



## IMPORTANT INFORMATION



A patient's guide to treating  
Premature Ejaculation  
with PRILIGY® (dapoxetine)

This guide is intended only for patients who have been  
prescribed PRILIGY® by their Physician.

If you are preparing to use PRILIGY® for the first time to treat your premature ejaculation, you should take time to read the following information.

This leaflet is designed to provide you with information on the condition of premature ejaculation. It also contains important information on PRILIGY® which is broken down into the following sections:

- What is premature ejaculation?
- How common is premature ejaculation?
- What is PRILIGY®?
- How does PRILIGY® work?
- What to expect during treatment with PRILIGY®?
- How to take PRILIGY®
- Important safety information about PRILIGY®
- What are the possible side effects while taking PRILIGY®?
- How to be sure that you have genuine PRILIGY®
- How PRILIGY® is packaged

If you would like more information on PRILIGY®, please consult with your doctor or pharmacist. You should also read carefully the Patient Information Leaflet provided with PRILIGY®.

*Premature  
ejaculation  
affects more than  
one in five men*

## What is premature ejaculation?

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**Premature ejaculation is when a man ejaculates with little sexual stimulation and before the man wants. This can cause problems for the man and may cause problems in sexual relationships.**

## How common is premature ejaculation?

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Premature ejaculation is the most common male sexual dysfunction and affects more than one in five men. It is not dependant on age and affects men of all ages.

## What is PRILIGY®?

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PRILIGY® contains an active substance called 'dapoxetine'. This belongs to a group of medicines called 'selective serotonin reuptake inhibitors' (SSRIs).

## How does PRILIGY® work?

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PRILIGY® works by increasing the levels of serotonin, a natural chemical that may extend time to ejaculation. PRILIGY® works fast and is quickly eliminated from the body.

## What to expect during treatment with PRILIGY®?

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### Men who have been treated with PRILIGY® have experienced:

- Increased time to ejaculation.
- Increased sense of control over ejaculation.
- Increased satisfaction with sexual intercourse.
- Decreased distress related to premature ejaculation.
- Improved relationships with their partners.
- An overall impression that premature ejaculation has improved.

*Do not take PRILIGY® more than once every 24 hours or every day.*

## How to take PRILIGY®

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Take PRILIGY® 1 to 3 hours before anticipated sexual activity, but not more than once every 24 hours.

- The recommended starting dose for all patients is 30mg. Your doctor may increase your dose to 60mg.
- Swallow tablets whole to avoid bitter taste, with at least one full glass of water.
- PRILIGY® can be taken with or without food.
- Avoid alcohol while taking PRILIGY®. Combining PRILIGY® with alcohol may increase the chance of fainting and may also increase alcohol-related effects, such as feeling dizzy, sleepy and having slow reactions.
- Do not use PRILIGY® in combination with recreational drugs (such as ecstasy, LSD, narcotics or benzodiazepines) which may lead to potentially serious reactions if combined with PRILIGY®.

**Do NOT take more PRILIGY® than prescribed. Do NOT take PRILIGY® more than once every 24 hours or every day.**

*For more information, please refer to the Patient Information Leaflet.*

## Important safety information about PRILIGY®

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Do NOT share your PRILIGY® with others, even if their symptoms seem to be the same or similar to yours.

### Do NOT take PRILIGY® if:

- A diagnosis of premature ejaculation was not made by your doctor.
- You have an allergy to dapoxetine or any of the other ingredients in PRILIGY®.
- You have heart problems, such as heart failure or problems with heart rhythm.
- You have moderate or severe liver problems.
- You suffer from mania or severe depression, presently or in the past.
- You are taking certain medicines such as monoamine oxidase inhibitors (MAOIs) or other medication for depression; thioridazine for schizophrenia; certain medicines for fungal infections; certain medicines for HIV; certain antibiotics for treating infections; lithium for bipolar disorder; tryptophan used to help you sleep; St. John's Wort, a herbal medicine; tramadol used to treat serious pain; and medicines used to treat migraine.

*Do NOT share  
your PRILIGY®  
with others*

### Also:

- You should not take PRILIGY® if you use certain medicines to treat erectile dysfunction, such as sildenafil, tadalafil or vardenafil, as combining PRILIGY® with these drugs may increase the chance of fainting.
- Review all of your medicines, including herbal medicines, with your doctor or pharmacist.
- PRILIGY® is not to be used by women.

**If you are unsure if you should take PRILIGY®,  
talk with your doctor or pharmacist.**



## What are the possible side effects while taking PRILIGY®?

Like all medicines, PRILIGY® can cause side effects. Not everybody gets them and they may vary from person to person.

