

Priligy 60mg and 30mg Film Coated Tablets

Dapoxetine Hydrochloride (60mg & 30mg)

What is in this leaflet

1. What Priligy is used for
2. How Priligy works
3. Before you use Priligy
4. How to use Priligy
5. While you are using it
6. Side effects
7. Storage and Disposal of Priligy
8. Product Description
9. Manufacturer
10. Product Registration holder

What Priligy is used for

PRILIGY is indicated for the treatment of premature ejaculation (PE) in men 18 to 64 years of age, who have all of the following:

- An intravaginal ejaculatory latency time (IELT) of less than two minutes
- Persistent or recurrent ejaculation with minimal sexual stimulation before, on, or shortly after penetration and before the patient wishes
- Marked personal distress or interpersonal difficulty as a consequence of PE
- Poor control over ejaculation

How Priligy works

PRILIGY containing the active ingredients dapoxetine, is a type of drug called a selective serotonin reuptake inhibitor (SSRI) and belongs to a group of drugs known as other urologicals. PRILIGY increases your time to ejaculation and can improve your control over ejaculation and reduce your distress over how fast you ejaculate. This may improve your satisfaction with sexual intercourse.

Before you use Priligy

When you must not use it

Do not take Priligy if you have an allergy to:

- Any medicine containing dapoxetine
- Any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include rash, itching, or hives on the

skin, shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body.

Do not take Priligy:

- If you are taking a MAOI (monoamine oxidase inhibitor) used to treat depression, or have taken a MAOI within the last 14 days.
- If you are taking thioridazine used to treat schizophrenia, or have taken thioridazine within the last 14 days.
- If you are taking a selective serotonin reuptake inhibitor (SSRI), other medicines used to treat depression or other medicinal/herbal products with serotonergic effects (St.John's Wort), or have taken these medicines within the last 14 days.
- If you are a woman. Safety and effectiveness in women have not been established.
- If you have heart problems, such as heart failure or problems with the heart rhythm.
- If you have moderate to severe liver problem.
- If you are under 18 years of age, or over 65 years of age.
- If you have rare hereditary problems of galactose intolerance, total lactase deficiency or glucose–galactose malabsorption

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Eusure that you have been diagnosed with premature ejaculation by your physician.

Tell your doctor if you are taking any other drugs including the use of recreational drugs such as ecstasy, lysergic acid diethylamide (LSD), narcotics, or benzodiazepines.

Tell your doctor if you have or have had any of the following medical conditions:

- History of dizziness from low blood pressure
- Heart and blood vessel problems
- Bleeding tendencies

- Depression
- Psychiatric disease, such as schizophrenia (severe brain disorders)
- History of mania (great excitement, hallucinations, difficulty in concentrating or staying still) or bipolar disorder (extreme mood swings) or develop these disorders
- Seizures (fits) or have uncontrolled epilepsy
- Severe liver or kidney problems
- Eye disorders such as raised intraocular pressure. It may worsen Angle-closure glaucoma (high pressure in the eye that can lead to blindness)

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines you buy without a prescription from a pharmacy, supermarket or health food shop.

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

- MAOIs (monoamine oxidase inhibitors) used to treat depression, such as moclobemide, phenelzine and tranylcypromine
- Selective serotonin reuptake inhibitor (SSRI) or other medicines used to treat depression.
- Thioridazine used to treat schizophrenia
- Medicines for fungal infections, including ketoconazole itraconazole and fluconazole

These medicines may be affected by PRILIGY or may affect how well it works., You may need different amounts of your medicines or you may need to take different medicines.

How to use Priligy

How much to take

The usual dose is 30mg, taken when you need it about 1 to 3 hours before sexual activity. Your doctor may increase the dose to 60mg.

Do not exceed takings a single tablet in 24 hours.

Swallow the tablets whole with at least one full glass of water.

PRILIGY may be taken with or without food.

