

# PRILIGY®

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## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

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**WARNING:** Important safety information is provided in a boxed warning in the [full CMI](#). Read before using this medicine.

## 1. Why am I taking PRILIGY?

PRILIGY contains the active ingredient dapoxetine hydrochloride. PRILIGY is a treatment for premature ejaculation (PE) in men 18 to 64 years old. For more information, see Section [1. Why am I taking PRILIGY?](#) in the full CMI.

## 2. What should I know before I take PRILIGY?

Do not use if you have ever had an allergic reaction to dapoxetine hydrochloride or any of the ingredients listed at the end of the CMI. There are a number of circumstances in which a person should not take this medicine or may need to use caution. It is important to understand if these apply to you before taking PRILIGY.

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Talk to your doctor or pharmacist if you have any concerns about taking this medicine. See Section [2. What should I know before I use PRILIGY?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with PRILIGY and affect how it works. A list of these medicines is included in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use PRILIGY?

- The recommended dose is one tablet (30 mg) taken when you need it, about 1 to 3 hours before sexual activity. Do not take more than one tablet in a 24 hour period. It is not intended for continuous daily use.
- Swallow the tablet whole with at least one full glass of water. PRILIGY can be taken with or without food.
- Avoid alcohol when taking PRILIGY. Do not drink grapefruit juice within 24 hour prior to taking PRILIGY.

More instructions can be found in Section [4. How do I use PRILIGY?](#) in the full CMI.

### 5. What should I know while taking PRILIGY?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist</li></ul>
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	<p>you visit that you are taking PRILIGY.</p> <ul style="list-style-type: none"> <li>● Keep all doctor appointments so your progress can be checked.</li> <li>● Talk to your doctor before you stop taking this medicine. You may have problems sleeping and feel dizzy after you stop taking it, even if you have not taken it every day.</li> </ul>
<p><b>Things you should not do</b></p>	<ul style="list-style-type: none"> <li>● Do not take PRILIGY to treat any other complaints unless your doctor tells you to.</li> <li>● Do not give your medicine to anyone else, even if they have the same condition as you.</li> </ul>
<p><b>Driving or using machines</b></p>	<ul style="list-style-type: none"> <li>● Be careful before you drive or use any machines or tools as PRILIGY may cause dizziness, light-headedness, tiredness, drowsiness, fainting, having difficulty</li> </ul>

	concentrating and blurred vision.
<b>Drinking alcohol</b>	<ul style="list-style-type: none"> <li>• Avoid alcohol while taking PRILIGY as the effects of alcohol may be increased, such as dizziness, drowsiness, slow reflexes or impaired judgement.</li> </ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• Keep your tablets in the pack until it is time to take them. Store in a cool dry place below 25°C and keep out of reach of children.</li> </ul>

For more information, see Section [5. What should I know while taking PRILIGY?](#) in the full CMI.

## 6. Are there any side effects?

Common side effects include nausea; headache; dizziness; fainting or feeling dizzy upon standing; increased blood pressure; flushing; trembling; tingling or numbness; blurred vision, eye pain; ringing in ears; nasal congestion; dry mouth, vomiting, diarrhoea, constipation, abdominal pain, indigestion, intestinal gas, bloating ; excessive sweating; fatigue, sleepiness, yawning; difficulty paying attention, feeling irritable; erectile dysfunction (difficulty getting or keeping an erection); difficulty sleeping; anxiety, nervousness;

decreased sexual desire; and abnormal dreams. Serious side effects requiring medical attention include fits (seizures); changes in your mood, thoughts of suicide or harming yourself; an allergic reaction; unusual bruising and bleeding. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

## **WARNING:**

PRILIGY can make you faint. You may experience warning symptoms such as nausea, dizziness or light-headedness before you faint. Immediately lie down or sit down with your head between your knees if you feel nauseous, dizzy or light-headed until the symptoms pass. This will prevent falls and injury (see While you are taking PRILIGY and Side Effects). Do not take more than one PRILIGY tablet once every 24 hours due to the increased risk of fainting.