**The following side effects of PRILIGY® are very common (may affect more than 1 in 10 men):**

- Feeling dizzy.
- Headache.
- Feeling sick (nausea).

Fainting can occur after taking PRILIGY®, but it is reported to occur uncommonly (may affect up to 1 in 100 men).

*For a complete list of common side effects (may affect up to 1 in 10 men), please refer to the Patient Information Leaflet.*

*Avoid alcohol  
and recreational  
drugs while  
taking PRILIGY®*

**Stop taking PRILIGY® and see your doctor straight away if:**

- You have fits (seizures).
- You faint or feel light-headed when you stand up.
- You notice any changes in your mood.
- You have any thoughts of suicide or harming yourself.

**If you notice any of the above, stop taking this medicine and see your doctor straight away.**

*For more detailed safety information, please refer to the Patient Information Leaflet.*

**Take care while taking PRILIGY® as it may cause fainting or dizziness.**

- Avoid driving or operating hazardous machinery if you feel dizzy or light-headed.
- Avoid alcohol while taking PRILIGY®. Combining PRILIGY® with alcohol may increase the chance of fainting, thereby increasing the risk of accidental injury. It may also increase alcohol-related effects.

Three steps to decrease the risk of fainting and low blood pressure while taking PRILIGY®.

**1 Take PRILIGY® with water and do not take PRILIGY® if you are dehydrated.**

You can become dehydrated, or not have enough water in your body, if you:

- Have not had anything to drink in the past 4 to 6 hours.
- Have been sweating for a long time.
- Have an illness where you have a high temperature or diarrhoea or are being sick.

**2 Do not stand up quickly after you have been sitting or lying down for a long time after taking PRILIGY®.**

**3 If you feel like you might faint 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 keep you from falling and hurting yourself if you do faint.**

Signs that fainting may occur include feeling:

- Sick
- Sweaty
- Confused
- Light-headed
- Dizzy
- An abnormal heartbeat

**If you feel faint when taking PRILIGY®, avoid driving or operating hazardous machinery.**

**Tell your doctor if you faint when taking this medicine.**



## How to be sure that you have genuine PRILIGY®

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As with all medicines today, the risk of counterfeit PRILIGY® is a possibility. Counterfeit products may not contain the correct medicine, may contain no medicine at all, or may even contain harmful substances.

To protect your health, please take the following steps:

- 1 Only buy PRILIGY® from a legitimate source, like your local pharmacy. You should never buy medicines online, as many websites sell counterfeit medicines. The supply of prescription medicines through the internet is against the law in Ireland.**
- 2 Be aware of what the product and package should look like (see the section “How PRILIGY® is packaged” at the end of this guide). If there are any differences in appearance, do not take the product.**

### **3 Log on to [www.genuinepriligy.ie](http://www.genuinepriligy.ie) to verify that you have genuine PRILIGY®.**

- There is a serial number printed on the back of the package. This serial number is different on every package of PRILIGY® and was applied at the time of manufacture. It is a 12-digit number that starts with the letters SN.
- When you log on to [www.genuinepriligy.com](http://www.genuinepriligy.com), you will first be allowed to select your language, then follow the instructions to enter the 12-digit number.
- Please enter the 12-digit number (do not enter the letters SN). You will be told if your PRILIGY® is genuine or not.

*Counterfeit products may contain harmful substances*

## How PRILIGY® is packaged

PRILIGY® is provided in a multi-fold package containing 3 or 6 film-coated tablets. The pack contains important information you must read before taking PRILIGY®. This multi-fold package is sealed with a silver tamper-evident sticker.

Once the seal has been removed, it will leave behind a sticky residue that has a pattern like a checkerboard. If the seal is open or missing, please do not use the product. The tablets are round and marked with a “30” (light-grey tablet) or a “60” (grey tablet) inside a triangle on one side.

**If you suspect that you do not have the real PRILIGY®, do not take the product. Talk to your Doctor or Pharmacist, or call the Menarini hotline at 1800 283045.**



PRILIGY® 60 mg



PRILIGY® 30 mg



## Reporting of side effects

**A. Menarini encourages patients to report side effects with PRILIGY® to the Irish Medicines Board (online at [www.imb.ie](http://www.imb.ie), telephone 01 6764971). In addition, this information may be reported to A. Menarini via telephone at 1800 283 045 or via email at [ireland@menarini.ie](mailto:ireland@menarini.ie).**



