

Package leaflet: information for the user

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

Read the entire 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.

Do you have any questions? Please contact your doctor, pharmacist, or nurse.

Do not pass this medicine on to others, as it has been prescribed for you only. It may harm them, even if their symptoms are the same as yours.

Do you experience a lot of side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor, pharmacist, or nurse.

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1. What is Priligy and what is it used for?

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

Priligy delays the time it takes to ejaculate and can improve control over ejaculation. This can reduce the frustration or worry about rapid ejaculation.

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

Premature ejaculation means that a man ejaculates with minimal sexual stimulation and before he wants to. This can be difficult for the man and can cause problems in sexual relationships.

2. When should you not use this medicine or be extra careful with it?

When should you not use this medicine?

You are allergic to dapoxetine or any of the other ingredients in this medicine. You can find these ingredients in section 6 of this leaflet.

You have heart problems, such as heart failure or arrhythmias.

You have fainted in the past.

You have ever had mania (symptoms include feeling excessively excited, irritable, or unable to think clearly) or severe depression.

You are using:

- medicines for depression from the group 'monoamine oxidase inhibitors' (MAO inhibitors)
- thioridazine for the treatment of schizophrenia
- other antidepressants
- lithium a medicine used in bipolar disorder
- linezolid an antibiotic to treat infections
- tryptophan a medicine to sleep better
- St. John's wort a herbal medicine
- tramadol for the treatment of severe pain
- medicines for the treatment of migraine

Do not take Priligy simultaneously with any of the medicines mentioned above. If you have used any of these medicines, you must wait 14 days after stopping before you can start with Priligy. After stopping Priligy, you must wait 7 days before you can use any of the medicines mentioned above. If you are unsure what to do, ask your doctor or pharmacist before taking this medicine (see section Are you taking any other medicines?).

- certain medicines for the treatment of fungal infections, including ketoconazole and itraconazole (see section Are you taking any other medicines?)
- certain medicines for the treatment of HIV, including ritonavir, saquinavir, nelfinavir, and atazanavir (see section Are you taking any other medicines?)
- certain antibiotics for the treatment of infections, including telithromycin (see section
- Are you taking any other medicines?)
- nefazodone an antidepressant (see section Are you taking any other medicines?)
- You have moderate or severe liver problems

Do not use this medicine if any of the above situations apply to you. If you are in doubt, contact your doctor or pharmacist before using this medicine.

When should you be extra careful with this medicine?

Contact your doctor, pharmacist, or nurse before taking Priligy in any of the following cases:

- your doctor has not determined that you suffer from premature ejaculation
- you also have another sexual problem such as erectile dysfunction
- you have previously experienced dizziness due to low blood pressure
- you use (party) drugs such as ecstasy, LSD, narcotics, or benzodiazepines
- you drink alcohol (see section What to consider with food, drink, and alcohol?)
- you have ever suffered from a mental disorder such as depression, mania (where you are excessively excited or irritable or cannot think clearly), bipolar disorder (symptoms include severe mood swings between mania and depression), or schizophrenia (a psychiatric disorder)
- you have epilepsy
- you have had bleeding or blood clotting problems in the past

you have kidney problems  
you have high pressure in your eye (glaucoma) or you are at risk for it

If any of the above situations apply to you (or if you are in doubt), contact your doctor or pharmacist before taking this medicine.

Before you start using this medicine, your doctor should check whether your blood pressure does not drop too much when you stand up from a lying position.

Children and adolescents under 18 years  
This medicine should not be used in children or adolescents under 18 years.

Are you taking any other medicines?

Are you taking any other medicines besides Priligy, have you done so recently, or are you planning to do so soon? Then tell your doctor or pharmacist. This also applies to medicines for which you do not need a prescription, such as herbal medicines. This is because Priligy can affect the action of certain medicines. Conversely, other medicines can also affect the action of Priligy. Therefore, the use of other medicines can affect the maximum dose of Priligy you are allowed to take.

