Package Leaflet: Information for the user

Priligy 30 mg film–coated tablets
Priligy 60 mg film–coated tablets
dapoxetine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Priligy is and what it is used for
2. What you need to know before you take Priligy
3. How to take Priligy
4. Possible side effects
5. How to store Priligy
6. Contents of the pack and other information

1. What Priligy is and what it is used for

Priligy contains an active substance called ‘dapoxetine’. This belongs to a group of medicines called ‘selective serotonin reuptake inhibitors’ (SSRIs). Priligy may also be known as a ‘urological’ medicine.

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.

Priligy is used to treat premature ejaculation in adult men aged 18 to 64 years.

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.

2. What you need to know before you take Priligy

Do not take Priligy

- if you are allergic to dapoxetine or any of the other ingredients of this medicine (listed in section 6)
- if you have heart problems, such as heart failure or problems with the heart rhythm
- if you have a history of fainting
- if you have ever had mania (symptoms include feeling over–excited, irritable or not being able to think clearly) or severe depression
- if you are taking:
  - Medicines for depression called ‘monoamine oxidase inhibitors’ (MAOIs)
  - Thioridazine used for schizophrenia
  - Other medicines for depression
  - Lithium – a medicine for bipolar disorder
  - Linezolid – an antibiotic used to treat infections

- Tryptophan – a medicine to help you sleep
- St John's wort – an herbal medicine
- Tramadol – used to treat serious pain
- Medicines used to treat migraines.

Do not take Priligy at the same time as any of the medicines listed above. If you have taken any of these medicines, you will need to wait 14 days after you stop taking it before you can start taking Priligy. Once you have stopped taking Priligy, you will need to wait 7 days before taking any of the medicines listed above. If you are not sure about what to do, talk to your doctor or pharmacist before taking this medicine. (see section "**Other medicines and Priligy**")

- Certain medicines for fungal infection, including ketoconazole and itraconazole (see section "**Other medicines and Priligy**")
- Certain medicines for HIV, including ritonavir, saquinavir, nelfinavir and atazanavir (see section "**Other medicines and Priligy**")
- Certain antibiotics for treating infection, including telithromycin (see section "**Other medicines and Priligy**")
- Nefazodone – an antidepressant (see section "**Other medicines and Priligy**")

- If you have moderate or severe liver problems.

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking this medicine.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Priligy if:

- You have not been diagnosed with premature ejaculation
- You also have another sexual problem, such as erectile dysfunction
- You have a history of dizziness from low blood pressure
- You use recreational drugs such as ecstasy, LSD, narcotics or benzodiazepines
- You drink alcohol (see section "**Priligy with food, drink and alcohol**")
- You have ever had a mental health problem such as depression, mania (symptoms include feeling over–excited, irritable or not being able to think clearly), bipolar disorder (symptoms include serious mood swings between mania and depression) or schizophrenia (a psychiatric disease)
- You have epilepsy
- You have a history of bleeding or blood clotting problems
- You have kidney problems
- You have, or are at risk of, high pressure in the eye (glaucoma).

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking this medicine.

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 lying down.

Children and adolescents

<u>This medicine should not be used in children or adolescents under age 18 years.</u>

Other medicines and Priligy

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. This includes medicines you get without a prescription, such as herbal medicines. This is because Priligy can affect the way some other medicines work. Also some other medicines can affect the way Priligy works. Therefore, use of other medicines may affect the maximum dose of Priligy you're allowed to take.

Do not take Priligy at the same time as any of the following medicines:

- Medicines for depression called 'monoamine oxidase inhibitors' (MAOIs)
- Thioridazine used for schizophrenia
- Other medicines for depression
- Lithium – a medicine for bipolar disorder
- Linezolid – an antibiotic used to treat infections
- Tryptophan – a medicine to help you sleep
- St John's wort – an herbal medicine
- Tramadol – used to treat serious pain
- Medicines used to treat migraines.

Do not take Priligy at the same time as any of the medicines listed above. If you have taken any of these medicines, you will need to wait 14 days after you stop taking it before you can start taking Priligy. Once you have stopped taking Priligy, you will need to wait 7 days before taking any of the medicines listed above. If you are not sure about what to do, talk to your doctor or pharmacist before taking this medicine.

- Certain medicines for fungal infection, including ketoconazole and itraconazole
- Certain medicines for HIV, including ritonavir, saquinavir, nelfinavir and atazanavir
- Certain antibiotics for treating infection, including telithromycin
- Nefazodone – an antidepressant.

Tell your doctor or pharmacist if you are taking any of the following medicines:

- Medicines for mental health problems other than depression
- Non–steroidal anti–inflammatory medicines such as ibuprofen or acetylsalicyclic acid
- Medicines to thin your blood, such as warfarin
- Certain medicines used to treat erectile dysfunction, such as sildenafil, tadalafil or vardenafil, as these medicines may lower your blood pressure, possibly upon standing
- Certain medicines used to treat high blood pressure and chest pain (angina) (such as verapamil and diltiazem), or enlarged prostate, as these medicines may also lower your blood pressure, possibly upon standing
- Certain other medicines for fungal infection, such as fluconazole
- Certain other medicines for HIV, such as amprenavir and fosamprenavir
- Certain other antibiotics for treating infection, such as erythromycin and clarithromycin
- Aprepitant – used to treat nausea.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking this medicine.

