

## **PACKAGE LEAFLET: INFORMATION FOR THE USER**

### **PROTHIADEN 25 mg HARD CAPSULES** **dosulepin hydrochloride.**

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 questions or are not sure about anything, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it onto others. It may harm them, even if their symptoms are the same as yours.
- If you get any of the 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 Prothiaden Hard Capsules are and what they are used for
2. What you need to know before you take Prothiaden
3. How to take Prothiaden
4. Possible side effects
5. How to store Prothiaden
6. Contents of the pack and other information

#### **1. WHAT PROTHIADEN HARD CAPSULES ARE AND WHAT THEY ARE USED FOR**

The name of your medicine is Prothiaden 25mg Hard Capsules (called Prothiaden in this leaflet). The active ingredient in Prothiaden is dosulepin hydrochloride. Prothiaden belongs to a group of medicines called antidepressants.

PROTHIADEN is used to treat depression and can also help reduce feelings of anxiety. Please ask your doctor or pharmacist if you need more information.

#### **2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PROTHIADEN**

##### **Do not take Prothiaden Capsules if**

- You are allergic to dosulepin or any of the other ingredients in this medicine (see Section 6).
- Prothiaden Capsules contains soya oil (see section 6). If you are allergic to peanut or soya, do not use this medicinal product.
- You have the eye condition known as glaucoma
- You are pregnant or planning to become pregnant, or are breast feeding.
- You have an irregular heartbeat, recent heart attack or any other heart problem
- You have severe liver problems.
- You suffer from periods of exaggerated behaviour (mania).
- You are a child or adolescent under age of 18 years.
- You are taking any of the following medicines:
  - A mono-amine oxidase inhibitor (MAOI), used to treat depression. You should not take Prothiaden with MAOI's or within 14 days of stopping them.
  - Any hay fever/allergy treatment which contains terfenadine or astemizole.
  - Sotalol (for heart or blood pressure problems) or halofantrine (for malaria).

## **Warnings and precautions**

Talk to your doctor or pharmacist before taking Prothiaden if

- You have difficulty in passing urine or have prostate problems
- You have epilepsy
- You have a thyroid problem

The elderly are at higher risk of experiencing side effects while taking this medicine, especially agitation, confusion and lightheadedness.

Tell your surgeon or dentist that you are taking Prothiaden if surgery is planned. It may affect the anaesthetic used.

A risk of suicide, self-harm and hostility cannot be excluded with Dosulepin.

## **Thoughts of suicide and worsening of your depression or anxiety disorder**

If you are depressed and/or have anxiety disorders you can sometimes have thoughts of harming or killing yourself. These may be increased with first starting antidepressants, since these medicines all take time to work, usually about two weeks but sometimes longer. You may be more likely to think like this:

- If you previously had thoughts about killing or harming yourself.
- If you are a young adult. Information from clinical trials has shown an increased risk of suicidal behaviour in adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant.

If you have thoughts of harming or killing yourself at any time, **contact your doctor or go to a hospital straight away.**

**You may find it helpful to tell a relative or close friend** that you are depressed or have an anxiety disorder, and to ask them to read this leaflet. You might ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.

## **Other medicines and Prothiaden**

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

- If you are taking any of the following medicines.
  - Any of the class of medicines known as SSRI's (selective serotonin re-uptake inhibitors), used to treat depression.
  - Any thyroid medication such as Levothyroxine (thyroxine)
  - Any barbiturate (e.g. phenobarbitone for epilepsy, amylbarbitone for insomnia) or methylphenidate (used to treat behavioural problems)
  - Any medicine containing an opioid. (These include codeine, morphine, dihydrocodeine, co-proxamol and co-dydramol)
  - Sympathomimetic agents-these include ephedrine, pseudoephedrine, adrenaline and noradrenaline. (These may be found in medicines used to treat heart problems and asthma as well as some decongestants and cough/cold remedies. This list contains medicines that are prescribed by a doctor and also some that you can buy from your pharmacist)
  - You are receiving any treatment for hypertension (high blood pressure)
- In particular if you are using:
  - Any monoamine oxidase inhibitor, nor within fourteen days of ceasing such treatment.
  - Any of the class of medicines known as SSRIs (selective serotonin re-uptake inhibitors) used to treat depression as it may increase tricyclic antidepressant levels in plasma.

- Sympathomimetic agents - these include ephedrine, pseudoephedrine, adrenaline and noradrenaline (These may be found in medicines used to treat heart problems and asthma as well as some decongestants and cough/cold remedies). This list contains medicines that are prescribed by a doctor and also some that you can buy from a pharmacist.
- Any barbiturates (e.g. phenobarbitone for epilepsy, amylbarbitone for insomnia) or methylphenidate to treat behavioural problems as they may affect the antidepressant action.
- Any medicines that are used to regulate the heart beat (e.g. sotalol, terfenadine, astemizole, halofantrine).

### **Prothiaden with food, drink and alcohol**

Drinking alcohol with Prothiaden can make the feeling of drowsiness worse.

### **Pregnancy, Breast feeding and Fertility**

You should not take Prothiaden if you are pregnant or breastfeeding. If you think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Patients should be advised that withdrawal of this medicine should be gradual. If you stop taking this medicine suddenly you may experience some withdrawal symptoms including insomnia, irritability and excessive perspiration. Similar symptoms may occur in newborn babies whose mothers have received this medicine during the last 3 months of pregnancy.