Do not take Priligy simultaneously with any of the following medicines:

antidepressants from the group 'monoamine oxidase inhibitors' (MAO inhibitors)  
thioridazine for the treatment of schizophrenia  
other antidepressants  
lithium a medicine used in bipolar disorder  
linezolid an antibiotic to treat infections  
tryptophan a medicine that helps you sleep better  
St. John's wort a herbal remedy  
tramadol for the treatment of severe pain  
medicines for the treatment of migraine

Do not take Priligy simultaneously with any of the medicines mentioned above. If you have used any of these medicines, you must wait 14 days after stopping before you can start taking Priligy. After stopping Priligy, you must wait 7 days before you can use any of the medicines mentioned above. If you are unsure what to do, consult your doctor or pharmacist before taking this medicine.

certain medicines for the treatment of fungal infections, including ketoconazole and itraconazole  
certain medicines for the treatment of HIV, including ritonavir, saquinavir, nelfinavir, and atazanavir  
certain antibiotics for the treatment of infections, including telithromycin  
nefazodone an antidepressant

Consult your doctor or pharmacist if you are using any of the following medicines:

medicines for mental disorders other than depression  
non-steroidal anti-inflammatory drugs such as ibuprofen or acetylsalicylic acid  
medicines that 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 when you stand up  
certain medicines used for the treatment of high blood pressure and chest pain (angina) (for example, verapamil and diltiazem), or an enlarged prostate, as these medicines may also lower your blood pressure when you stand up  
certain other medicines for the treatment of fungal infections, such as fluconazole  
certain other medicines for the treatment of HIV, such as amprenavir and fosamprenavir  
certain other antibiotics for the treatment of infections, such as erythromycin and clarithromycin  
aprepitant used against nausea

If you are not sure whether the above applies to you, consult your doctor or pharmacist before taking this medicine.

What should you pay attention to with food, drink, and alcohol?

Do not drink grapefruit juice within 24 hours prior to using this medicine, as it may increase the level of this medicine in your body.  
You can take this medicine with or without food.  
You should take this medicine with at least one full glass of water.  
Avoid alcohol when using this medicine.  
The effects of alcohol such as dizziness, drowsiness, and slow reactions may be stronger when using this medicine.  
If you drink alcohol while using this medicine, the chance of injuring yourself from fainting or other side effects increases.

Pregnancy, breastfeeding, and fertility

Women should not use this medicine.

Driving and using machines

If you use this medicine, you may feel drowsy, dizzy, or light-headed, have difficulty concentrating, and experience blurred vision. If you experience these or similar effects, do not drive or use dangerous machines. The effects of alcohol may be stronger when used with this medicine, and the risk of injury from fainting or other side effects may increase if you use this medicine and alcohol simultaneously.

Priligy contains lactose

This medicine contains lactose (a type of sugar). If your doctor has told you that you cannot tolerate certain sugars, contact your doctor before taking this medicine.

Priligy contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, meaning it is essentially 'sodium-free'.

### 3. How do you use this medicine?

Always use this medicine exactly as your doctor or pharmacist has told you. Are you unsure about the correct use? Then contact your doctor or pharmacist.

The recommended dose is 30 mg. Your doctor may increase the dose to 60 mg. Take the medicine only 1 to 3 hours before you expect sexual activity. Do not take this medicine more than once every 24 hours or every day. Swallow the tablets whole (otherwise they taste bitter) with at least one full glass of water. This reduces the 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 men younger than 18 years or men 65 years or older. Discuss your Priligy treatment with your doctor after the first 4 weeks or after 6 doses, to see if you should continue the treatment. If you continue the treatment, you should see your doctor at least every 6 months to discuss this.

Have you taken too much of this medicine?

Contact your doctor or pharmacist if you have taken more tablets than you should. You may feel nauseous or need to vomit.

If you stop using this medicine

Contact your doctor before stopping this medicine. You may experience sleep problems or feel dizzy after stopping this medicine, even if you did not use it every day.

Do you have any other questions about the use of this medicine? Then contact your doctor, pharmacist, or nurse.

### 4. Possible side effects

Like all medicines, this medicine can cause side effects. Not everyone experiences them.

Stop taking Priligy immediately in the following cases and contact your doctor immediately:

- you have seizures (epileptic fits)
- you faint or feel light-headed when standing up
- you notice changes in your mood
- you think about suicide or harming yourself

If you notice any of the above symptoms in yourself, stop using this medicine and contact your doctor immediately.