## **PRILIGY®**

**Active ingredient(s):** *dapoxetine hydrochloride*

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### **Consumer Medicine Information (CMI)**

This leaflet provides important information about using PRILIGY. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using PRILIGY. Where to find information in this leaflet:**

- [1. Why am I taking PRILIGY?](#)
- [2. What should I know before I take PRILIGY?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take PRILIGY?](#)
- [5. What should I know while taking PRILIGY?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I taking PRILIGY?

**PRILIGY contains the active ingredient dapoxetine hydrochloride.** PRILIGY is a type of drug called a selective serotonin reuptake inhibitor (SSRI) and it is also known as a urological medicine.

PRILIGY is a treatment for premature ejaculation (PE) in men 18 to 64 years old who have all of the following:

- ejaculation in less than 2 minutes following vaginal penetration, on most occasions, with little stimulation and before the man wishes to; and
- marked personal distress and interpersonal difficulty as a result of premature ejaculation (premature ejaculation troubles the man and his partner); and
- poor control over ejaculation.

PRILIGY increases your time to ejaculation and can improve your control over ejaculation and reduce your distress over how fast you ejaculate. This may improve your satisfaction with sexual intercourse.

## 2. What should I know before I take PRILIGY?

### Warnings

#### Do not take PRILIGY if:

- you are allergic to dapoxetine hydrochloride, or any of the ingredients listed at the end of this leaflet. Always

check the ingredients to make sure you can take this medicine.

- you are taking a monoamine oxidase inhibitor (MAOI ) medicine used to treat depression, or have taken a MAOI within the last 14 days (see Section [3. What if I am taking other medicines?](#)). Once you stop taking PRILIGY you will need to wait 7 days before taking a MAOI.
- you are taking thioridazine used to treat schizophrenia, or have taken thioridazine within the last 14 days. Once you stop taking PRILIGY you will need to wait 7 days before taking thioridazine.
- you are taking a serotonin reuptake inhibitor (such as a selective serotonin reuptake inhibitor (SSRI), serotonin-norepinephrine reuptake inhibitor (SNRI), tricyclic antidepressant (TCA)), and certain other medicines and herbal products to treat depression or have taken these medicines within the last 14 days (see Section [3. What if I am taking other medicines?](#) for examples of serotonin reuptake inhibitors and other medicines used to treat depression). Once you stop taking PRILIGY you will need to wait 7 days before taking these medications/herbal products.
- you are taking certain medicines to treat fungal infections or medicines to treat HIV (see Section [3. What if I am taking other medicines?](#) for examples of these medicines).
- you have a history of mania or severe depression.
- you have heart problems, such as heart failure or problems with the heart rhythm.
- you have moderate to severe liver problems.



- you are prone to fainting or passing out caused by a temporary drop in blood pressure (Syncope).

Before you start taking this medicine, your doctor should perform a test to make sure that your blood pressure doesn't drop too much when you stand up from sitting or lying down.

### **Check with your doctor if:**

- you have not been diagnosed with premature ejaculation
- you use recreational drugs such as ecstasy or LSD (lysergic acid diethylamide). Taking PRILIGY with these drugs can cause serious reactions.
- you take narcotics (strong pain medicines) or benzodiazepines such as Valium. These medicines can increase the drowsiness and dizziness of PRILIGY.
- you consume alcohol. Alcohol can increase the risk of fainting and should be avoided while taking PRILIGY.
- you are being treated for depression
- you are currently using medications to treat fungal infections
- you are currently taking medicine that thins your blood such as aspirin, anticoagulants such as warfarin, non-steroidal anti-inflammatory medicines (NSAIDs) such as ibuprofen, or medicine used to treat psychiatric conditions such as depression. Taking PRILIGY together with these medications can increase the risk of bleeding abnormalities.

- you have a history of dizziness from low blood pressure
- you have or have had heart and blood vessel problems
- you have a history of bleeding or blood clotting problems
- you have or have had depression
- you have or have had a history of fainting (see [Section.5 What should I know while taking PRILIGY?](#))
- you have or have had any thoughts of suicide or harming yourself.

All thoughts of suicide must be taken seriously.

**Tell your doctor or a mental health professional immediately if you have any suicidal thoughts or other mental/mood changes.**

- you have or have had psychiatric disorders, such as schizophrenia
- you have history of mania (great excitement, hallucinations, difficulty in concentrating or staying still) or bipolar disorder (extreme mood swings between mania and depression) or develop these disorders
- you have or have had seizures (fits) or have uncontrolled epilepsy
- you have moderate or severe liver problems
- you have severe kidney problems
- you have or have had other forms of sexual problems such as erectile dysfunction. It is not known whether PRILIGY can worsen these conditions.