Priligy with food, drink and alcohol

- Do not drink grapefruit juice within 24 hours prior to taking this medicine as this can increase the level of this medicine in your body.
- This medicine can be taken with or without food.
- You should take this medicine with at least one full glass of water.
- Avoid alcohol when taking this medicine.
- The effects of alcohol such as feeling dizzy, sleepy and having slow reactions, may be increased if taken with this medicine.
- Drinking alcohol while taking this medicine may increase your risk of injury from fainting or from other side effects.

Pregnancy, breast–feeding and fertility

This medicine should not be taken by women.

Driving and using machines

You may feel sleepy, dizzy, faint, have difficulty concentrating and blurred vision while taking this medicine. If you experience any of these or similar effects, you should avoid driving or operating hazardous machinery. The effects of alcohol may be increased if taken with this medicine and you may be more at risk of injury from fainting or from other side effects if you take this medicine with alcohol.

Priligy contains lactose

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 medicinal product.

Priligy contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium free'.

3. How to take Priligy

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- The recommended dose is 30 mg. Your doctor may increase the dose to 60 mg.
- Only take the medicine 1 to 3 hours before sexual activity is anticipated.
- **Do not take this medicine more than once every 24 hours or every day.**
- Swallow the tablets whole to avoid a bitter taste, with at least one full glass of water. This may help lower your chance of fainting (see 'Fainting and low blood pressure' in section 4).
- This medicine can be taken with or without food.
- This medicine should not be used by either men under the age of 18 or men 65 years or older
- Discuss your Priligy treatment with your doctor after the first 4 weeks or after 6 doses to see whether you should continue treatment. If treatment is continued, you should see your doctor again to discuss this at least every six months.

If you take more Priligy than you should

Tell your doctor or pharmacist if you have taken more tablets than you should. You may feel sick or be sick.

If you stop taking Priligy

Talk to your doctor before you stop taking this medicine. You may have problems sleeping and feel dizzy after you stop taking this medicine, even if you have not taken it every day.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

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.

Fainting and low blood pressure

This medicine can make you faint or make your blood pressure drop when you stand up. To help lower the chance of this happening:

- Take this medicine with at least one full glass of water.
- Do not take this medicine if you are dehydrated (you do not have enough water in your body).

This can happen if:

- You have not had anything 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.

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

Very common side effects (may affect more than 1 in 10 men):

- Feeling dizzy
- Headache
- Feeling sick.

Common side effects (may affect up to 1 in 10 men):

- Feeling irritable, anxious, agitated or restless
- Feeling numb or having 'pins and needles'
- Difficulty getting or keeping an erection
- Sweating more than normal or flushing
- Diarrhoea, constipation or having wind
- Stomach pain, bloating or being sick
- Problems sleeping or strange dreams
- Feeling tired or sleepy, yawning
- Blocked nose (nasal congestion)
- A rise in blood pressure
- Difficulty concentrating
- Shaking or trembling
- Lower interest in sex
- Ringing in the ears
- Blurred vision
- Indigestion
- Dry mouth.

Uncommon side effects (may affect up to 1 in 100 men):

- Fainting or feeling dizzy upon standing (see advice above)
- Change in mood, feeling overly excited or feelings of paranoia
- Feeling confused, disoriented or unable to think clearly
- Slow or irregular heartbeat or increase in heart rate
- Loss of sex drive, problems reaching orgasm
- Feeling weak, sedated, lethargic or fatigued
- Feeling depressed, nervous or indifferent
- Feeling hot, jittery, abnormal or drunk

- Vision problems, eye pain or dilated pupils
- Low or high blood pressure
- Feeling itchy or cold sweat
- Spinning sensation
- Abnormal taste
- Teeth grinding.

Rare side effects (may affect up to 1 in 1,000 men):

- Feeling dizzy following exertion
- Sudden onset of sleep
- Urgency of bowel action.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.
You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Ireland
HPRA Pharmacovigilance
Website: www.hpra.ie

Malta
ADR Reporting
Website: www.medicinesauthority.gov.mt/adrportal

5. How to store Priligy

- This medicinal product does not require any special storage conditions.
- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Priligy contains

The active substance is dapoxetine. Each tablet contains 30 mg or 60 mg dapoxetine as a hydrochloride salt.

The other ingredients are:
- Tablet core: lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, colloidal anhydrous silica, magnesium stearate.
- Tablet coating: lactose monohydrate, hypromellose, titanium dioxide (E171), triacetin, Iron Oxide Black (E172), Iron Oxide Yellow (E172).

What Priligy looks like and contents of the pack

- Priligy 30 mg film−coated tablets are light grey, round, convex, approximately 6.5 mm in diameter and debossed with “30” inside a triangle on one side.
- Priligy 60 mg film−coated tablets are grey, round, convex, approximately 8 mm in diameter and debossed with “60” inside a triangle on one side.

The tablets are provided in blister packs containing 1, 2, 3 and 6 film-coated tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Phoenix Labs Unlimited Company
Suite 12, Bunkilla Plaza
Bracetown Business Park
Clonee, County Meath
Ireland

Manufacturer
Menarini - Von Heyden GmbH, Leipziger Strasse 7-13, 01097 Dresden, Germany

This medicinal product is authorised in the Member States of the EEA under the following names:
Austria, Belgium, Bulgaria, Croatia**,** Cyprus, Czech Republic, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, United Kingdom (Northern Ireland): Priligy

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