PACKAGE LEAFLET: INFORMATION FOR THE USER

PROTHIADEN 75 mg COATED TABLETS
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, 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 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 PROTHIADEN IS AND WHAT IT IS USED FOR

The name of your medicine is Prothiaden 75mg Coated Tablets (called Prothiaden in this leaflet). The active ingredient in Prothiaden is dosulepin hydrochloride. Prothiaden belongs to a group of medicines called tricyclic 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 Coated Tablets if
- You are allergic to dosulepin, ponceau 4R (E124), sunset yellow (E110) or any of the other ingredients in this medicine (see Section 6).
- 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 the 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 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 small number of people may be sensitive to the ponceau 4R (El24) and sunset yellow (E110) contained in Prothiaden coated tablets. They may cause allergic reaction. Allergy is more common in those people who are allergic to aspirin.

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 when 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, amylobarbitone for insomnia) or methylphenidate (used to treat behavioural problems)
  - Any medicine containing an opioid (such as 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) e.g. guanethidine.

- 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, pseudoephrine, 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, amylobarbitone 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 tablets affect you. Feeling drowsy in the day can improve with time, but if drowsiness becomes a problem, you should tell your doctor.

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

Prothiaden contains sodium benzoate (E211)
The amount of sodium benzoate (E211) is less than 7.5mg per tablet.

Prothiaden contains ponceau 4R (El24) and sunset yellow (El10) which may cause allergic reactions.

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 coated tablets should be swallowed whole with a drink of water.
If you chew the tablet, 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 tablets until your doctor tells you to stop. Don't stop just because you feel better. If you stop taking the tablets too soon, your condition may get worse.
The exact number of tablets 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 coated tablets and Prothiaden capsules. If you need more information, you should ask your doctor or pharmacist.

The following are given as guidelines.

Adults: As a starting dose, l tablet a day. The dose may be increased to a total of 2 or 3 tablets a day. The tablets may be taken in divided doses throughout the day, or as a single dose each evening, usually a couple of hours before you go to bed.

Normally, not more than 3 tablets (equivalent to 225 mg dosulepin) should be taken each day.

Elderly: Initially, 50 mg to 75 mg a day (this medicine is also available in 25 mg hard capsules)

Children: Not recommended.

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 tablets until your doctor tells you to stop. Don't stop just because you feel better. If you stop taking the tablets too soon, your condition may get worse.

If you take more Prothiaden Coated Tablets 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 tablets and any other medicines that may have been taken.

If you forget to take Prothiaden Coated Tablets
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 Coated Tablets
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 everyone 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 tablets 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; E-mail: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 carton or bottle. The expiry date refers to the last day of that month.
Blister pack: 'Store in the original package in order to protect from light and moisture'.
HDPE bottle: 'Keep the container tightly closed in order to protect from moisture, and store in the original package to protect from light'.
Do not store them above 25°C. They should be kept in a safe place (preferably a locked cupboard) where they are out of the reach and sight 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 tablets 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 OTHER INFORMATION

What Prothiaden Coated Tablets contain
The active ingredient in PROTHIADEN is dosulepin hydrochloride. Each tablet contains 75mg of dosulepin hydrochloride with calcium phosphate, maize starch, talc, povidone and magnesium stearate. The coating of the tablets also contains small amounts of sucrose, liquid glucose, sandarac, white beeswax, sodium benzoate (E211), titanium dioxide (E171), ponceau 4R (E124), sunset yellow (E110), and povidone.

What Prothiaden Coated Tablets Looks Like and Contents of the Pack
PROTHIADEN coated tablets are red, biconvex, sugar coated tablets and are available in blister packs of 100 tablets, calendar packs of 28 tablets and in bottles of 100 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Teofarma S.r.l. - Via F.lli Cervi, 8 - 27010 Valle Salimbene (PV) - Italy
e-mail: 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…