

ANNEX III

**SUMMARY OF PRODUCT CHARACTERISTICS,
LABELLING AND PACKAGE LEAFLET**

Note: This SmPC, labelling and packages leaflet is the version valid at the time of Commission decision.
After the Commission decision the Member State competent authorities, in liaison with the reference Member State, will update the product information as required. Therefore, this SmPC, labelling and package leaflet may not necessarily represent the current text.

SUMMARY OF PRODUCT CHARACTERISTICS

The valid summary of product characteristics is the final version achieved during the Coordination group procedure.

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARDBOARD CARTON

1. NAME OF THE MEDICINAL PRODUCT

Priligy 30 mg Film-Coated Tablets
Priligy 60 mg Film-Coated Tablets
Dapoxetine

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each film-coated tablet contains 30 mg of dapoxetine (as hydrochloride)

Each film-coated tablet contains 60 mg of dapoxetine (as hydrochloride)

3. LIST OF EXCIPIENTS

Contains Lactose. See leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Film-coated tablets
1 tablet
2 tablets
3 tablets
6 tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use
Read the package leaflet before use.
Tablet should be swallowed whole

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

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

Take Priligy 1 to 3 hours before sexual activity.

Take with at least 1 full glass of water.

Do not take Priligy more than once every 24 hours.

8. EXPIRY DATE

EXP {MM/YYYY}

9. SPECIAL STORAGE CONDITIONS

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

To be completed nationally

12. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally

13. BATCH NUMBER

SN

Lot:

14. GENERAL CLASSIFICATION FOR SUPPLY

To be completed nationally

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Priligy 30 mg

Priligy 60 mg

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS**PVC-PE-PVDC Blisters in Aluminium Foil**

The medicinal product is provided in compliance multi-fold packages of 3 and 6 film-coated tablets. In these compliance multi-fold packages, the blisters are glued onto the carton. Therefore, information printed on the blister foil would not be visible. In the compliance multi-fold packages, blister strips and cardboard carton are one unit. For these reasons, there is no requirement for any minimum particulars to appear on blisters or strips.

PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

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

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Priligy is and what it is used for
2. Before you take Priligy
3. How to take Priligy
4. Possible side effects
5. How to store Priligy
6. Further information

1. What Priligy is and what it is used for

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

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

Priligy is used to treat premature ejaculation, in men between 18 and 64 years old.

Premature ejaculation is when a man ejaculates with little sexual stimulation and before the man wants. This can cause problems for the man and may cause problems in sexual relationships.

2. Before you take Priligy

Do not take Priligy if:

- You are allergic (hypersensitive) to dapoxetine or any of the other ingredients of Priligy (listed in section 6)
- You have heart problems, such as heart failure or problems with the heart rhythm
- You have a history of fainting
- You have ever had mania (symptoms include feeling over-excited, irritable or not being able to think clearly) or severe depression
- You are taking:
 - Medicines for depression called ‘monoamine oxidase inhibitors’ (MAOIs)
 - Thioridazine used for schizophrenia
 - Other medicines for depression

- Lithium – a medicine for bipolar disorder
- Linezolid – an antibiotic used to treat infections
- Tryptophan – a medicine to help you sleep
- St John’s wort – an herbal medicine
- Tramadol – used to treat serious pain
- Medicines used to treat migraines.

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 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 Priligy. (see section “**Taking other medicines**”)

- Certain medicines for fungal infection, including ketoconazole and itraconazole (see section “**Taking other medicines**”)
- Certain medicines for HIV, including ritonavir, saquinavir, nelfinavir and atazanavir (see section “**Taking other medicines**”)
- Certain antibiotics for treating infection, including telithromycin (see section “**Taking other medicines**”)
- Nefazodone – an antidepressant (see section “**Taking other medicines**”)
- You have moderate or severe liver problems.

Do not take Priligy if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Priligy.

Take special care with Priligy

Check with your doctor or pharmacist before taking your medicine if:

- You drink alcohol (see section “**Taking Priligy with food and drink**”)
- You have not been diagnosed with premature ejaculation
- You use recreational drugs such as ecstasy, LSD, narcotics or benzodiazepines
- You 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)
- You have a history of bleeding or blood clotting problems
- You have kidney problems
- You have epilepsy
- You have a history of dizziness from low blood pressure
- You also have another sexual problem, such as erectile dysfunction.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Priligy.

