APPROPRIATE USE GUIDE

PRILIGY® is indicated for the treatment of premature ejaculation in adult men aged 18 to 64 years[1]*

PRILIGY® should only be prescribed to patients who meet all the following criteria:[1]

- An intravaginal ejaculatory latency time (IELT) of less than two minutes; and
- Persistent or recurrent ejaculation with minimal sexual stimulation before, on, or shortly after penetration and before the patient wishes; and
- Marked personal distress or interpersonal difficulty as a consequence of premature ejaculation; and
- Poor control over ejaculation; and
- A history of premature ejaculation in the majority of intercourse attempts over the prior 6 months

PRILIGY® should be administered only as on-demand treatment before anticipated sexual activity. PRILIGY® should not be prescribed to delay ejaculation in men who have not been diagnosed with premature ejaculation.

** For more information refer to the Summary of Product Characteristics.*

Simple recommendations for proper administration[1]*

Before treatment is initiated

A careful medical examination including history of orthostatic events should be performed by the physician. An orthostatic test should be performed before initiating therapy (blood pressure and pulse rate, supine and standing). **In case of a history of documented or suspected orthostatic reaction, treatment with PRILIGY® should be avoided**.

Initial prescription

The recommended starting dose for all patients is 30 mg, taken as needed approximately 1 to 3 hours prior to sexual activity. **Treatment with PRILIGY® should not be initiated with the 60 mg dose**. Inform and counsel the patient about the possibility of experiencing syncope at any time with or without prodromal symptoms during treatment with PRILIGY®, the importance of maintaining adequate hydration and about how to recognise prodromal signs and symptoms to decrease the likelihood of serious injury associated with falls due to loss of consciousness.

Continuation of treatment

In the clinical trials cases of syncope characterized as loss of consciousness, with bradycardia or sinus arrest observed in patients wearing Holter monitors, were considered vasovagal in etiology. Subjects with underlying cardiovascular disease were excluded from Phase 3 clinical trials. The risk of adverse cardiovascular outcomes from syncope (cardiac syncope and syncope from other causes) is increased in patients with underlying structural cardiovascular disease (e.g. documented outflow obstruction, valvular heart disease, carotid stenosis and coronary artery disease). There are insufficient data to determine whether this increased risk extends to vasovagal syncope in patients with underlying cardiovascular disease.

If the individual's response to 30 mg is insufficient and the patient has not experienced moderate or severe adverse reactions or prodromal symptoms suggestive of syncope, the dose may be increased to a **maximum recommended dose of 60 mg** taken as needed approximately 1 to 3 hours prior to sexual activity. The incidence and severity of adverse events is higher with the 60 mg dose. **If the patient experienced orthostatic reactions on the starting dose, no dose escalation to 60 mg should be performed**.

Follow-up

A careful appraisal of individual benefit/risk of PRILIGY® should be performed by the physician **after the first four weeks** of treatment (or at least after 6 doses of treatment) to determine whether continuing treatment with PRILIGY® is appropriate. The clinical need of continuing and the benefit risk balance of treatment with PRILIGY® should be **re-evaluated at least every six months**.

Appropriate use for optimal benefit[1]*

Important considerations for the following patients

- Patients receiving moderate CYP3A4 inhibitors – the maximum dose should be 30 mg and caution is advised.
- Patients known to be CYP2D6 poor metabolizers or patients concomitantly treated with potent CYP2D6 inhibitors – use with caution when increasing the dose to 60 mg.
- Patients being treated with drugs that affect platelet function or patients with a history of bleeding or clotting disorders – use with caution.
- Patients being treated with nitrates or alpha-adrenergic receptor antagonists, as concomitant use may reduce orthostatic tolerance - use with caution.
- Patients being treated with PDE-5 inhibitors – PRILIGY® should not be used, due to possible reduced orthostatic tolerance.
- Patients with unstable epilepsy – avoid use. Patients with controlled epilepsy should be carefully monitored and PRILIGY® should be discontinued in any patient who develops seizures.
- Patients with raised intraocular pressure or those at risk of angle closure glaucoma – use with caution.
- Patients with problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption – avoid use.

PRILIGY® is not recommended in patients with serious renal impairment and caution is advised in cases of mild to moderate renal impairment.

