

PRILIGY[®] Tablets

dapoxetine hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about PRILIGY tablets. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given PRILIGY against the benefits this medicine is expected to have for you.

If you have any concerns about taking PRILIGY ask your doctor.

Keep this leaflet while you are taking PRILIGY. You may need to read it again.

What PRILIGY is used for

PRILIGY is a treatment for men 18 to 64 years old with frequent premature ejaculation (PE), which troubles the man and affects the relationship with his sexual partner. PE is a common sexual disorder in which ejaculation happens with minimal sexual stimulation before, on, or shortly after penetration, and before the man wishes it.

PRILIGY, containing the active ingredient 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.

Ask your doctor if you have any questions about why PRILIGY has been prescribed for you.

This medicine is available only with a doctor's prescription.

Before you take PRILIGY

When you must not use it:

Do not take PRILIGY if you are allergic 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.

- If you are taking a MAOIs (monoamine oxidase inhibitors) used to treat depression, or have taken a MAOIs within the last 14 days.
- If you are taking thioridazine used to treat schizophrenia, or have taken thioridazine within the last 14 days.

Do not take PRILIGY if you have heart problems, such as heart failure or problems with the heart rhythm.

Do not take PRILIGY if you have moderate to severe liver problems

Do not take PRILIGY if you are under 18 years of age, or over 65 years of age.

Safety and effectiveness in patients under 18 years or over 65 years have not been established.

Do not take PRILIGY if you are a woman.

Safety and effectiveness in women have not been established.

Do not take PRILIGY after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to use it:

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

Tell your doctor if you have not been diagnosed with premature ejaculation.

Tell your doctor if you use recreational drugs such as ecstasy, LSD, narcotics, or benzodiazepines.

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

- History of dizziness from low blood pressure
- Heart and blood vessel problems
- Bleeding tendencies
- Depression
- Psychiatric disease, such as schizophrenia
- 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

Taking other medicines:

PRILIGY might interact with other medicines. Tell your doctor if you are taking any other medicines, including medicines you can 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 (Aurix®[®], Nardil®, Parnate®)
- Selective serotonin reuptake inhibitor (SSRI) or other medicines used to treat depression amitriptyline, citalopram, doxepin, fluoxetine, fluvoxamine, mianserin, mirtazepine, nefazodone, nortriptyline, paroxetine, venlafaxine (e.g. Allergron®, Aropax®, Avanza®, Cipramil®, Dothep®, Efexor®, Lexapro®, Luvox®, Prozac®, Lovan®, Serzone®, Sinequan®, Zoloft®)
- Thioridazine (Aldazine®) used to treat schizophrenia
- Triptans medicines, used to treat migraine (eg sumatriptan, Imigran®).
- Tramadol (Tramal®), used for pains
- Lithium (Lithicarb®), used for mood disorders
- St John's wort (hypericum perforatum), an herbal preparation.

- Medicines to thin your blood, such as warfarin (Coumadin®, Marevan®), or medicines that can cause bleeding, such as non-steroidal anti-inflammatory medicines like ibuprofen (Nuorfen®) and aspirin (Disprin®).
- Certain medicines for fungal infection, including ketoconazole (Nizoral®), itraconazole (Sporanox®) and fluconazole (Diflucan®)
- Certain medicines for HIV, including ritonavir (Norvir®), saquinavir (Invirase®), nelfinavir (Viracept®) and atazanavir (Reyataz®).
- Certain medicine used to treat high blood pressure and chest pain (angina), enlarged prostate or erectile dysfunction as these medicines may lower your blood pressure, possibly upon standing.
- Anti-inflammatory medicines such as ibuprofen (Nurofen®) or aspirin.
- Certain antibiotics for treating infection.

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.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

Taking PRILIGY

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

When and how much to take

Always take PRILIGY exactly as your doctor has told you. You must check with your doctor if you are not sure.

