

PRILIGY[®] Tablets

Dapoxetine hydrochloride

Consumer Medicine Information

What is in this leaflet

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

This leaflet was last updated on the date at the end of this leaflet.

Speak to your pharmacist or doctor to obtain the most up to date information on this medicine.

You can also download the most up to date leaflet from www.menarini.com.au

All medicines have risks and benefits. Your doctor has weighed the risks of you taking PRILIGY against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What PRILIGY is used for

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

- ejaculation in less than 2 minutes following penetration, on most occasions, with little stimulation and before the man wishes to; and
- marked personal distress and interpersonal difficulty as a result of premature ejaculation (premature ejaculation troubles the man and his partner); and
- poor control over ejaculation.

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 this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

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

WARNING: PRILIGY can make you faint or make you feel dizzy or light-headed when you stand up (see **While you are taking PRILIGY and Side Effects**).

Before you take PRILIGY

When you must not take 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.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

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 (see **Taking other medicines** for examples of MAOIs).
- If you are taking thioridazine (Aldazine[®]) 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 (see **Taking other medicines** for examples of SSRIs and 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 taking certain medicines to treat fungal infections or medicines to treat HIV (see **Taking other medicines** for examples of these medicines).

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 this medicine 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 take 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 of the following medical conditions:

- History of dizziness from low blood pressure
- Heart and blood vessel problems
- Bleeding tendencies
- Depression
- Fainting (see **Things to be careful of**)
- You have any thoughts of suicide or harming yourself
- Psychiatric disorders, 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
- Sexual dysfunction (impaired sexual function in males)
- Glaucoma, a condition that may or may not be characterised by high pressure in the eye and can lead to blindness.

If you have not told your doctor about any of the above, tell them before you start taking PRILIGY.

Taking other medicines

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

Some medicines and PRILIGY may interfere with each other. These include:

- MAOIs (monoamine oxidase inhibitors) used to treat depression, such as moclobemide, phenelzine and tranylcypromine (Aurorix[®], Nardil[®], Parnate[®])
- Selective serotonin reuptake inhibitors (SSRIs) or other medicines used to treat depression: amitriptyline, citalopram, doxepin, fluoxetine, fluvoxamine, mianserin, mirtazepine, nefazodone, nortriptyline, paroxetine, venlafaxine (e.g. Allegron[®], Aropax[®], Avanza[®], Cipramil[®], Dothep[®], Efexor[®], Lexapro[®], Luvox[®], Prozac[®], Lovan[®], Serzone[®], Sinequan[®], Zoloft[®]).
- Thioridazine (Aldazine[®]) used to treat schizophrenia
- Triptans, medicines used to treat migraine (e.g. sumatriptan, Imigran[®]).
- Tramadol (Tramal[®]), used for pain.
- Lithium (Lithicarb[®]), used for mood disorders.
- St John's wort (hypericum perforatum), a herbal preparation.
- Medicines to thin your blood, such as warfarin (Coumadin[®], Marevan[®]).
- Certain medicines for fungal infections, including ketoconazole (Nizoral[®]), itraconazole (Sporanox[®]) and fluconazole (Diflucan[®]).
- Certain medicines for HIV, including ritonavir (Norvir[®]), saquinavir (Invirase[®]), nelfinavir (Viracept[®]) and atazanavir (Reyataz[®]).
- Certain medicines used to treat high blood pressure and chest pain (angina), enlarged prostate (Flomaxtra[®]), or erectile dysfunction (impotence), 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, such as erythromycin and clarithromycin.
- Aprepitant (Emend[®]) used to treat nausea.
- Midazolam (Hypnovel[®]) used as a sedative.

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.

Other medicines not listed here may be affected by PRILIGY or may affect how well it works. Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take 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.

How much to take

The recommended dose is a single tablet (30mg), taken when you need it about 1 to 3 hours before sexual activity.

Do not exceed taking a single tablet in 24 hours.

How to take it

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

PRILIGY may be taken with or without food.

Avoid alcohol when taking PRILIGY.

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.

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 or the Poisons Information Centre (in Australia telephone 13 11 26) for advice, or go to Emergency at the nearest hospital, if you think that you or anyone else may have taken too much PRILIGY. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking PRILIGY

WARNING: PRILIGY can make you faint or make you feel dizzy or light-headed 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 water 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 do

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

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

Keep all of your doctor's appointments so that your progress can be checked.

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.

Things to be careful of

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

This medicine may cause dizziness, light-headedness, tiredness, drowsiness, or fainting in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

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, light-headed, 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

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

This medicine helps most people, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

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 (see **While you are taking PRILIGY**)
- increased blood pressure
- trembling
- tingling or numbness
- blurred vision
- eye pain
- ringing in the ears
- nasal congestion
- diarrhoea, abdominal pain, dry mouth, vomiting, ingestion, intestinal gas, 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

If any of the following happen, tell your doctor immediately or go to 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.

After using PRILIGY

Storage

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

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

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 sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

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

PRILIGY is supplied in blister packs containing 3 or 6 tablets.

Ingredients

PRILIGY contains 30 mg of dapoxetine hydrochloride as the active ingredient.

It also contains:

- lactose
- cellulose – microcrystalline
- croscarmellose sodium
- silica - colloidal anhydrous
- magnesium stearate
- hypromellose
- titanium dioxide
- iron oxide black
- iron oxide yellow
- glycerol triacetate.

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

Supplier

PRILIGY is supplied in Australia by:

A.Menarini Australia Pty. Ltd.
Level 8, 67 Albert Ave
Chatswood, NSW, 2067

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