania</td>
<td>Tel: +351 21 4329 500</td>
</tr>
<tr>
<td>Country</td>
<td>Company Name</td>
</tr>
<tr>
<td>--------------</td>
<td>---------------------------------------------</td>
</tr>
<tr>
<td>France</td>
<td>Laboratoires BOUCHARA-RECORDATI</td>
</tr>
<tr>
<td>România</td>
<td>Nicobrand Limited</td>
</tr>
<tr>
<td>Ireland</td>
<td>Recordati Ireland Ltd.</td>
</tr>
<tr>
<td>Slovenija</td>
<td>Nicobrand Limited</td>
</tr>
<tr>
<td>Island</td>
<td>Nicobrand Limited</td>
</tr>
<tr>
<td>Slovenská republika</td>
<td>Herbacos Recordati s.r.o.</td>
</tr>
<tr>
<td>Italia</td>
<td>Innova Pharma S.p.A.</td>
</tr>
<tr>
<td>Suomi/Finland</td>
<td>Orion Corporation</td>
</tr>
<tr>
<td>Κύπρος</td>
<td>Recordati Hellas Pharmaceuticals A.E.</td>
</tr>
<tr>
<td>Sverige</td>
<td>Orion Pharma AB</td>
</tr>
<tr>
<td>Latvija</td>
<td>Nicobrand Limited</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>Orion Pharma (UK) Ltd</td>
</tr>
<tr>
<td>Lietuva</td>
<td>Nicobrand Limited</td>
</tr>
<tr>
<td>Hrvatska</td>
<td>Nicobrand Limited</td>
</tr>
</tbody>
</table>

This leaflet was approved in July 2014

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