

DEPTRAN

Consumer Medicine Information (CMI) summary

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

1. Why am I taking DEPTRAN?

DEPTRAN contains the active ingredient doxepin (as hydrochloride). DEPTRAN is used to treat depression.

For more information, see Section [1. Why am I taking DEPTRAN?](#) in the full CMI.

2. What should I know before I take DEPTRAN?

Do not take if you have ever had an allergic reaction to any medicine containing doxepin hydrochloride, any other tricyclic antidepressants 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 take DEPTRAN?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with DEPTRAN 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 take DEPTRAN?

- The dose of DEPTRAN varies from 30 mg to 300 mg daily. Your doctor will decide the right dose for you.

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

5. What should I know while taking DEPTRAN?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are taking DEPTRAN. • If you are about to start any new medicine, tell your doctor and pharmacist that you are taking DEPTRAN. • Tell your doctor immediately if you have any suicidal thoughts or other mental/mood changes.
Things you should not do	• Do not stop taking DEPTRAN, or change the dose, without first checking with your doctor. • Do not give DEPTRAN to anyone else, even if they have the same condition as you.
Driving or using machines	• Be careful driving or operating machinery until you know how DEPTRAN affects you. • DEPTRAN may cause drowsiness and affect coordination in some people.
Drinking alcohol	• Be careful when drinking alcohol while taking DEPTRAN. • Combining DEPTRAN and alcohol can make you more sleepy, dizzy or light-headed.
Looking after your medicine	• Store DEPTRAN 10 mg and DEPTRAN 25 mg below 25°C, and DEPTRAN 50 mg below 30°C, in a cool dry place away from moisture, heat or sunlight. • Keep your capsules or tablets in their blister pack until it is time to take them.

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

6. Are there any side effects?

Less serious side effects include light-headedness, difficulty sleeping, constipation, diarrhoea or vomiting. **Serious side effects** include anxiety, aggressive behaviour, fast or irregular heartbeat, chest pain, bruising or bleeding more easily than normal, shakiness or unwanted movements. **Very serious side effects** include thoughts of suicide or attempting suicide or self-harm, symptoms of an allergic reaction, sudden pain or ache around eye. **This is not a complete list of side effects.**

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.

DEPTRAN

Active ingredient: *doxepin (as hydrochloride)*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I taking DEPTRAN?

DEPTRAN contains the active ingredient **doxepin (as hydrochloride)**. DEPTRAN belongs to a group of medicines called tricyclic antidepressants (TCAs). Antidepressants are thought to work by their action on brain chemicals called amines which are involved in controlling mood.

DEPTRAN is used to treat depression.

DEPTRAN 10 mg and DEPTRAN 25 mg capsules can be used at any stage in the treatment of depression. However, the higher strength, DEPTRAN 50 mg tablets, is approved only for the maintenance treatment of depression (after your symptoms have improved).

Your doctor, however, may prescribe DEPTRAN for another purpose.

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

2. What should I know before I take DEPTRAN?

Warnings

Do not take DEPTRAN if:

- you are allergic to any medicine containing doxepin hydrochloride, any other tricyclic antidepressants such as amitriptyline and imipramine, or any of the ingredients listed at the end of this leaflet. Some of the symptoms of an allergic reaction to DEPTRAN may include:
 - o shortness of breath
 - o wheezing or difficulty breathing
 - o skin rash, itching or hives on the skin
 - o swelling of the face, lips, tongue or other parts of the body
 - o increased sensitivity of the skin to the sun.

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

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

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

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

MAOIs are medicines used to treat depression and symptoms of Parkinson's Disease. Examples of MAOIs are phenelzine, tranylcypromine, moclobemide and selegiline.

- you have glaucoma, a condition where the pressure in the eye is increased, including a type of glaucoma called angle closure glaucoma
- you have urinary retention (difficulty in passing urine)
- the expiry date (EXP) printed on the pack has passed or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Check with your doctor if you:

- are allergic to any other medicines, or any other substances such as foods, dyes or preservatives
- take any medicines for any other condition
- are not well or have any other health problems or history of, including:
 - o any mental illness
 - o heart disease
 - o liver or kidney problems
 - o diabetes.

If you have not told your doctor or pharmacist about these things, tell them before you start taking DEPTRAN.

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 intend to become pregnant.