- you have eye problems such as glaucoma, (high pressure in the eye )
- you have HIV.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## **Pregnancy and breastfeeding**

Do not take PRILIGY if you are a woman. PRILIGY has been studied for use by men with premature ejaculation. Its safety in women has not been established.

## **Children and adolescents**

Do not take PRILIGY if you are under 18 years of age, or over 65 years of age. Safety and effectiveness in patients under 18 years or over 65 years have not been established.

## **Lactose intolerance**

This medicine contains lactose (a type of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

### 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

**Some medicines and PRILIGY may interfere with each other. These include:**

- monoamine oxidase inhibitors (MAOIs) used to treat depression, such as moclobemide, phenelzine and tranylcypromine
- medicines used to treat depression such as amitriptyline, citalopram, escitalopram, doxepin, fluoxetine, fluvoxamine, mianserin, mirtazapine, nortriptyline, paroxetine, sertraline, nefazodone, venlafaxine or vortioxetine
- triptans, medicines used to treat migraine (e.g. sumatriptan)
- tramadol, used for pain
- lithium, used for mood disorders
- thioridazine, used to treat schizophrenia
- linezolid, an antibiotic used to treat infection
- tryptophan, used to help your mood and help you sleep
- St John's wort (*Hypericum perforatum*), a herbal preparation.

PRILIGY should not be taken with the above listed medicines/ herbal preparations or within 14 days of stopping these medicines.

Once you stop taking PRILIGY you will need to wait 7 days before taking these medicines/ herbal preparations.

**Other medicines or food and PRILIGY may interfere with each other. These include:**

- medicines for mental health problems other than depression
- medicines to thin your blood, such as warfarin
- certain medicines for fungal infections, including ketoconazole, itraconazole and fluconazole
- certain medicines for HIV, including ritonavir, saquinavir and atazanavir
- certain medicines used to treat high blood pressure and chest pain (angina), enlarged prostate, or erectile dysfunction (impotence), as these medicines may lower your blood pressure, possibly upon standing
- anti-inflammatory medicines such as ibuprofen or aspirin
- certain antibiotics for treating infection, such as erythromycin, telithromycin and clarithromycin
- aprepitant used to treat nausea
- grapefruit. Do not drink grapefruit juice within 24 hours prior to taking PRILIGY
- narcotics (strong pain medicines) or benzodiazepines such as valium. These medicines can increase the drowsiness and dizziness of PRILIGY.
- alcohol. Alcohol can increase the risk of fainting and should be avoided while taking PRILIGY.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect PRILIGY.**

These medicines may be affected by PRILIGY or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Other medicines not listed here may be affected by PRILIGY or may affect how well it works. Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

## **4. How do I take PRILIGY?**

### **How much to take**

The recommended dose is one tablet (30mg), taken when you need it, about 1 to 3 hours before sexual activity.

**Do not take more than one tablet once every 24 hours due to increased risk of side effects and lack of additional benefit.**

Swallow the tablet whole to avoid a bitter taste, with at least one full glass of water. PRILIGY may be taken with or without food.

Avoid alcohol when taking PRILIGY.

Do not drink grapefruit juice within 24 hours prior to taking PRILIGY. Grapefruit juice can increase the level of this medicine in your body.

## **When to take PRILIGY**

PRILIGY should be taken as needed, when sexual activity is anticipated. It is not intended for continuous daily use.

## **If you forget to take PRILIGY**

As PRILIGY is only taken when needed, it is not a problem if you forget to take it.

## **If you take too much PRILIGY**

Tell your doctor or pharmacist if you have taken more PRILIGY tablets than you should. You may feel sick or be sick. Symptoms of overdose in PRILIGY are drowsiness, nausea, vomiting, rapid heartbeat, tremor, agitation and dizziness. If you think that you have taken too much PRILIGY, you may need urgent medical attention.

