

DOTHEP

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using DOTHEP?

DOTHEP contains the active ingredient dosulepin. DOTHEP is used to treat depression. For more information, see Section [1. Why am I using DOTHEP?](#) in the full CMI.

2. What should I know before I use DOTHEP?

Do not use if you have ever had an allergic reaction to DOTHEP or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding. For more information, see Section [2. What should I know before I use DOTHEP?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with DOTHEP and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use DOTHEP?

- 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.

More instructions can be found in Section [4. How do I use DOTHEP?](#) in the full CMI.

5. What should I know while using DOTHEP?

Things you should do

- Remind any doctor, dentist or pharmacist you visit that you are using DOTHEP.
- Tell your doctor immediately if you have any suicidal thoughts or other mental/mood changes.
- Tell your doctor immediately if you

	become pregnant while taking DOTHEP.
Things you should not do	<ul style="list-style-type: none"> • Do not stop using this medicine suddenly or lower the dose, without checking with your doctor. • 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.
Driving or using machines	<ul style="list-style-type: none"> • Do not drive or operate machinery until you know how DOTHEP affects you.
Drinking alcohol	<ul style="list-style-type: none"> • Be careful when drinking alcohol while taking DOTHEP. Combining DOTHEP and alcohol can make you more drowsy, dizzy or lightheaded.
Looking after your medicine	<ul style="list-style-type: none"> • Keep the pack in a cool, dry place below 25°C for capsules and below

30°C for tablets in its original packaging.

- Do not store DOTHEP in the bathroom, near a sink or leave it in the car on hot days.
- Keep your tablets where young children cannot reach it.

For more information, see Section [5. What should I know while using DOTHEP?](#) in the full CMI.

6. Are there any side effects?

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. **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, uncontrollable movements. **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.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

DOTHEP

Active ingredient(s): *dosulepin (dothiepin) hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about using DOTHEP. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using DOTHEP.**

Where to find information in this leaflet:

- [1. Why am I using DOTHEP?](#)
- [2. What should I know before I use DOTHEP?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use DOTHEP?](#)
- [5. What should I know while using DOTHEP?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using DOTHEP?

DOTHEP contains the active ingredient dosulepin hydrochloride.

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.

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).

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.

2. What should I know before I use DOTHEP?

Warnings

Do not use DOTHEP if:

- you are allergic to medicines containing dosulepin (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

Always check the ingredients to make sure you can use this medicine.

- you have epilepsy.
DOTHEP may increase the chance of fitting or having convulsions.
- you recently had a heart attack, for example within the past two months.
DOTHEP may cause irregular and/or rapid heartbeat.
- you have liver failure.

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

- **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).

- **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.

- **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.

Check with your doctor if you:

- **are allergic to any other medicines, foods, dyes or preservatives.**

- 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.
- **plan to have surgery or if you are undergoing electroshock therapy.**
- take any medicines for any other condition

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

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

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.

Withdrawal symptoms such as difficulty sleeping, irritability and excessive sweating in newborn infants have been reported in mothers who have taken this medicine during the third trimester.

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.

3. What if I am 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 or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription

from your 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.

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect DOTHEP.

4. How do I use 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 DOTHEP 75 mg tablets can be divided in half along the breakline if advised by your doctor or pharmacist.

When to take DOTHEP

- 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 use DOTHEP

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 use too much DOTHEP

If you think that you have used too much DOTHEP, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

Taking too much DOTHEP at once can be dangerous. The onset of toxicity develops rapidly within 4-6 hours. Too much DOTHEP may make you tremble, agitated and/or have difficulty walking. Other signs and symptoms can include dry mouth, blurred vision, dilated pupils, constipation, difficulty passing urine, fitting or convulsions, unusual muscle movements, difficulty breathing, a very high temperature or irregular heartbeat, shock and/or cardiac arrest as well as other serious heart problems which can be life-threatening or fatal.

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.

5. What should I know while using DOTHEP?

Things you should 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 should not do

- **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 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.

Driving or using machines

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.

Drinking alcohol

Be careful when drinking alcohol while taking DOTHEP. Combining DOTHEP and alcoholic drinks may affect you much more than usual and can make you more drowsy, dizzy or lightheaded.

Taking DOTHEP and alcohol together can be dangerous and may cause death.

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

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

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

Store away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it 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.

When to discard your medicine

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.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any 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. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

Ask your doctor or pharmacist to answer any questions you may have.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

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

You may not experience any of them.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">● dry mouth● increased sweating● feeling sick (nausea), vomiting● constipation● blurred vision● drowsiness, dizziness, light-headedness● tremor● increased or decreased sex drive <p>The above list includes the common and mild side effects of DOTHEP.</p>	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">● fast or irregular heart beat● ongoing difficulty with passing urine	<p>Tell your doctor as soon as possible if you notice any of the following.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> ● 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 	

Serious side effects	What to do
<p>trembling and shaking of the hands and fingers, twisting movements of the body, shuffling walk or stiffness of the arms and legs</p> <ul style="list-style-type: none"> ● Disorganised speech or behaviour ● Difficulty with concentration and memory <p>The above side effects are serious and may require medical attention.</p>	

More serious side effects

More serious side effects	What to do
<ul style="list-style-type: none"> ● 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 	<p>Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following.</p>

More serious side effects	What to do
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 or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some patients.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What DOTHEP 25 capsules contains

Active ingredient (main ingredient)	dosulepin (dothiepin) hydrochloride 25 mg
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• Lactose• Lactose monohydrate• 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)
Potential allergens	DOTHEP contains sulfites and sugars as lactose.

What DOTHEP 75 tablets contains

Active ingredient (main ingredient)	dosulepin (dothiepin) hydrochloride 75 mg
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• lactose monohydrate• 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])
Potential allergens	DOTHEP contains sulfites, soya bean products and sugars as lactose.

Do not take this medicine if you are allergic to any of these ingredients.

What DOTHEP looks like

DOTHEP 25 is a hard capsule with green and red cap in PVC/PVdC/aluminium blister packs. Each pack contains 50 capsules. (AUST R 34419).

DOTHEP 75 is a 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. (AUST R 62910).

Who distributes DOTHEP

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

This leaflet was prepared in August 2022.

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