

Dothep

contains the active ingredient dothiepin hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Dothep.

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 Dothep against the benefits expected for you.

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

Please read this leaflet carefully and keep it with your medicine.

You may need to read it again.

What Dothep is used for

Dothep is used to treat depression.

Dothep 25 mg capsules can be used at any stage in the treatment of depression. However, the higher strength Dothep 75 mg tablets are approved only for the maintenance treatment of depression (after your symptoms have improved).

Dothep belongs to a group of medicines called tricyclic antidepressants (TCAs). TCA medicines work by correcting the imbalance of certain chemicals in the brain. These chemicals, called amines, are involved in controlling mood. By correcting this imbalance, TCAs can help relieve the symptoms of depression.

Ask your doctor if you have any questions about why Dothep has been prescribed for you.

Your doctor may have prescribed Dothep for another reason.

Dothep is not approved for use in children and adolescents below 18 years of age for the treatment of depression.

The safe use and effectiveness of Dothep in treating depression, for this age group, has not been established.

Dothep is available only with a doctor's prescription.

Before you take Dothep

When you must not take it

Do not take Dothep if you are allergic to medicines containing dothiepin (e.g. Prothiaden) or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin
- discolouration of the skin upon exposure to sunlight

Do not take Dothep if you have:

- epilepsy
Dothep may increase the chance of fitting or having convulsions.
- recently had a heart attack, for example within the past two months

Dothep may cause irregular and/or rapid heartbeat.

- liver failure.

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

Do not take Dothep if you are taking a medicine called a monoamine oxidase inhibitor (MAOI), or have taken a MAOI within the last 14 days.

Stop taking MAOIs at least 14 days before starting Dothep.

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

Ask your doctor or pharmacist if you are not sure if you have been taking a MAOI medicine.

MAOIs are medicines used to treat depression and symptoms of Parkinson's disease, such as phenelzine (Nardil), tranylcypromine (Parnate), moclobemide (eg. Aurorix Arima) and selegiline (Eldepryl, Selgene).

Do not take Dothep if the expiry date (EXP.) printed on the pack has passed.

If you take this medicine after the expiry date has passed, it may not work as well.

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

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Tell your doctor if you are pregnant or plan to become pregnant.

There have been reports of some babies experiencing complications immediately after delivery. Your doctor will discuss the possible risks and benefits of taking Dothep during pregnancy.

Tell your doctor if you are breastfeeding or wish to breastfeed.

Like many other medicines, Dothep passes into breast milk.

Your doctor will discuss the risks and benefits of taking Dothep when breastfeeding.

Tell your doctor if you have, or have had, any medical conditions, especially the following:

- heart or blood vessel problems
- liver problems or hepatitis
- kidney problems or difficulty passing urine (water)
- glaucoma, a condition characterised by an increased pressure in the eye
- prostate problems
- difficulty in passing urine
- thyroid problems
- any other mental illness, such as schizophrenia or manic depression (alternating periods of elation/overactivity and depressed mood)
- family history of suicide or manic depression.

Tell your doctor if you plan to have surgery or if you are undergoing electroshock therapy.

If you have not told your doctor about any of the above, tell them before you start taking Dothep.

Taking other medicines

Do not take Dothep if you are taking a monoamine oxidase inhibitor (MAOI) such as:

- phenelzine (Nardil) and tranylcypromine (Parnate), moclobemide (eg. Aurorix, Arima), used to treat depression

- selegiline (Eldepryl, Selgene), used to treat symptoms of Parkinson's disease.

Wait at least 14 days after stopping your MAOI before starting Dothep.

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Medicines that may be affected by Dothep or may affect how well it works include:

- sleeping tablets/sedatives, anti-anxiety medicines
- medicines used to treat epilepsy
- some medicines used to treat high blood pressure or other heart conditions
- some medicines used to relieve stomach cramps
- medicines used to treat Parkinson's disease
- medicines for travel sickness
- some cough and cold preparations
- some medicines for hayfever and allergies
- certain medicines for weight loss
- thyroid hormone medicines.

