
PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S5

PRILIGY® 30 mg film-coated tablets

PRILIGY® 60 mg film-coated tablets

Dapoxetine

Contains sugar:

PRILIGY 30 contains 46 mg lactose monohydrate.

PRILIGY 60 contains 92 mg lactose monohydrate.

Read all of this leaflet carefully before you start taking PRILIGY.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- PRILIGY has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

1. What PRILIGY is and what it is used for
2. What you need to know before PRILIGY is administered
3. How PRILIGY is administered
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. Dapoxetine belongs to a group of medicines called selective serotonin reuptake inhibitors (SSRIs). PRILIGY is also known as a urological medicine.

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 when a man ejaculates with little sexual stimulation and before the man wants. PRILIGY increases the time it takes to ejaculate and can improve the control over the ejaculation.

2. What you need to know before you take PRILIGY

Do not take PRILIGY:

- If you are hypersensitive (allergic) to dapoxetine hydrochloride or any of the other ingredients of PRILIGY (listed in section 6).
- If you are taking:
 - medicines called MAOIs (monoamine oxidase inhibitors) (used to treat depression)
 - thioridazine (used to treat schizophrenia)
 - medicines for depression
 - lithium (used to treat bipolar disorder)
 - linezolid (an antibiotic, used to treat infections)
 - tryptophan (used to help your sleep)
 - St John's wort (a herbal medicine, used to for depression)
 - tramadol (used to treat serious pain)
 - medicines used to treat migraines (such as zolmitriptan, sumatriptan, rizatriptan).

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 PRILIGY, you will need to wait 7 days before

taking any of the medicines listed above.

- With certain medicines for fungal infection (such as ketoconazole and itraconazole).
- With medicines for HIV, including ritonavir, saquinavir, nelfinavir and atazanavir.
- With antibiotics (to treat infections), including telithromycin.
- With nefazodone (used as an antidepressant).
- If you suffer from severe depression.
- If you have a history of mania (great excitement, hallucinations, difficulty in concentrating or staying still).
- If you develop seizures (fits) or have uncontrolled epilepsy.
- If you have moderate and severe liver problems.
- If you have experienced syncope (sudden loss of consciousness, fainting) regardless of the underlying cause.
- If you have underlying heart problems such as heart failure or problems with the heart rhythm.
- If you are under 18 of age.
- If you are a woman.

Warnings and precautions:

Talk to your doctor before taking PRILIGY if you:

- Have not been diagnosed with premature ejaculation.
- Have another sexual problem, such as erectile dysfunction.
- Have a history of dizziness from low blood pressure. Before you start taking PRILIGY, 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.
- Use recreational drugs such as ecstasy, LSD, narcotics or benzodiazepines.
- Drink alcohol (see section PRILIGY with food, drink and alcohol).
- 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).

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- Have epilepsy.
 - Have a history of bleeding or blood clotting problems.
 - Have kidney problems.
 - Have, or are at risk of high pressure in the eye (glaucoma).

Take special care 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.
- Tell your doctor if you have any of these side effects.

Children and adolescents:

PRILIGY should not be used in children or adolescents under the age of 18 years.

Other medicines and PRILIGY:

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

Do not take PRILIGY at the same time as any of the following medicines listed below. 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:

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

Do not take PRILIGY with:

- 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 for mental health problems other than depression.
- Nonsteroidal anti-inflammatory medicines such as ibuprofen or aspirin.
- Medicines to prevent blood clotting, such as warfarin, or medicines that can cause bleeding.
- 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 pectoris) (such as verapamil and diltiazem), or enlarged prostate (such as tamsulosin), 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:

PRILIGY may be taken with or without food and should be taken with at least one full glass of water.

Avoid alcohol when taking PRILIGY. The effects of alcohol, such as dizziness, drowsiness, slow reflexes or impaired judgement, may be increased if taken with PRILIGY. Drinking alcohol while taking PRILIGY may increase your risk of injury from fainting.

Do not drink grapefruit juice within 24 hours prior to taking PRILIGY, as this can increase the level of dapoxetine in your body.

Pregnancy and breastfeeding:

PRILIGY should not be taken by women.

Driving and using machines:

PRILIGY might make some people feel sleepy, dizzy, lightheaded or faint. If you experience any of these or similar effects, you should avoid driving and using machines.

PRILIGY contains lactose:

PRILIGY contains "lactose" (a type of sugar). If you have been told by your doctor that you cannot tolerate or digest some sugars, talk to your doctor before taking PRILIGY.