When to take it

Take the tablet when you need it about 1 to 3 hours before sexual activity.

Do not take more than one tablet once every 24 hours due to increased risk of side effects and lack of additional benefit.

How long to take it

Always take Priligy exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

If you forget to take it

As PRILIGY is only taken when needed, it is not a problem if you forget to take it.

If you take too much (overdose)

Immediately telephone your doctor for advice or go to Accident and Emergency at your nearest hospital if you think you or anyone else may have taken too much Priligy. Do this even if there are no sign of discomfort or poisoning. You may need urgent medical attention.

While you are using Priligy

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

- Take Priligy with at least one full glass of water
- Do not take Priligy if you are dehydrated. 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

Patients need to be made aware that they could experience syncope at any time with or without prodromal symptoms during their treatment with PRILIGY®. These symptoms include nausea, dizziness, lightheadedness, palpitations, asthenia, confusion, and diaphoresis.

Things you must do

If you are about to be started on any new medicine, remind your doctor and

pharmacist that you are taking PRILIGY.

Things you must not do

Do not take PRILIGY to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

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.

PRILIGY should not be taken if you are using PDE5 inhibitors.

Avoid alcohol when taking PRILIGY

- Combining Priligy with alcohol may increase the chance of fainting and may also increase alcohol-related effects.

Things to be careful of

Use with 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 stop you from falling and hurting yourself if you do faint.
- Avoid driving or operating hazardous machinery if you feel affected in this way

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking PRILIGY

Stop taking PRILIGY and see your doctor right 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

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- nausea
- headache

- dizziness

Tell your doctor as soon as possible if you notice any of the following:

- fainting or feeling dizzy upon standing
- increased blood pressure
- trembling
- tingling or numbness
- blurred vision
- eye pain
- ringing in the ears
- nasal congestion
- diarrhoea, abdominal pain, dry mouth, vomiting, ingestion, constipation, bloating
- excessive sweating
- fatigue, sleepiness and yawning
- difficulty paying attention and feeling irritable
- erectile dysfunction (difficulty getting or keeping an erection)
- difficulty sleeping
- anxiety, nervousness, decreased sexual desire, depression,
- indifference
- abnormal dreams

Signs of allergy may include the following symptoms such as rash, itching or hives on the skin; shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body.

You may report any side effects or drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring visiting the website npra.gov.my (Consumers→ Reporting Side Effect to Medicines (ConSERF) or Vaccines (AEFI))

Storage and Disposal of Priligy

Storage

Keep your tablets in a cool dry place where the temperature stays below 30°C.

Do not store PRILIGY or any other medicine in the bathroom or near a sink.

Do not leave it on a window sill or in the car.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description**What it looks like**

Priligy Tablets are round, convex, film-coated tablets.

30mg: grey tablets debossed with “30” inside a triangle on one side.

60mg: grey tablets debossed with “60” inside a triangle on one side.

Date of revision

31 May 2022

Serial Number:

NPRA (R1/3) 05072022/215

Ingredients**Active ingredients**

Each PRILIGY 30 mg film-coated tablet contains 30 mg of dapoxetine base (33.60 mg dapoxetine hydrochloride).

Each PRILIGY 60 mg film-coated tablet contains 60 mg of dapoxetine base (67.20 mg dapoxetine hydrochloride).

Inactive ingredients**Tablet core**

- Lactose monohydrate
- Microcrystalline cellulose
- Croscarmellose sodium
- Colloidal anhydrous silica
- Magnesium stearate

Tablet coating

- Lactose monohydrate
- Hypromellose
- Titanium dioxide (E171)
- Triacetin
- Black iron oxide (E172)
- Yellow iron oxide (E172)

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

MAL number:

PRILIGY 30mg: MAL20102027AZ

PRILIGY60mg: MAL20102028AZ

Manufacturer

Menarini-Von Heyden GmbH
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Product Registration Holder:

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