## Fainting and low blood pressure

This medicine can cause you to faint or your blood pressure to drop when you stand up. The following measures can help reduce the risk of this:

- take this medicine with at least one full glass of water
- do not use this medicine if you are dehydrated (if you do not have enough water in your body) This may be the case

- if you have not drunk anything in the past 4 to 6 hours
- if you have been sweating for a long time
- if you are ill, with fever, diarrhea, or vomiting

if you feel like you are going to faint (for example, if you feel nauseous or dizzy, feel lightheaded or confused, are sweaty, or have an abnormal heartbeat), or if you feel lightheaded when you stand up, lie down immediately (so that your head is lower than the rest of your body), or sit with your head between your knees until you feel better. This way you cannot fall and injure yourself if you faint.

do not stand up quickly if you have been sitting or lying down for a long time

do not drive or use machines or tools if you feel lightheaded when using this medicine

contact your doctor if you faint while using this medicine

Side effects that are very common (may occur in more than 1 in 10 men):

dizziness  
headache  
nausea

Side effects that are common (may occur in up to 1 in 10 men):

irritability, anxiety, excitement, or restlessness  
numbness or tingling sensation  
difficulty getting or maintaining an erection  
sweating more than usual or flushing  
diarrhea, constipation, or flatulence  
stomach pain, bloating, or vomiting  
sleep problems or strange dreams  
feeling tired or sleepy, yawning  
a blocked nose (nasal congestion)  
increase in blood pressure  
difficulty concentrating  
shaking or trembling  
reduced libido  
ringing in the ears  
blurred vision  
digestive problems  
dry mouth

Side effects that sometimes occur (can occur in up to 1 in 100 men):

fainting or feeling dizzy when standing up (see advice above)

mood changes, feeling overly excited, or paranoid thoughts  
feeling confused or disoriented or unable to think clearly  
slow or irregular heartbeat or faster heartbeat  
no libido, difficulty achieving orgasm  
a weak, sleepy, lethargic or tired feeling  
a depressed, nervous or indifferent feeling  
a hot, nervous, abnormal or drunk feeling  
difficulty seeing, eye pain or dilated pupils  
low or high blood pressure  
feeling of itchiness or clammy sweat  
dizzy feeling  
strange taste  
teeth grinding

Side effects that rarely occur (may occur in up to 1 in 1,000 men):

dizziness after exertion  
suddenly falling asleep  
urgent bowel movements

#### Reporting side effects

If you experience side effects, contact your doctor, pharmacist, or nurse. This also applies to side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb, Website: [www.lareb.nl](http://www.lareb.nl). By reporting side effects, you help us gather more information about the safety of this medicine.

#### 5. How to store this medicine?

There are no special storage conditions for this medicine.

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. You can find it on the packaging after EXP. It includes a month and a year. The last day of that month is the expiry date.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. Proper disposal of medicines ensures they are destroyed correctly and do not enter the environment.

#### 6. Contents of the package and other information What substances are in this medicine?

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

The other substances in this medicine are:

core of the tablet: lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, colloidal anhydrous silica, magnesium stearate  
coating of the tablet: lactose monohydrate, hypromellose, titanium dioxide (E171), triacetin, black iron oxide (E172), yellow iron oxide (E172).

What does Priligy look like and how much is in a package?

Priligy 30 mg film-coated tablets are light gray, round, convex, with a diameter of approximately 6.5 mm and one side is marked with '30' in a triangle.

Priligy 60 mg film-coated tablets are gray, round, convex, with a diameter of approximately 8 mm and one side is marked with '60' in a triangle.

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

Marketing authorization holder and manufacturer Marketing authorization holder  
Phoenix Labs Unlimited Company,  
Suite 12, Bunkilla Plaza,  
Bracetown Business Park,  
Clonee, Co. Meath,  
Ireland

#### Manufacturer

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

#### Registration numbers

Priligy 30 mg: RVG 108199

Priligy 60 mg: RVG 108200

This medicine is registered in EEA member states under the following names: Belgium, Bulgaria, Cyprus, Germany, Estonia, Finland, France, Greece, Hungary, Ireland, Italy, Croatia, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Austria, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Czech Republic, United Kingdom (Northern Ireland), Sweden: Priligy

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