Do not take PRILIGY more than once every 24 hours. 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 60 mg.

How to take it

Swallow the tablet with at least one full glass of water. PRILIGY may be taken with or without food.

Avoid alcohol when taking PRILIGY.

If you forgot 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):

If you think you or anybody else has taken too much PRILIGY, contact your doctor, pharmacist or the Poisons Information Centre who will advise you what to do.

You can contact the Poisons Information Centre by dialling:

- Australia: 13 11 26
- New Zealand: 0800 POISON or 0800 764 766.

While you are taking PRILIGY

Things you must do:

If you are about to start on any new medicine, remind your doctor and pharmacist that you are taking PRILIGY.

Tell any other doctors and pharmacists who are treating you that you are taking PRILIGY.

If you are about to be started on any new medicines, tell your doctor or pharmacist that you are taking PRILIGY.

Be sure to keep all your doctor's appointments so your progress can be checked.

Priligy can 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 (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.

Things you must not do:

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

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

Avoid alcohol when taking PRILIGY

The effects of alcohol such as feeling dizzy, sleepy and having slow reactions, may be increased if taken with PRILIGY. Drinking alcohol while taking Priligy may increase your risk of injury from fainting or from other side effects.

Things to be careful of

Be careful driving or operating machinery until you know how PRILIGY affects you.

You may feel sleepy, dizzy, faint, have difficulty concentrating and blurred vision while taking PRILIGY. If you experience any of these or similar effects, you should avoid driving or operating hazardous machinery. **Avoid alcohol while you are taking this medicine.**

The effects of alcohol, such as dizziness, drowsiness, slow reflexes or impaired judgement, may be increased if taken with PRILIGY.

Make sure you are not dehydrated (don't have enough water in your body).

This can occur if you have not had anything to drink in the past 4-6 hours or you have been sweating for a long period or have an illness involving fever, diarrhoea or vomiting.

PRILIGY may cause fainting. To help lessen your chance of fainting or being injured by fainting:

- Take PRILIGY with at least one full glass of water
- If you begin to feel dizzy, lightheaded, sweaty, shaky, clammy, nauseated, or otherwise unwell, lie down immediately so you don't get hurt falling from a fainting spell
- If you are sitting or lying down, do not stand up quickly after you take PRILIGY
- If you experience any of these or similar effects, you should avoid driving and using machines.

Side Effects

Like all medicines, PRILIGY can have side effects. Some of these effects may be serious.

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

Do not be alarmed by the following list of side effects, you may not experience any of them.

Tell your doctor if you experience 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:

- Increased blood pressure
- Trembling
- Tingling or numbness
- Blurred vision
- Ringing in the ears
- Nasal congestion
- Diarrhoea, abdominal pain, dry mouth, vomiting, ingestion, intestinal gas, constipation, bloating
- Excessive sweating
- Fatigues, 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

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- Signs of allergy 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

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store PRILIGY or any other medicine in the bathroom or near a sink. Do not leave it on a window sink or in the car.

Heat and dampness can destroy some medicines.

What it looks like:

PRILIGY 30 mg film-coated tablets are light grey, round and marked “30” inside a triangle on one side.

PRILIGY 60 mg film-coated tablets are grey, round and marked “60” inside a triangle on one side.

Ingredients

Active ingredient:

- Dapoxetine hydrochloride

Other ingredients:

- Lactose
- Cellulose – microcrystalline
- Croscarmellose sodium
- Silica - colloidal anhydrous
- Magnesium stearate
- Hypromellose
- Titanium dioxide
- Iron oxide black
- Iron oxide yellow

Sponsor

JANSSEN-CILAG Pty Ltd

NZ Office: Auckland, New Zealand

Telephone: (09) 523 8700 or 0800 800 806

This leaflet was prepared in October 2009.

Product Description

Storage

Keep PRILIGY in the pack until it is time to take them.

If you take the tablets out of the pack, they may not keep well.