PRILIGY contains sodium:

PRILIGY contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium

free'.

3. How to take PRILIGY

Do not share medicines prescribed for you with any other person.

Always take PRILIGY exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

- 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 PRILIGY 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.
- PRILIGY can be taken with or without food.
- PRILIGY should not be used by men under 18 or over 65 years of age.

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:

Taking more PRILIGY than your doctor tells you to, may cause more side effects like nausea and vomiting and may not delay your ejaculation any longer or improve your control over ejaculation anymore. Tell your doctor or pharmacist if you have taken more tablets than you should.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take PRILIGY:

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

Effects when treatment with PRILIGY is stopped:

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

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

4. Possible side effects

PRILIGY can have side effects.

Not all side effects reported for PRILIGY are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking PRILIGY, please consult your doctor, pharmacist or other health care provider for advice.

If any of the following happens, stop taking PRILIGY and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of your hands, feet, ankles, face lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.

These are all very serious side effects. If you have them, you may have had a serious reaction to PRILIGY. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- You have fits (seizures).
- You feel faint or feel lightheaded when you stand up. To lessen your chance of fainting or being injured by fainting, please refer to the instructions in section "Warnings and precautions".
- You notice any changes in your mood.
- You have thoughts of suicide or harming yourself.
- Slow or irregular heartbeat or increase in heart rate.

- Increased blood pressure.
- Vision problems, eye pain or dilated pupils.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following

Frequent side effects:

- Dizziness.
- Headache.
- Nausea.
- Sleepiness.
- Trembling or shaking.
- Difficulty paying attention.
- Tingling or numbness.
- Blurred vision.
- Ringing in the ears.
- Nasal congestion (blocked nose).
- Yawning.
- Diarrhoea.
- Abdominal pain.
- Dry mouth.
- Vomiting.
- Indigestion.
- Intestinal gas.
- Constipation.
- Bloating.
- Excessive sweating.
- Flushing.
- Fatigue.

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- Feeling irritable.
 - Erectile dysfunction (difficulty getting or keeping an erection).
 - Difficulty sleeping.
 - Anxiety.
 - Nervousness.
 - Decreased sexual desire, depression.
 - Abnormal dreams.

Less frequent side effects:

- Change in mood, feeling overly excited or feelings of paranoia.
- Feeling confused, disoriented or unable to think clearly.
- Sudden onset of sleep.
- Feeling depressed, nervous or indifferent.
- Loss of sex drive, problems reaching orgasm.
- Having nightmares (unpleasant dream that can cause a strong emotional response from the mind, typically fear but also despair).
- Feeling weak, sedated, lethargic (loss of energy or motivation to do your tasks) or tired.
- Feeling hot, jittery (feeling nervous), abnormal or drunk.
- Low blood pressure.
- Spinning sensation (vertigo).
- Stomach discomfort.
- Urgency of bowel action.
- Feeling itchy or cold sweat.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org)

found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of PRILIGY.

5. How to store PRILIGY

Store at or below 25 °C.

Keep blister strips in the outer carton until required for use.

Store all medicine out of reach of children.

Do not use PRILIGY after the expiry date.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What PRILIGY contains:

The active substance is dapoxetine.

PRILIGY 30 mg: Each light grey tablet contains 30 mg dapoxetine base as (hydrochloride).

PRILIGY 60 mg: Each grey tablet contains 60 mg dapoxetine base (as hydrochloride).

The other ingredients are:

Tablet core: Colloidal anhydrous silica, croscarmellose sodium, lactose monohydrate, magnesium stearate and microcrystalline cellulose.

Tablet coating: Black iron oxide, hypromellose, lactose monohydrate, titanium dioxide, triacetin and yellow iron oxide.

What PRILIGY looks like and contents of the pack:

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.

The tablets are provided in opaque blister strips containing 1, 2, 3, 6 or 18 film-coated tablets. The blisters are packed into an outer container

Holder of certificate of registration and manufacturer:

LeBasi Pharmaceuticals (Pty) Ltd

San Domenico Building, Unit 6, Ground Floor

10 Church Street

Durbanville 7551

Tel. no.: 087 551 3245

This leaflet was last revised:

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Registration numbers:

PRILIGY® 30 mg: 43/18.10/0692

PRILIGY® 60 mg: 43/18.10/0693

Access to the corresponding professional information:

Request via the email address: info@lebasi.co.za