What is in this leaflet

This leaflet answers some common questions asked about Prothiaden. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking Prothiaden against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine. You may need to read it again later.

What is Prothiaden used for

Prothiaden is used to treat depression. It belongs to a group of medicines called tricyclic antidepressants.

Depression is longer lasting and/or more severe than the 'low moods' that everyone has from time to time due to the stress of everyday life. It is thought to be caused by a chemical imbalance in parts of the brain. This imbalance affects your whole body and can cause emotional and physical symptoms such as loss of interest in activities, being unable to enjoy life, disturbed sleep, often waking up early, poor appetite or overeating, loss of sex drive, lack of energy and feeling guilty over nothing.

Prothiaden corrects this chemical imbalance and may help relieve the symptoms of depression.

Your doctor, however, may prescribe Prothiaden for a purpose that is not listed above. Ask your doctor if you have any questions about why Prothiaden has been prescribed for you.

Prothiaden is only available with a doctor's prescription.

Before you take Prothiaden

When you must not take it

Do not take Prothiaden if:

* you have an allergy to Prothiaden, or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may be an itchy skin rash, skin blisters or discolouration of the skin upon exposure to sunlight.

* you are taking another medicine called a monoamine oxidase inhibitor (MAOI) or have been taking it within the last 14 days.

Prothiaden may cause a serious reaction with a sudden increase in body temperature, extremely high blood pressure and severe convulsions.

* you are pregnant.

Medicines like Prothiaden may harm the developing baby.

* you are breast-feeding.

Like many other medicines, Prothiaden can pass into breastmilk and may harm your baby.

* you have epilepsy or have had any fits or convulsions.

Prothiaden may increase the chance of fitting or having convulsions.

* you have recently had a heart attack, for example within the past two months.

Prothiaden may cause irregular and/or rapid heart beat.

* you have liver failure.

Your body may not be able to remove Prothiaden from your body.

If you are not sure whether you should be taking Prothiaden, consult your doctor.

Do not take Prothiaden if the packaging is torn or shows signs of tampering or the tablets or capsules do not look quite right.

Do not take Prothiaden if the expiry date (Exp) printed on the pack has passed.

Before you start to take it

You must tell your doctor if:

1. You are allergic to any other medicines, foods, dyes or preservatives.
2. You have or have had any other health problems or medical conditions, including:
* thyroid problems
* liver problems or hepatitis
* heart problems
* glaucoma (high pressure in the eye)
* kidney problems or difficulty passing urine (water)
* a mental disorder, particularly manic-depression or schizophrenia

3. You are pregnant or intend to become pregnant.
Your doctor will discuss the risks and benefits of using Prothiaden when pregnant.

4. You are breastfeeding or wish to breastfeed.
Your doctor will discuss the risk and benefits of using Prothiaden when breastfeeding.

5. You are going to have an operation, particularly if it will involve general anaesthesia.

6. You are receiving any other medicines or therapy for your depression from another doctor.

Taking other medicines
Tell your doctor if you are taking any other medicines, including medicines you buy without a prescription from pharmacy, health food shops or supermarkets.

Some commonly used medicines that may interfere with Prothiaden include medicines for:
* anxiety or nerves
* fitting or convulsions
* blood pressure
* sleeping problems
* depression
* thyroid problems
* weight reduction
* Parkinson's disease
* Hayfever
* cough and cold
* epilepsy

These medicines may be affected by Prothiaden or they may affect how well it works.
Your doctor or pharmacist can tell you what to do when you are taking any of these medicines. They also have a more complete list of medicines to be careful with or avoid while taking Prothiaden.

How to take Prothiaden

Swallow Prothiaden with water.
Prothiaden can be taken with or apart from food or meals.

How to take it

If you forget to take Prothiaden
If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, then go back to taking it as you would normally.

Do not take a double dose to make up for the missed dose.

If you have trouble remembering when to take Prothiaden, ask your pharmacist for some hints.

How long to take it

For depression, the length of treatment will depend on how quickly your symptoms improve. Most antidepressants take some time to work, so do not be discouraged if you do not feel better straight away. Some of your symptoms may improve in 1 or 2 weeks, but it can be up to 4 to 6 weeks before you feel any real improvement. Even when you feel well, you will usually have to take Prothiaden for several months or even longer to make sure that the benefits will last. You should take Prothiaden until your doctor tells you to stop.

If you take too much Prothiaden (overdose)
Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to the Casualty Department at your nearest hospital, if you think that you or anyone else may have taken too much Prothiaden even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Keep telephone numbers for these places handy.
Too much Prothiaden may make you tremble, agitated and/or have difficulty walking. Other signs include fitting or convulsions, unusual muscle movements, difficulty breathing, a very high temperature or irregular heartbeat as well as other serious heart problems.

If you are not sure what to do, contact your doctor or pharmacist.

While you are using Prothiaden

Things you must do

Tell your doctor immediately if you become pregnant while taking Prothiaden.

If you are about to be started on any new medicines, tell your doctor or pharmacist that you are taking Prothiaden.

Do not take any other medicines, whether they require a prescription or not, without first telling your doctor.

Tell all doctors, dentists and pharmacists who are treating you that you are taking Prothiaden.

Your doctor may ask you to stop taking Prothiaden a few days before elective surgery.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Tell your doctor if you feel the tablets or capsules are not helping your condition.