Do not administer PRILIGY® to patients with the following contraindications

- Hypersensitivity to the active substance or to any of the excipients.
- Significant pathological cardiac conditions such as:
  - Heart failure (NYHA class II-IV).
  - Conduction abnormalities such as AV block or sick sinus syndrome.
  - Significant ischemic heart disease.
  - Significant valvular disease.
  - A history of syncope.
- A history of mania or severe depression.
- Concomitant treatment with MAO inhibitors, thioridazine, SSRIs, SNRIs, tricyclic antidepressants, other products or herbal medicines with serotonergic effects and potent inhibitors of CYP3A4.
- Moderate or severe hepatic impairment.

** For more information refer to the Summary of Product Characteristics.*

Important patient information[1]*

Patients should be counselled to talk to their healthcare professional if signs of depression develop

Patients need to be made aware that they could experience syncope at any time with or without prodromal symptoms during their treatment with PRILIGY®

- Counsel patients about the importance of maintaining adequate hydration and about how to recognise prodromal signs and symptoms to decrease the likelihood of serious injury associated with falls due to loss of consciousness.
- If the patient experiences possible prodromal symptoms, the patient should immediately lie down so his head is lower than the rest of his body or sit down with his head between his knees until the symptoms pass. The patient should be cautioned to avoid situations where injury could result, including driving or operating hazardous machinery, should syncope or other CNS effects occur.

Patients should be advised not to use PRILIGY® in combination with alcohol

Combining alcohol with dapoxetine may increase alcohol-related neurocognitive effects and may also enhance neurocardiogenic adverse events such as syncope, thereby increasing the risk of accidental injury; therefore, patients should be advised to avoid alcohol while taking PRILIGY®.

Patients should be advised not to use PRILIGY® in combination with recreational drugs

Recreational drugs with serotonergic activity such as ketamine, methylenedioxymethamphetamine (MDMA) and lysergic acid diethylamide (LSD) may lead to potentially serious reactions if combined with PRILIGY®. These reactions include, but are not limited to, arrhythmia, hyperthermia, and serotonin syndrome. Use of PRILIGY® with recreational drugs with sedative properties such as narcotics and benzodiazepines may further increase somnolence and dizziness.

- **PRILIGY® is to be taken approximately 1 to 3 hours prior to sexual activity.**
- **PRILIGY® should be taken only when sexual activity is anticipated.**
- **PRILIGY® is recommended to be taken with at least one full glass of water.**
- **PRILIGY® is not intended for continuous daily use. PRILIGY® must not be taken more frequently than once every 24 hours.**

For Medical Information please contact
A. Menarini Pharmaceuticals Ireland Ltd on 1800 283045.

Reporting of side effects

A. Menarini Pharmaceuticals encourages healthcare professionals to continue to be vigilant and to report suspected adverse reactions occurring with PRILIGY® to the Health Products Regulatory Authority by phone on +353 (1) 676 4971 or email at medsafety@hpra.ie (online at www.hpra.ie). In addition, this information may be reported to A. Menarini Pharmaceuticals via telephone at 1800 283 045 or via email at Ireland@menarini.ie.

