



Information for the user  
Dapocitin 30 mg film-coated tablets  
Dapoxetine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Dapocitin is and what it is used for
2. What you need to know before you take Dapocitin
3. How to take Dapocitin
4. Possible side effects
- 5 How to store Dapocitin
6. Contents of the pack and other information

1. What Dapocitin is and what it is used for

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

Dapocitin 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.

Dapocitin 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. What you need to know before you take Dapocitin

Do not take Dapocitin if:

- You are allergic (hypersensitive) to dapoxetine or any of the other ingredients of Dapocitin (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 Dapocitin 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 Dapocitin. Once you have stopped taking Dapocitin, 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 Dapocitin.(see

section **“Taking other medicines”**)

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

Take special care with Dapocitin

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

- You drink alcohol (see section **“Taking Dapocitin 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 Dapocitin.

Before you start taking Dapocitin, 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 Dapocitin can affect the way some other medicines work. Also some other medicines can affect the way Dapocitin works. Therefore, use of other medicines may affect the maximum dose of Dapocitin you’re allowed to take.

Do not take Dapocitin 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 Dapocitin 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 Dapocitin. Once you have stopped taking Dapocitin, 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 Dapocitin.

- 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 Dapocitin.

Taking Dapocitin with food and drink

- Dapocitin can be taken with or without food.
- You should take Dapocitin with at least one full glass of water.
- Avoid alcohol when taking Dapocitin.
- The effects of alcohol such as feeling dizzy, sleepy and having slow reactions, may be increased if taken with Dapocitin.
- Drinking alcohol while taking Dapocitin may increase your risk of injury from fainting or from other side effects.

Pregnancy and breast-feeding

Dapocitin should not be taken by women.

Driving and using machines

You may feel sleepy, dizzy, faint, have difficulty concentrating and blurred vision while taking Dapocitin.

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

Important information about some of the ingredients of Dapocitin

Dapocitin 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 Dapocitin

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

How to take Dapocitin

- 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 Dapocitin 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).
- Dapocitin can be taken with or without food.
- Dapocitin should not be used by either men under the age of 18 or men 65 years or older
- Discuss your Dapocitin 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 Dapocitin 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 Dapocitin

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, this medicine can cause side effects, although not everybody gets them. These effects are normally mild to moderate in nature.

**Stop taking Dapocitin and see your doctor straight away if:**

- You have fits (seizures)
- You faint or feel light headed when you stand up
- 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**

Dapocitin can make you faint or make your blood pressure drop when you stand up. To help lower the chance of this happening:

- Take Dapocitin with at least one full glass of water.
- Do not take Dapocitin 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 Dapocitin**

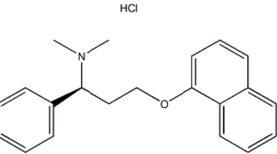
- Keep out of the reach and sight of children.
- Do not use Dapocitin after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines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

**6. Contents of the pack and other information**

**What Dapocitin contains**

The active substance is dapoxetine. Each tablet contains 30 mg dapoxetine as a

hydrochloride salt.dapoxetine is a short-acting selective serotonin reuptake inhibitor.The structural formula is:



The other ingredients are:

- Tablet core: lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, colloidal anhydrous silica, magnesium stearate.
- Tablet coating: lactose monohydrate, hypromellose, titanium dioxide, triacetin, black

iron oxide, yellow iron oxide.

**What Dapocitin looks like and contents of the pack**

Dapocitin 30 mg film-coated tablets are round and marked "TLPH" on one side.

Dapocitin is supplied in blister packs or bottle containing 3 or 6 tablets.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder**

Tongmeng(Lao) Pharmaceutical and Food Co., Ltd

Rd13 South,31km,Ban Naphasuk,Saithany District

Vientiane

Lao PDR

**Manufacturer**

Tongmeng(Lao) Pharmaceutical **and Food** Co., Ltd

Rd13 South,31km,Ban Naphasuk,Saithany District

Vientiane

Lao PDR

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