Do not stop taking Prothiaden, or lower the dose, without first checking with your doctor.

Do not let yourself run out of medicine over the weekend or on holidays.

Suddenly stopping Prothiaden may cause your condition to get worse and/or cause headache, nausea, fits or blood clots.

Things to be careful of

Make sure you know how you react to Prothiaden before you drive or operate machinery.

Prothiaden may cause drowsiness, sleepiness or dizziness in some people and affect alertness. Please discuss with your doctor whether you should be driving or operating machinery whilst taking Prothiaden.

Be careful when drinking alcohol while taking Prothiaden.

Combining Prothiaden and alcohol can make you more sleepy, dizzy or lightheaded.

Your doctor may suggest you avoid alcohol while you are being treated for depression.

All of the above precautions are important even after you have stopped taking Prothiaden.

The effects of Prothiaden may last for several days after you have stopped it because some of the medicine may still be in your body.

Things to be careful of

Families and caregivers of children and adolescents being treated with Prothiaden need to monitor these patients for the emergence of:

* anxiety
* agitation
* panic attacks
* insomnia
* irritability
* aggressiveness
* impulsivity
* restlessness or difficulty sitting still
* hypomania
* mania
* unusual changes in behaviour

This will help your doctor determine the best way to control these feelings.

Tell your doctor or dentist if your mouth feels dry and this lasts for more than 2 weeks.

Prothiaden may cause dry mouth. Continuing dryness of the mouth may increase the chance of dental disease, including tooth decay and gum disease. This can be relieved by frequent sips of water, sucking sugarless lollies or chewing sugarless gum.

Things you must not do

Tell your doctor if you feel the tablets or capsules are not helping your condition.

If you are being treated for depression, be sure to discuss with your doctor any problems you may have on how you feel, especially feelings of severe sadness, bursts of unusual energy or anger or any feelings of wanting to harm yourself (suicide).

Tell your doctor if you notice any of the following and they worry you:

* dry mouth
* palpitations
* difficulty in passing urine
* constipation

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Prothiaden.

Prothiaden helps most people with depression, but it may have unwanted side effects in some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

* dry mouth
* palpitations
* difficulty in passing urine
* constipation
* nausea or vomiting
* dizziness, faintness or weakness
* confusion or disorientation
* blurred vision
* changes in sex drive
* tremor
* tingling or numbness in the hands or feet
* sweating

These are the more common side effects of Prothiaden.

If any of the following happen, stop taking Prothiaden and tell your doctor immediately or go to casualty at your nearest hospital:
* symptoms of allergy (eg. itchy skin rash, skin blisters or discolouration of skin upon exposure to sunlight)
* severe dizziness, drowsiness or disorientation
* severe constipation
* unusual bruising or bleeding
* yellowing of the skin or eyes (jaundice)
* fast or irregular heart beat
* chest pain
* seizures or fitting

These may be serious side effects of Prothiaden. You may need urgent medical attention. These side effects are rare.

Other side effects not listed above may also occur in some patients. Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Ask your doctor or pharmacist if you don’t understand anything in this list.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

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### After using Prothiaden

#### Storage

Keep your tablets or capsules in their container until it is time to take them.

If you take them out of their container they may not keep well.

Keep Prothiaden in a cool, dry place where the temperature stays below 25 degrees C.

Do not store it or any other medicine, in a bathroom or near a sink. Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep this medicine where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

#### Disposal

If your doctor tells you to stop taking Prothiaden or you find that they have passed their expiry date, ask your pharmacist what to do with any medicine left over.

#### Product description

### What it looks like

Prothiaden is available as either tablets or capsules.

Prothiaden tablets are provided in packs of 30 tablets. The tablets are red, marked with 'P75' on one side and plain on the other.

Prothiaden capsules are provided in packs of 50 capsules. The capsules are brown and red, marked 'P' on one end and '25' on the other.

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### Ingredients

Prothiaden tablets contain 75mg of dothiepin hydrochloride as the active ingredient.

The other ingredients in Prothiaden tablets are:
* Calcium Phosphate (341)
* Starch - Maize
* Titanium Dioxide (171)
* Povidone
* Talc - Purified (553)
* Beeswax - White (901)
* Sucrose
* Glucose - liquid
* Magnesium Stearate (470)
* Brilliant Scarlet Red CI 16255 (124)
* Sunset Yellow FCF CI 15985 (110)

Prothiaden capsules contain 25mg of dothiepin hydrochloride as the active ingredient.

The other ingredients in Prothiaden capsules are:
* Starch - Maize
* Titanium Dioxide (171)
* Gelatin
* Magnesium Stearate (470)
* Brilliant Scarlet Red CI 16255 (124)
* Iron Oxide Yellow CI 77492 (172)
* Iron Oxide Red CI 77491 (172)
* Iron Oxide Black CI 77499 (172)

Prothiaden tablets and capsules do not contain gluten, lactose or tartrazine.

### Supplier

Prothiaden is distributed by:

Abbott Australasia Pty Ltd
32-34 Lord Street
Botany NSW 2019
(ABN 95 000 180 389)
Prothiaden Australian registration numbers:
25 mg capsules: AUST R 14967
75 mg tablets: AUST R 61568

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