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.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines as certain medicines may increase your risk of side effects. This includes medicines you get without a prescription, such as herbal medicines. This is because Priligy can affect the way some other medicines work. Also some other medicines can affect the way Priligy works. Therefore, use of other medicines may affect the maximum dose of Priligy you’re allowed to take.

Do not take Priligy at the same time as any of the following medicines:

- Medicines for depression called ‘monoamine oxidase inhibitors’ (MAOIs)
- Thioridazine used for schizophrenia
- Other medicines for depression
- Lithium – a medicine for bipolar disorder
- Linezolid – an antibiotic used to treat infections
- Tryptophan – a medicine to help you sleep
- St John’s wort – an herbal medicine
- Tramadol – used to treat serious pain
- Medicines used to treat migraines.

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 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 Priligy.

- 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:

- Medicines for mental health problems other than depression
- Non-steroidal anti-inflammatory medicines such as ibuprofen or acetylsalicylic acid
- Medicines to 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, possibly upon standing
- Certain medicines used to treat high blood pressure and chest pain (angina) (such as verapamil and diltiazem), or enlarged prostate, 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 Priligy.

Taking Priligy with food and drink

- Priligy can be taken with or without food.
- You should take Priligy with at least one full glass of water.
- 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.

Pregnancy and breast-feeding

Priligy should not be taken by women.

Driving and using machines

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. The effects of alcohol may be increased if taken with Priligy and you may be more at risk of injury from fainting or from other side effects if you take Priligy with alcohol.

Important information about some of the ingredients of Priligy

Priligy contains lactose (a type of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Priligy

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

How to take Priligy

- The usual 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 (see 'Fainting and low blood pressure' in section 4).
- Priligy can be taken with or without food.
- Priligy should not be used by either men under the age of 18 or men 65 years or older
- 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

Tell your doctor or pharmacist if you have taken more tablets than you should. You may feel sick or be sick.

If you stop taking Priligy

Talk to your doctor before you stop taking this medicine. You may have problems sleeping and feel dizzy after you stop taking this medicine, 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

Like all medicines, Priligy can cause side effects, although not everybody gets them. The following side effects may occur with this medicine:

Stop taking Priligy and see your doctor straight 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.

If you notice any of the above, stop taking this medicine and see your doctor straight away.

Fainting and low blood pressure

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.**

Very common side effects (affects more than 1 user in 10):

- Feeling dizzy
- Headache
- Feeling sick.

Common side effects (affects 1 to 10 users in 100):

- Feeling irritable, anxious, agitated or restless
- Feeling numb or having 'pins and needles'
- Difficulty getting or keeping an erection
- Sweating more than normal or flushing
- Diarrhoea, constipation or having wind
- Stomach pain, bloating or being sick
- Problems sleeping or strange dreams
- Feeling tired or sleepy, yawning
- Blocked nose (nasal congestion)
- A rise in blood pressure
- Difficulty concentrating
- Shaking or trembling
- Lower interest in sex
- Ringing in the ears
- Blurred vision
- Indigestion
- Dry mouth.

Uncommon side effects (affects 1 to 10 users in 1,000):

- Fainting or feeling dizzy upon standing (see advice above)
- Change in mood, feeling overly excited or feelings of paranoia
- Feeling confused, disoriented or unable to think clearly

- Slow or irregular heartbeat or increase in heart rate
- Loss of sex drive, problems reaching orgasm
- Feeling weak, sedated, lethargic or fatigued
- Feeling depressed, nervous or indifferent
- Feeling hot, jittery, abnormal or drunk
- Vision problems or dilated pupils
- Low or high blood pressure
- Feeling itchy or cold sweat
- Spinning sensation
- Abnormal taste
- Teeth grinding.

Rare side effects (affects 1 to 10 users in 10,000):

- Feeling dizzy following exertion
- Sudden onset of sleep
- Urgency of bowel action.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Priligy

- This medicinal product does not require any special storage conditions.
- Keep out of the reach and sight of children.
- Do not use Priligy after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Priligy contains

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

The other ingredients are:

- 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).

What Priligy looks like and contents of the pack

- Priligy 30 mg film-coated tablets are light grey, round, convex and marked “30” inside a triangle on one side.
- Priligy 60 mg film-coated tablets are grey, round, convex and marked “60” inside a triangle on one side.

The tablets are provided in compliance multi-fold blister packs containing 1, 2, 3 and 6 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

<[To be completed nationally]>

This medicinal product is authorised in the Member States of the EEA under the following names:

<{Name of the Member State}> <{Name of the medicinal product}>

This leaflet was last approved in .