### **You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## 5. What should I know while taking PRILIGY?

**WARNING: PRILIGY can make you faint or make you feel dizzy or light-headed.**

**To help lower the chance of this happening:**

- Take PRILIGY with at least one full glass of water.
- Do not take PRILIGY if you are dehydrated (you do not have enough water in your body). This can happen if:
  - You have not had water to drink in the past 4 to 6 hours
  - You have been sweating for a long time
  - You have an illness where you have a high temperature, diarrhoea or being sick
  - You have had alcohol
- If you feel like you might faint (such as feeling sick, feeling dizzy, light-headed, feeling weak, confused, sweaty or an abnormal heart beat), or feel light-headed when you stand up, immediately lie down so your head is lower than the rest of your body or sit down with your head between your knees until you feel better. This will stop you from falling and hurting yourself if you do faint.
- Do not stand up quickly after you have been sitting or lying down for a long time.
- Do not drive or use any tools or machines if you feel faint when taking this medicine.
- Tell your doctor if you faint when taking this medicine.



## **Things you should do**

- Remind any doctor, dentist or pharmacist you visit that you are taking PRILIGY.
- Keep all of your doctor's appointments so that your progress can be checked.
- Talk to your doctor before you stop taking this medicine. You may have problems sleeping and feel dizzy after you stop taking it, even if you have not taken it every day.

## **Things you should not do**

- Do not take PRILIGY to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.

## **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how PRILIGY affects you.**

This medicine may cause dizziness, light-headedness, tiredness, drowsiness, fainting, having difficulty concentrating and blurred vision in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

## **Drinking alcohol**

**Avoid alcohol while you are taking this medicine.**

The effects of alcohol, such as dizziness, drowsiness, slow reflexes or impaired judgement, may be increased if taken with PRILIGY.

## **Looking after your medicine**

Follow the instructions on the carton on how to take care of your medicine properly.

Keep your tablets in the pack until it is time to take them. If you take the tablets out of the pack they may not keep well.

Store it in a cool dry place below 25°C and away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

### **Keep it where young children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

## **Getting rid of any unwanted medicine**

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"><li>• nausea</li><li>• headache</li><li>• dizziness</li><li>• fainting or feeling dizzy upon standing (see <a href="#">Section 5 What should I know while taking PRILIGY?</a>)</li><li>• increased blood pressure</li><li>• flushing</li><li>• trembling</li><li>• tingling or numbness</li><li>• blurred vision</li><li>• eye pain</li><li>• ringing in the ears</li></ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● nasal congestion</li> <li>● diarrhoea, abdominal pain, dry mouth, vomiting, indigestion, intestinal gas, constipation, bloating</li> <li>● excessive sweating</li> <li>● fatigue, sleepiness and yawning</li> <li>● difficulty paying attention and feeling irritable</li> <li>● erectile dysfunction (difficulty getting or keeping an erection)</li> <li>● difficulty sleeping</li> <li>● anxiety, nervousness, decreased sexual desire</li> <li>● abnormal dreams</li> <li>● unusual bruising and bleeding</li> </ul>	

## **Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● fits (seizures)</li> <li>● fainted or feeling light-headed when you stand up</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● any changes in your mood</li> <li>● having any thoughts of suicide or harming yourself</li> </ul> <p><b>Allergy reaction -related:</b></p> <ul style="list-style-type: none"> <li>● rash, itching or hives on the skin; shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body</li> </ul>	<p><b>nearest hospital if you notice any of these serious side effects.</b></p>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## **Reporting side effects**

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## **7. Product details**

This medicine is only available with a doctor's prescription.

### **What PRILIGY contains**

<b>Active ingredient (main ingredient)</b>	Dapoxetine (as hydrochloride)
<b>Other ingredients (inactive ingredients)</b>	Lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, colloidal anhydrous silica, magnesium stearate, hypromellose, titanium dioxide, iron oxide black, iron oxide yellow and triacetin

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

**Do not take this medicine if you are allergic to any of these ingredients.**

## **What PRILIGY looks like**

PRILIGY 30 mg film-coated tablets are light grey, round and marked "30" inside a triangle on one side (AUST R 147946).

PRILIGY is supplied in blister packs containing 3 or 6 tablets.

## **Who distributes PRILIGY**

A. Menarini Australia Pty Ltd

Sydney, Australia

Tel: 1800 644 542

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