

DOTHEP TABLET

Dothiepin hydrochloride (75 mg)

What is in this leaflet

1. What *Dothep* is used for
2. How *Dothep* works
3. Before you use *Dothep*
4. How to use *Dothep*
5. While you are using it
6. Side effects
7. Storage and Disposal of *Dothep*
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What *Dothep* is used for

Dothep is used to treat depression.

How *Dothep* works

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

Before you use *Dothep*

- *When you must not use 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 (see section **Product description**). 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
- Recently had a heart attack, for example within the past two months
- Liver Failure

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 (see also *Taking other medicines*).

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

- *Before you start to use it*

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

Pregnancy and lactation

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: n

- heart or blood vessel problems
- liver problems or hepatitis
- kidney problems
- 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 (a severe brain disorder in which people interpret reality abnormally) 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*

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription from a pharmacy, supermarket or health food shop.

Do not take *Dothep* if you are taking a monoamine oxidase inhibitor (MAOI) such as (see also *When you must not use it*):

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

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.

Other medicines not listed above may also interact with *Dothep*. Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine. Follow all directions given to you by your doctor and pharmacist carefully.

DOTHEP TABLET

Dothiepin hydrochloride (75 mg)

How to use Dothep

- How much to use

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.

For *adult*, the recommended initial dose is 25mg three times daily for one to two weeks. Your doctor may gradually increase the dose based on your response to *Dothep*. The daily dose should not exceed 200 mg.

For *paediatric*, *Dothep* is not recommended for use in children under 16 years.

For *geriatric*, use adult dose with care, particularly in elderly people with liver, kidney or heart problem.

- When to use 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.

- How long to use it

Keep taking *Dothep* for as long as your doctor recommends.

- If you forget to use 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.

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 use too much (overdose)

Immediately telephone your doctor for advice, or go to Accident and Emergency Department 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.

While you are using it

- Things you must do

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

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.

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 behavior

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*.

DOTHEP TABLET

Dothiepin hydrochloride (75 mg)

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.

Tell your doctor if you notice any of the following:

- 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.

You may report any side effects or adverse drug reactions directly to The National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website npra.moh.gov.my (Consumers -> Reporting -> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage and Disposal of *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 below 30°C.

Do not store *Dothep* or any other medicine in the bathroom or near a sink.

DOTHEP TABLET

Dothiepin hydrochloride (75 mg)

Do not leave *Dothep* in the car or on window sills.

- Disposal

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.

Product Description

- What it looks like

Dothep 75 - round, red, scored 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

- Active Ingredient

Dothiepin hydrochloride 75 mg.

- Inactive ingredients

Lactose, Maize starch, Povidone, Sodium starch glycollate, Purified talc, Magnesium stearate, Opadry Red OY-B-25005 (includes colours brilliant scarlet 4R CI 16255 [124] and Titanium dioxide [171]).

- MAL number :

MAL19970063A

Manufacturer

ALPHAPHARM PTY LIMITED
Cnr. Garnet and Antimony Streets,
Carole Park 4300,
Brisbane, Queensland,
Australia.

Product Registration Holder

Pahang Pharmacy Sdn. Bhd.
Lot 5979, Jalan Teratai,
5 ½ Miles off Jalan Meru,
Klang, Selangor, MALAYSIA.

Date of Revision

09/05/2019

Serial Number

NPRA(R2/1)190509/131