

## PACKAGE

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

dapoxetine

Please read this leaflet carefully before you start taking this medicine.

Keep this leaflet. You may need it later.

If you have any questions, please ask your doctor or pharmacist.

This medicine has been prescribed for you and not pass it on to others. It may harm them, even if their symptoms are the same as yours.

If you notice any side effects not listed in this leaflet, or side effects become severe, tell your doctor or pharmacist.

In this leaflet:

What Priligy is and what it is used

Before you take Priligy

How to take Priligy

Possible Side Effects

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Further information

1. Priligy WHAT IS AND WHAT IT IS USED

What is Priligy

Priligy contains dapoxetine, names of the active ingredient. It belongs to a selective serotonin reuptake inhibitors (SSRI) class of medicines called. Priligy can also be called urological medicine.

What Priligy used

Priligy for 18-64 year old men premature ejaculation.

Premature ejaculation is a common sexual disorder.

It is premature ejaculation, when a man ejaculate with little sexual stimulation and before he himself wants it to happen.

This can cause problems as well as the man in the relationship.

How Priligy influence

Priligy prolong ejaculation and the time it takes to improve his own ability to control when you ejaculate. This rapid reduction of ejaculate anxiety and concern.

Priligy may also increase the satisfaction with sexual intercourse.

2. BEFORE YOU Priligy

Do not take Priligy

If you are allergic (hypersensitive) to dapoxetine or Priligy any of the ingredients (listed in Section 6).  
if you have heart disease such as heart failure or arrhythmias

if you use the following medicines:

monoamine oxidase inhibitors (MAOIs), called anti-depressants

thioridazine, which is used to treat schizophrenia

other medicines used to treat depression

Lithium - bipolar disorder, medicine used to treat

Linezolid - an antibiotic used to treat infections

Tryptophan - a hypnotic

St. John's Wort - a herbal remedy

tramadol - serious pain treatment

Medicines used to treat migraines.

Do not take Priligy at the same time the medicines listed above. The medicines listed above shall be followed at the 14-day break before starting treatment with Priligy. Priligy after cessation of treatment is to wait 7 days before the medicines listed above to get started. If you are unsure, ask your doctor or pharmacist before taking Priligy. (See other medicines).

certain antifungal medicines such as ketoconazole and itraconazole (see other medicines)

certain anti-HIV medicines such as ritonavir, saquinavir, nelfinavir and atazanavir (see other medicines)

certain antibiotics used to treat infections, such as telithromycin (see other medicines)

nefazodone - an antidepressant (see other medicines).

If you have severe liver disease.

Do not take Priligy if any of the above applies to you. If you are unsure, ask your doctor or pharmacist before taking Priligy.

Take special care with Priligy relationship

Talk to your doctor or pharmacist before taking this medicine

if you drink alcohol (see section Priligy with food and drink)

If you have not been diagnosed with premature ejaculation

if you use recreational drugs such as ecstasy, LSD, narcotics or benzodiazepines

If you have ever had a mental health problem such as depression, mania (symptoms include excessive enthusiasm, irritability, inability to think clearly), bipolar disorder (symptoms include severe mood swings between mania and depression) or schizophrenia (a mental illness)

If you have previously been associated with bleeding or blood clotting problems

If you have renal dysfunction or moderate hepatic impairment

if you suffer from epilepsy

If you have a history of low blood pressure due to dizziness.

If any of the above applies to you (or you're not sure), talk to your doctor or pharmacist before taking Priligy use.

Before you start taking Priligy, your doctor will perform a test to make sure that your blood pressure drop too much when you get lying in an upright position.

Other medicines

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines because some medicines may increase the risk of side effects. This also applies to medicines obtained without a prescription, such as herbal remedies. This is due to the fact that Priligy can affect how other medicines work. Also certain other medicines may affect how Priligy influence.