Your doctor can tell you what to do if you are taking any of these medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Dothep.

How to take Dothep

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist.

How much to take

The dose varies from person to person.

Your doctor will tell you how much Dothep you need to take each day and when to take it. This depends how well you respond to Dothep and whether or not you are taking any other medicines.

The usual starting dose is 25 mg three times daily for one to two weeks. Your doctor may then increase your dose, up to a maximum of 200 mg per day.

Once your symptoms improve, your doctor will then slowly reduce your dose to the lowest effective dose which maintains relief of symptoms.

Elderly people over 65 years of age and those with liver or kidney problems may need smaller doses.

How to take it

Swallow the tablets or capsules with a glass of water.

The 75 mg tablets can be divided in half along the breakline if advised by your doctor or pharmacist.

When to take it

Dothep can be taken as a single dose (e.g. at bedtime) or as divided doses (e.g. three times a day). Your doctor will advise you.

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How long to take it for

Keep taking Dothep for as long as your doctor recommends.

The length of treatment will depend on how quickly your symptoms improve.

Most medicines for depression take time to work, so do not be

discouraged if you do not feel better right away. Some of your symptoms may improve in 1 or 2 weeks but it can take up to 4 or 6 weeks to feel the full benefit of Dothep.

Even when you feel well, you will usually have to take Dothep for several months or longer, to make sure that the benefits last.

If you forget to take it

IF YOU TAKE ONE DOSE A DAY (AT BEDTIME)

If you forget to take Dothep before you go to bed and wake up late in the night or early in the morning, do not take the missed dose until you have checked with your doctor.

You may have difficulty waking up, or experience drowsiness in the morning and during the day.

IF YOU TAKE MORE THAN ONE DOSE A DAY

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 the missed dose as soon as you remember, and then go back to taking Dothep as you would normally.

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

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

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

If you take too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much Dothep.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Too much Dothep 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.

Keep Dothep out of the reach of children.

Children are much more sensitive than adults to medicines such as Dothep. An accidental overdose is especially dangerous in children.

While you are taking Dothep

Things you must do

Tell your doctor immediately if you have any suicidal thoughts or other mental/mood changes.

Occasionally, the symptoms of depression or other psychiatric conditions may include thoughts of harming yourself or committing suicide.

These symptoms may continue or get worse during the first one to two months of treatment until the full antidepressant effect of the medicine becomes apparent. This is more likely to occur in young adults under 25 years of age.

Contact your doctor or a mental health professional right away or go to the nearest hospital for treatment if you or someone you know is showing any of the following warning signs of suicide:

- worsening of your depression
- thoughts or talk of death or suicide
- thoughts or talk of self-harm or harm to others
- any recent attempts of self-harm
- increase in aggressive behaviour, irritability or any other unusual changes in behaviour or mood.

All mentions of suicide or violence must be taken seriously.

Families and caregivers of children and adolescents being treated with Dothep 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 if you feel Dothep is not helping your condition.

Keep all of your appointments with your doctor so that your progress can be checked.

If you are taking Dothep for a long time, your doctor may ask you to have your eyes tested regularly.

Tell your doctor immediately if you become pregnant while taking Dothep. Do not stop taking your tablets or capsules until you have spoken to your doctor.

Before starting any new medicine, tell your doctor or pharmacist that you are taking Dothep.

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

If you plan to have surgery, including dental surgery, tell your doctor that you are taking Dothep.

Your doctor may ask you to temporarily stop taking Dothep 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.

Things you must not do

Do not drive or operate machinery until you know how Dothep affects you.

Dothep may cause drowsiness, dizziness or light-headedness in some people. If any of these occur, do not drive, operate machinery or do anything else that could be dangerous.

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

If you stop taking Dothep suddenly you may feel sick (nausea), irritable, have a headache, difficulty sleeping or excessive sweating. Other more serious complications such as fits (convulsions) or blood clots may occur.

Your doctor will tell you how to gradually reduce the amount of Dothep you are taking before stopping completely.

Do not use Dothep to treat any other conditions unless your doctor tells you to.