### **Driving and Using Machines**

Prothiaden can make you feel drowsy. Do not drive, operate machinery or do anything that requires you to be alert until you know how the capsules affect you. Feeling drowsy in the day can improve with time, but if drowsiness becomes a problem, you should tell your doctor.

### **Prothiaden contains lactose monohydrate**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

## **3. HOW TO TAKE PROTHIADEN**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Prothiaden capsules should be swallowed whole with a drink of water. If you chew the capsule, you may experience a bitter taste and a temporary numbness of your tongue.

It may take two to four weeks of treatment before you begin to see an improvement in your mood. You may, however, notice an earlier improvement in your anxiety symptoms. It is important that you keep taking these capsules until your doctor tells you to stop. Don't stop just because you feel better. If you stop taking the capsules too soon, your condition may get worse.

The exact number of capsules that you will need to take will be decided by your doctor. Your doctor will also tell you when you should take them. Some patients may be told to take a mixture of Prothiaden capsules and Prothiaden tablets. If you need more information, you should ask your doctor or pharmacist. The following are given as guidelines.

*Adults:* As a starting dose, 3 capsules a day. This may be taken as one capsule three times a day **or** 3 capsules as a single dose each evening. The evening dose is best taken a couple of hours before going to bed. Normally, not more than 9 capsules (equivalent to 225mg dosulepin) should be taken each day.

*Elderly:* Initially, 2 to 3 capsules a day.

*Children:* Not recommended.

**If you take more Prothiaden Capsules than you should:**

If you have taken more than the stated dose (an overdose), go to the nearest hospital casualty department immediately. Show them the capsules and any other medicines that may have been taken.

**If you forget to take Prothiaden Capsules**

If you forget to take a dose, take the next dose at the usual time. Never double up on a dose to make up for the one you have missed.

**If you stop taking Prothiaden**

Patients should be advised that withdrawal of this medicine should be gradual. If you stop taking this medicine suddenly you may experience some withdrawal symptoms including insomnia, irritability and excessive perspiration.

#### **4. POSSIBLE SIDE EFFECTS**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Contact your doctor (or go to a hospital straight away) if you get any of the following serious side effects:**

**Rare** (between 1 and 10 of every 10,000 patients treated):

- Bone marrow depression or reduction in some blood cells (you may experience unusual bruising or abnormal bleeding, sore throat and fever, mouth ulcers)
- Liver problems with yellowing of the skin and eyes (jaundice)
- Convulsions (fits)
- Irregular heartbeat (more likely with high dosage)

Other possible side effects during treatment

**Common** (between 1 and 10 of every 100 patients) treated:

- dry mouth,
- blurred vision,
- dizziness,
- constipation,
- sedation,
- difficulty in passing urine.

These problems tend to improve with time.

**Uncommon** (between 1 and 10 of every 1000 patients)

- severe allergic reaction to Prothiaden (you may experience a skin rash, itching, swollen face or tongue, shortness of breath, collapse). If you develop an unexpected skin rash or difficulty breathing stop taking the capsules and contact your doctor.

- severe low blood pressure,
- increased sweating,
- tiredness or sleepiness,
- confusion and hallucination (strange vision or sounds),
- tremors,
- changes in sex drive,
- changes in the heart beat.

If you have thoughts of harming or killing yourself at any time, **contact your doctor or go to a hospital straight away.**

An increased risk of bone fractures has been observed in patients taking these types of medicines.

### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRa Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. HOW TO STORE PROTHIADEN**

Do not take this product after the 'use by' (expiry) date shown on the bottle and on the carton. The expiry date refers to the last day of that month. Keep the container tightly closed in order to protect from moisture, and store in the original package to protect from light. Do not store above 25°C. They should be stored in a safe place (preferably a locked cupboard) out of the sight and reach of children. Your medicine could harm them.

If your doctor decides to stop the treatment, return any left over to your pharmacist. Only keep the capsules if your doctor tells you to. 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 FURTHER INFORMATION**

### **What Prothiaden Hard Capsules contain**

Each capsule contains 25mg of Dosulepin Hydrochloride with lactose monohydrate, maize starch and magnesium stearate. The capsule shell contains gelatin, with small amounts of iron oxide (E172), Erythrosine (E127), shellac, titanium dioxide (E171), dimeticone and soya lecithin.

### **What Prothiaden Hard Capsules Look Like and Contents of the Pack**

The capsules are available in bottles of 100 and in bulk packs of 500 capsules.  
Not all pack sizes may be marketed.

Appearance of capsules: A red/brown, hard gelatin capsule containing a white to off-white powder, imprinted with the identifying code "P25" on the capsule shell.

### **Marketing Authorisation Holder's Name and Address**

Teofarma S.r.l., Via F.lli Cervi, 8 - 27010 Valle Salimbene (PV), Italy  
e-mail: [servizioclienti@teofarma.it](mailto:servizioclienti@teofarma.it)

### **Manufactured by:**

Teofarma S.r.l., Viale Certosa, 8/A, 27100 Pavia, Italy

**Remember:** This leaflet provides a summary of the information available on your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist who have access to additional information.

**This leaflet was last approved in** May 2020