Do not use Priligy at the same time with the following medications:

monoamine oxidase inhibitors (MAOIs), called anti-depressants  
thioridazine, which is used to treat schizophrenia  
other medicines used to treat depression  
Lithium - bipolar disorder, medicine used to treat  
Linezolid - an antibiotic used to treat infections  
Tryptophan - a hypnotic  
St. John's Wort - a herbal remedy  
tramadol - serious pain treatment  
Medicines used to treat migraines.

Do not take Priligy at the same time the medicines listed above. The medicines listed above shall be followed at the 14-day break before starting treatment with Priligy. Priligy after cessation of treatment is to wait 7 days before the medicines listed above to get started. If you are unsure, ask your doctor or pharmacist before taking Priligy.

certain antifungal medicines such as ketoconazole and itraconazole  
certain anti-HIV medicines such as ritonavir, saquinavir, nelfinavir and atazanavir  
certain antibiotics used to treat infections, such as telithromycin  
nefazodone - an antidepressant.

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

medicines used to treat mental health, other than anti-depressants  
non-steroidal anti-inflammatories such as ibuprofen or aspirin  
blood-thinning medicines such as warfarin  
certain high blood pressure, chest pain (angina) (eg, verapamil and diltiazem), enlarged prostate or erectile dysfunction medicines used to treat, because these medications can lower blood pressure, possibly upon standing  
a number of other fungal infections, medications such as fluconazole  
a number of other anti-HIV drugs such as amprenavir and fosamprenavir  
certain antibiotics used to treat infections, 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.

Contact Priligy at least one full glass of water.

Do not take Priligy, when you're under the influence of alcohol.

The effects of alcohol, for example, dizziness, drowsiness and slow reactions, may be increased if you drink alcohol Priligy with.

Alcohol intake Priligy may increase your fainting or other side effects due to risk of injury.

Pregnancy and breast-feeding

Women are not allowed to take Priligy.

Driving and using machines

You may experience drowsiness, dizziness, weakness, difficulty concentrating, and blurred vision while taking Priligy. If you experience any of these or similar effects, avoid driving or requiring the use of machines. The effects of alcohol may be intensified Priligy use, so you might be prone to fainting or other side effects of injuries to the hazard, if you take Priligy with alcohol.

#### Important information about Priligy ingredients

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

### 3. HOW TO TAKE Priligy

Contact Priligy tablets exactly as your doctor has told you. Check with your doctor or pharmacist if you are unsure.

#### How to take Priligy

The usual dose is 30 mg. Your doctor may increase the dose to 60 mg.

Take the medicine 1-3 hours before sexual activity.

Swallow the tablets whole with a drug to avoid a bitter taste. Drink a tablet with at least one full glass of water. This may reduce the likelihood of syncope (see Syncope and hypotension in Section 4).

Priligy can be taken with or without food.

Do not take Priligy more than once a day (once every 24 hours).

Less than 18 years of age and over 65-year-old men should not be used Priligy.

If you take more Priligy than you should

If you have received too large a dose or for example, if a child has accidentally received the medicine, contact your doctor, hospital or Poison Information Centre, tel (09), 4711, to assess the risk and to get instructions.

Tell your doctor or pharmacist if you have taken more tablets than you should. You may experience nausea or vomiting.

#### If you stop taking Priligy use

Discuss with your doctor before stopping this medicinal product. You may experience trouble sleeping, or dizziness with this drug is discontinued, even if you have not used the tablets every day.

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

### 4. POSSIBLE SIDE EFFECTS

Like all medicines, the medicine can cause side effects. Not everybody gets them. This drug may occur with the following side effects:

Stop Priligy and see a doctor immediately

if you experience seizures (seizures)

if you pass out, or you experience a strange surreal presence stand up

if you notice any mood changes

If you have suicidal or self destructive thoughts about.

If you notice any of the above-mentioned effects, stop taking the medicine and go to a doctor immediately.