Do not give Dothep to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful when drinking alcohol while taking Dothep. Combining Dothep and alcohol can make you more drowsy, dizzy or lightheaded.

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

Be careful getting up from a sitting or lying position.

Dizziness, light-headedness or fainting may occur, especially when you get up quickly. Getting up slowly may help.

Be careful if you are older than 65 years of age.

Elderly people may become confused when taking Dothep. Families and carers should be aware of this. Special care may be needed.

Tell your doctor or dentist if your mouth continues to feel dry for more than 2 weeks.

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

Side effects

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

Dothep 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 to answer any questions you may have.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

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

- dry mouth
- increased sweating
- feeling sick (nausea), vomiting
- constipation
- blurred vision
- drowsiness, dizziness, light-headedness
- tremor
- increased or decreased sex drive.

The above list includes the common and mild side effects of Dothep.

Tell your doctor as soon as possible if you notice any of the following:

- fast or irregular heart beat
- ongoing difficulty with passing urine
- signs of frequent infections such as fever, chills, sore throat or mouth ulcers
- unusual bruising or bleeding
- tingling or numbness of the hands or feet
- severe pain in the stomach with bloating, gut cramps and vomiting
- symptoms of liver disease such as yellowing of the eyes or skin (jaundice) and passing dark coloured urine
- feeling anxious, restless, or confused
- abnormal ideas, hallucinations
- sudden mood swings alternating from one of excitement, overactivity and uninhibited behaviour to a depressed mood
- uncontrollable movements, including trembling and shaking of the hands and fingers, twisting movements of the body, shuffling walk or stiffness of the arms and legs.

The above side effects are serious and may require medical attention.

Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following:

- chest pain
- fainting or collapse
- allergic symptoms such as skin blisters, rash, itching or hives; swelling of the face, mouth, lips, throat or neck; difficulty swallowing or breathing;
- seizures or fits.

The above side effects are not common but very serious. You may require urgent medical attention or even hospitalisation if they occur.

Tell your doctor if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some patients.

After taking Dothep

Storage

Keep Dothep where children cannot reach it.

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

Keep Dothep in a cool, dry place where the temperature stays below 30°C for tablets and below 25°C for capsules.

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

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking Dothep, or your medicine has passed its expiry date, ask your pharmacist what to do with any that is left over.

Product description

What it looks like

Dothep is available in two strengths:

- Dothep 25 - hard capsule with green and red cap in PVC/PVdC/aluminium blister packs. Each pack contains 50 capsules.
- Dothep 75 - round, red, scored film-coated tablet marked "DT" over a breakline over "75" on one side and a Greek alpha symbol on the other. Each pack contains 30 tablets.

Ingredients

Dothep 25 capsules

Active ingredient:

- dothiepin hydrochloride 25 mg.

Ingredients of known effect:

- lactose (monohydrate and anhydrous)
- sulfites (present in trace amounts)

Inactive ingredients:

- povidone
- sodium starch glycollate
- purified talc
- magnesium stearate
- sodium lauryl sulfate
- colloidal anhydrous silica
- gelatin
- erythrosine CI 45430 (127)
- iron oxide red CI 77491 (172)
- titanium dioxide (171)
- brilliant blue FCF CI 42090 (133)
- quinoline yellow CI 47005 (104).

Dothep 75 tablets

Active ingredient:

- dothiepin hydrochloride 75 mg.

Ingredients of known effect:

- lactose
- sulfites (present in trace amounts)
- soya bean products (present in trace amounts)

Inactive ingredients:

- maize starch
- povidone
- sodium starch glycollate
- purified talc
- magnesium stearate
- Opadry Red OY-B-25005 (includes colours brilliant scarlet 4R CI 16255 [124], titanium dioxide [171]).

Dothep tablets and capsules are gluten free.

Manufacturer

Dothep is made in Australia by:

Alphapharm Pty Limited

(ABN 93 002 359 739)

Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000
Phone: (02) 9298 3999
www.mylan.com.au

Australian registration numbers:

Dothep 25 - AUST R 34419

Dothep 75 - AUST R 62910

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