Priligy 30 mg and 60 mg film-coated tablets Abbreviated Prescribing Information

Please consult the Summary of Product Characteristics (SPC) for full prescribing information. **Presentation:** Film-coated tablets containing dapoxetine hydrochloride equivalent to 30 mg or 60 mg dapoxetine. Contains lactose. **Use:** Treatment of premature ejaculation (PE) in adult men aged 18 to 64 years. Only for prescription to patients who meet all the following criteria: intravaginal ejaculatory latency time of less than two minutes; persistent or recurrent ejaculation with minimal sexual stimulation before, on, or shortly after penetration and before patient wishes; marked personal distress or interpersonal difficulty as a consequence of PE; poor control over ejaculation; and history of premature ejaculation in the majority of intercourse attempts over the prior 6 months. **Dosage:** Oral administration. Tablets should be swallowed whole with at least one full glass of water. Before treatment perform a careful medical examination including history of orthostatic events and orthostatic test (blood pressure and pulse rate, supine and standing). Adult men: Recommended starting dose 30 mg, taken as needed, approximately 1 to 3 hours prior to sexual activity. Not to be taken more frequently than once every 24 hours. If response to 30 mg insufficient and no moderate or severe adverse reactions or prodromal symptoms suggestive of syncope experienced, dose may be increased to a maximum recommended dose of 60 mg. Incidence and severity of adverse events is higher with the 60 mg dose. If orthostatic reactions experienced on starting dose, do not increase dose to 60 mg. Perform careful appraisal of individual benefit risk after the first four weeks (or at least after 6 doses). Clinical need for continuing and benefit risk balance should be re-evaluated at least every six months. No data in patients over 65. **Contra-indications:** Hypersensitivity to active substance or excipients, significant pathological cardiac conditions e.g. heart failure, conduction abnormalities, significant ischaemic heart disease, significant valvular disease, history of syncope. History of mania or severe depression. Concomitant treatment with MAOIs, thioridazine, SSRIs, SNRIs, tricyclic antidepressants or other medicinal/herbal products with serotonergic effects or within 14 days of discontinuing treatment of same. Do not administer an MAOI, thioridazine, SSRIs, SNRIs, tricyclic antidepressants or other medicinal/herbal products with serotonergic effects within 7 days after discontinuing Priligy. Concomitant treatment of potent CYP3A4 inhibitors. Moderate or severe hepatic impairment. **Warnings and Precautions:** Only indicated in men with PE who meet all the criteria listed under Use. Carefully investigate other forms of sexual dysfunction, including erectile dysfunction (ED) before treatment. Do not use in men who are using PDE5 inhibitors. Avoid treatment in men with history of documented or suspected orthostatic reaction. Advise patients in advance of possible prodromal symptoms and how to deal with, also inform patient not to rise too quickly after prolonged lying or sitting. Risk of suicide/suicidal thoughts, however no clear evidence in clinical trials. Caution patients to avoid situations where injury could result should syncope or prodromal symptoms occur. Patients with cardiovascular risk factors. Caution patients not to use with recreational drugs. Caution with medicinal products with vasodilatation properties. Do not use in mania and discontinue if symptoms develop. Discontinue in patients who develop seizures and avoid in unstable epilepsy. Carefully monitor patients with controlled epilepsy. Evaluate men with depression signs/symptoms before treatment, concomitant treatment with anti-depressants contra-indicated, not recommended to discontinue ongoing depression or anxiety treatment to start Priligy, not to be used in psychiatric disorders, encourage patients to report distressing thoughts/feelings, discontinue Priligy if signs/symptoms of depression develop during treatment. Caution in patients taking medicinal products known to affect platelet function or anti-coagulants, history of bleeding or coagulation disorders. Do not use in severe renal impairment, caution in mild or moderate renal impairment. Mild withdrawal effects. Caution in patients with raised intraocular pressure or risk of angle closure glaucoma. Do not give to patients with galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption. **Interactions:** Potential for interaction with MAOIs, thioridazine, medicinal/herbal products with serotonergic effects (see contra-indications). Caution with CNS active medicinal products. Do not use with potent CYP3A4 inhibitors, maximum dose of 30 mg with moderate CYP3A4 inhibitors, potent CYP2D6 inhibitors (caution if increasing dose to 60 mg), PDE5 inhibitors, tamsulosin, medicinal products metabolized by CYP2D6, CYP3A4, CYP2C19, CYP2C9, warfarin and medicinal products known to affect coagulation and/or platelet function, alcohol. Please consult the SPC for more details and other interactions. **Side-effects:** Very common (>10%): dizziness, headache, nausea. Common (1-10%): anxiety, agitation, restlessness, insomnia, abnormal dreams, libido decreased, somnolence, disturbance in attention, tremor, paraesthesia, vision blurred, tinnitus, flushing, sinus congestion, yawning, diarrhoea, vomiting, constipation, abdominal pain, dyspepsia, flatulence, stomach discomfort, abdominal distension, dry mouth, hyperhidrosis, erectile dysfunction, fatigue, irritability, blood pressure increased. For Uncommon and Rare Side-effects see SPC. **Legal category:** POM. **Marketing Authorisation Number:** PA 1833/1/1-2. **Marketing Authorisation Holder:** A. Menarini Pharmaceuticals Ireland Ltd., Castlecourt, Monkstown Farm, Monkstown, Glenageary, Co. Dublin. Further information is available on request to the Marketing Authorisation Holder or may be found in the SPC. **Last updated:** April 2014.

References:

1. PRILIGY® Summary of Product Characteristics. March 2014.

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