Fainting and low blood pressure

Priligy can cause you to faint or fall in blood pressure stand up. To reduce the likelihood of such:

Take the medicine at least one full glass of water.

Do not take Priligy, if you have a loss of fluids (in your body does not have enough fluids).

Such a state is possible if the

you do not drink anything 4-6 hours

you are sweating for a long time

you have an illness with high fever, diarrhea or vomiting.

If you feel that you might faint (eg you have nausea, dizziness, a strange, unreal feeling, confusion, sweating, or abnormal heart beats), or you feel dizzy when you stand up. Visit immediately to lie down so that the head is lower than the rest of his body or sit down and press the head between your knees until you feel better. These actions will prevent you from falling and damaging yourself, but if you pass out.

Do not get up quickly to stand, sit, or if you have been lying for a long time.

Do not drive or use tools or machines if you feel faint while taking this medicine.

Tell your doctor if you pass out while taking this medicine.

Very common side effects (which may affect more than one in 10 patients):

feeling dizzy

headache

nausea.

Common side effects (which may occur in up to one in 10 patients):

irritability, anxiety, agitation, or feeling restless

numbness or tingling, and tingling sensation

difficulty in achieving an erection or to maintain it

usual abundant sweating or flushing

diarrhea, constipation or flatulence

stomach pain, bloated feeling or being sick

difficulty sleeping or abnormal dreams

feeling tired or sleepy, yawning

nasal congestion

Increased blood pressure

difficulty concentrating

shaking or tremors

decreased interest in sex

ringing in the ears

blurred vision

indigestion

dry mouth.

Uncommon side effects (which may occur in up to one in every 100 patients):

fainting or feeling dizzy on standing up (see instructions above)  
mood changes, excessive emotion or enthusiasm harhaluuloisuus  
feeling confused, time and place of loss of consciousness or inability to think clearly  
slow or irregular heartbeat or heart rate acceleration  
Loss of sexual desire, anorgasmia  
light-headedness, sedation, lethargy, or burnout, emotional  
depression, anxiety or a feeling of indifference  
hot feeling jittery, feeling abnormal levels of drunkenness or emotional  
visual disturbances or ocular mydriasis  
low or high blood pressure  
itching or a feeling of cold sweat  
spinning sensation  
taste abnormalities  
teeth, scrunch.  
Rare side effects (which may occur in up to one in 1,000 patients):

feeling dizzy after exertion  
suddenly falling asleep  
sudden need for defecation.

If you notice any side effects not listed in this leaflet, or side effects become severe, tell your doctor or pharmacist.

## 5. Priligy STORE

This medicinal product does not require any special storage conditions.

Does not reach and sight of children.

Do not use Priligy outer carton expiry date (EXP) after. The expiry date refers to the last day of the month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist. These measures will help protect the environment.

## 6. FURTHER INFORMATION

What Priligy contains

The active substance is dapoxetine. Each tablet contains 30 mg or 60 mg of dapoxetine hydrochloride.

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).

Looks like and contents of container

Priligy 30 mg film-coated tablets are pale gray, round, convex, and the other side is engraved on the triangle in figure 30

Priligy 60 mg film-coated tablets are gray, round, convex, and the other side is engraved on the triangle

in figure 60

tablets are supplied in 3 or 6 film-coated tablet hoitomyöntövyystaittopakkauksissa.  
Not all pack sizes may be marketed.

The Marketing Authorisation Holder and Manufacturer

The MAH

Finland: Janssen-Cilag Ltd, Skyway 2, 02130 Espoo.

Sweden: Janssen-Cilag AB, Box 7073, 192 07 Sollentuna.

Manufactured

by Janssen-Cilag SpA, Via C Janssen, Borgo S. Michele 04 010, Italy.

This medicinal product is authorized in the European Economic Area Member States under the following names:

Austria, Finland, Germany, Italy, Portugal, Spain, Sweden: Priligy

This leaflet was last approved on 03/19/2010 (Finland).