IMPORTANT INFORMATION ABOUT PRILIGY®

the MENARINI group

Important Treatment Considerations

- PRILIGY® is used to treat premature ejaculation (PE) in men between 18 and 64 years old
- PRILIGY® should be taken 1 to 3 hours before sexual activity is anticipated, as directed by your health care provider
- PRILIGY® increases the time it takes to ejaculate and can improve the control over the ejaculation. This may reduce the frustration or worry about fast ejaculation
- The most common side effects are feeling dizzy, headache, and feeling sick
- Uncommonly, fainting may occur. If you feel like you might faint, immediately lie down or sit with your head between your knees until you feel better
- For more information:
  - Talk to your doctor or pharmacist
  - Refer to the Patient Information Leaflet that is included with your medication.

Managing Your PE

- To help you achieve success in the treatment of your PE with PRILIGY®, please read all of the important information in this brochure
- For more information, ask your doctor or pharmacist.

PE and PRILIGY®

Premature ejaculation is a distressing medical condition.

- Men with PE and their partners may experience distress, frustration, and relationship difficulty
- PE is defined as:
  - Persistent or recurrent ejaculation that occurs with minimal stimulation before, on, or shortly after vaginal penetration
  - Inability to control or delay ejaculation shortly before or during vaginal penetration
  - Negative personal consequences, such as distress.

PE is a distressing medical condition.

PRILIGY® Can Help Improve PE

- PRILIGY® contains an active substance called 'dapoxetine'. This belongs to a group of medicines called 'selective serotonin reuptake inhibitors' (SSRIs). It works by increasing the levels of serotonin, a natural chemical that may extend time to ejaculation by slowing the pathways in the body that are associated with PE. Moreover, PRILIGY® works fast and is quickly eliminated from the body.

PRILIGY® can help improve PE.

What to Expect During Treatment With PRILIGY®

Men treated with PRILIGY® may experience:

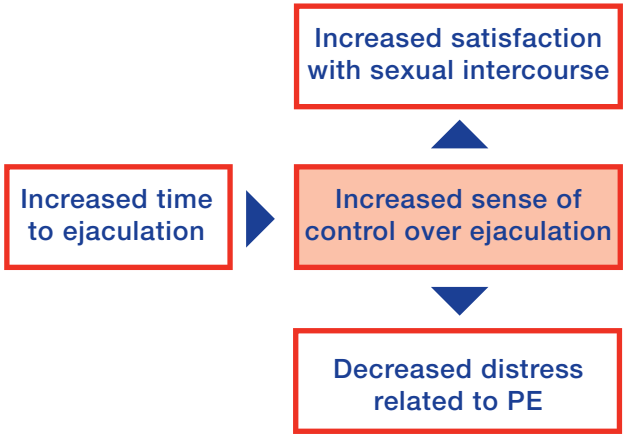
- Increased time to ejaculation
- Increased sense of control over ejaculation
- Increased satisfaction with sexual intercourse
- Decreased distress related to PE
- An overall impression that PE has improved.

PRILIGY® can increase sense of control over ejaculation and time to ejaculation.

Some men experience some improvement in PE the first time they use PRILIGY®, while other men may need to use PRILIGY® a few times for improvements to occur.

During treatment of PE, increased time to ejaculation leads to an increased sense of control over ejaculation. This increased sense of control can reduce frustration or worry about how fast ejaculation occurs and increase satisfaction with sexual intercourse.*

Improvements in PE With PRILIGY®*



* McMahon C et al. Efficacy and Safety of Dapoxetine for the Treatment of Premature Ejaculation: Integrated Analysis of Results from Five Phase 3 Trials. J Sex Med 2011;8:524–539

Priligy® Dapoxetine

Who Should Take PRILIGY®?

- PRILIGY® is indicated for the treatment of PE in men between 18 and 64 years of age
- PRILIGY® is only for men with a diagnosis of PE made by their health care provider.

PRILIGY® is only available by prescription from your doctor.

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:

- You had not a diagnosis of PE 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.

Also:

- You should not take PRILIGY® if you use PDE-5 inhibitors (indicated to treat erectile dysfunction), 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 indicated for use by women.

If you are unsure if you should take PRILIGY®, talk with your health care provider.

How to Take PRILIGY®

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

- The recommended starting dose for all patients is 30 mg. Your doctor may increase your dose to 60 mg
- 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®.

Take PRILIGY® 1 to 3 hours before sexual activity.

Do not take more PRILIGY® than prescribed.

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

For more information, consult the Patient Information Leaflet.

Important: Use Care while Taking PRILIGY®

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

If you feel like you might faint (such as feeling dizzy or light-headed), 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.

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, and may also increase alcohol-related effects.

For more information, consult the Patient Information Leaflet.

Possible Side Effects

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

Very common side effects of PRILIGY® (affecting 1 in 10 people or more) include:

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

The most common side effects of PRILIGY® are feeling dizzy, headache, and feeling sick (nausea).

Fainting can occur after taking PRILIGY®, but it is reported to occur uncommonly (affecting 1 to 10 users in 1000).

For a complete list of common side effects (affecting between 1 in 10 and 1 in 100 people), please refer to the Patient Information Leaflet.

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 complete safety information, consult the Patient Information Leaflet.

Three Steps to Decrease the Risk of Fainting and Low Blood Pressure

Fainting or low blood pressure may occur when you stand up, but 3 easy steps can decrease this risk.

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 diarrhea or are 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 lightheaded 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
  - Confused
  - Dizzy
  - Sweaty
  - Light-headed
  - 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®

Only buy PRILIGY® from a legitimate source.

As with all medicines today, the risk of counterfeit 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. Be cautious of buying medicines online, as many websites sell counterfeit products

- Check with the health authorities in your country to get a list of approved Internet pharmacies
- Be cautious of any websites that do not require a prescription from your personal physician, or offer special pricing on products, as these sites often sell counterfeit products

2. Be aware of what the product and package should look like (see the adjacent section "How PRILIGY® Is Packaged"). If there are any differences in appearance, do not take the product

3. Log on to www.genuinepriligy.com 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 *[update with local URL, if any]* you will first be allowed to select your language, then follow the instructions to enter the 12-digit number *[Instructions to be updated with upcoming info]*
- Please enter the 12-digit number (do not enter the letters SN). You will be told if your PRILIGY® is genuine or not.

How PRILIGY® is Packaged

PRILIGY® is provided in blister packs containing 3 or 6 film-coated tablets. The blister packs are enclosed in a trifold package with important information you must know before taking PRILIGY®. This trifold 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.

PRILIGY® 60 mg

PRILIGY® 30 mg

[Insert image of local packs and pills, only for locally approved dosage/s]

If you suspect that you do not have the real PRILIGY®, do not take the product.
Talk to your health care provider or pharmacist, or call the Menarini hotline at
[insert country customer line phone number].

[In those countries where promotional and consumer materials must be approved by local authorities, the reference that can be used is the RMP revised with the updated SmPC content.

"Annex 8.1 - The Patient Brochure will be updated upon national approval of the Summary of Product Characteristics (SmPC)"].

Please note that contents of this material can be used only if compliant with local laws and regulation.

Suspected adverse drug reactions (ADRs) should be reported to the Medicines Authority Post-Licensing Directorate, 203, Level 3, Rue D'Argens, Gzira GZR1368, Malta or at http://www.medicinesauthority.gov.mt/adrportal

Suspected adverse drug reactions may also be reported to AM Mangion Ltd via email to priligypv@ammangion.com.mt or tel (+356) 2397 6522 / (+356) 79373456

the MENARINI group