Your doctor will discuss the risks and benefits of taking DEPTRAN during pregnancy.

Do not take DEPTRAN if you are breastfeeding unless directed by your doctor.

Like many other medicines DEPTRAN can pass into breast milk and may affect your baby.

Use in children and adolescents

DEPTRAN should not be used in children and adolescents under the age of 18 years.

The safety and effectiveness of DEPTRAN in this age group has not been satisfactorily established.

3. What if I am taking other medicines?

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.

Some medicines may interfere with DEPTRAN and affect how it works. These include:

- Monoamine oxidase inhibitors (MAOIs), medicines used for the treatment of depression.

Taking DEPTRAN with, or within 14 days of stopping a MAOI may cause a serious reaction with a sudden increase in body temperature, extremely high blood pressure and convulsions.

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

- other medicines for depression for example fluoxetine, sertraline and paroxetine
- cimetidine, a medicine used to treat reflux and stomach ulcers
- medicines for diabetes (e.g. glibenclamide, glipizide)
- anti-anxiety medicines (e.g. diazepam, oxazepam)
- medicines containing atropine or medicines for irritable bowel syndrome (e.g. propantheline bromide, hyoscine butylbromide)
- tranquillisers such as risperidone, or chlorpromazine
- medicines for controlling abnormal heart beats (e.g. isosorbide mononitrate, flecainide acetate)
- medicines for epilepsy (e.g. phenytoin, carbamazepine)
- medicines containing adrenaline (epinephrine) or noradrenaline (norepinephrine) (e.g. nasal drops, decongestants, some cough mixtures, some local anaesthetics)
- stimulant medicines containing amphetamine (e.g. dexamphetamine)
- guanethidine
- Buprenorphine (an opioid).

DEPTRAN should be used with caution in the case of concomitant administration with Buprenorphine because the risk of developing serotonin syndrome, a potentially life-threatening disorder, is increased.

You may need different amounts of your medicines, or you may need to take different medicines. Your doctor will advise you.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking DEPTRAN.

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

4. How do I take DEPTRAN?

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

They may differ from the information in this leaflet.

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

How much to take

- The dose of DEPTRAN varies from 30 mg to 300 mg daily.
- Your doctor will decide the right dose for you. This depends on your condition, age, whether or not you are taking any other medicines, and how you respond to DEPTRAN.
- It is usual to start with a low dose and then, if necessary, increase it gradually until the right dose is reached.

How to take DEPTRAN

Swallow the capsules or tablets whole with a glass of water or other liquid.

When to take DEPTRAN

- DEPTRAN can be taken with or without food.
- DEPTRAN 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 DEPTRAN for

- **Keep taking DEPTRAN until your doctor tells you to stop.**
- Most antidepressants take time to work so do not be discouraged if you do not feel better straight away. It may take 2 to 3 weeks to feel the full benefit of DEPTRAN.
- Even when you feel well, you may need to take DEPTRAN for several months or longer, to make sure that the benefits last.
- **Do not stop taking DEPTRAN, or change the dose, without first checking with your doctor.**

If you forget to take DEPTRAN

If it is almost time for your next dose (e.g. within 2 or 3 hours), skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking it as you would normally.

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

This may increase the chance of you getting an unwanted side effect.

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 DEPTRAN

If you think that you or anyone else has taken too much DEPTRAN, urgent medical attention may be needed.

Deaths may occur from overdosage, so you should go to hospital as soon as possible for immediate monitoring and treatment.

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.

Symptoms of an overdose may include:

- feeling drowsy
- blurred vision
- dryness of mouth
- disturbed concentration
- hallucinations
- agitation
- unconsciousness
- difficulty control body temperature
- dilated pupils
- uncontrolled twitches
- muscle stiffness
- vomiting.

Major toxicity can develop rapidly within 6 hours. Too much DEPTRAN may cause slow breathing, confusion, convulsions, depression (including coma), abnormal heartbeat and low blood pressure.

5. What should I know while taking DEPTRAN?

Things you should do

- Tell all doctors, dentists and pharmacists who are treating you that you are taking DEPTRAN.
- If you are about to start any new medicine, tell your doctor and pharmacist that you are taking DEPTRAN.
- If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

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

Call your doctor straight away if you:

- become pregnant while taking DEPTRAN
If you are a woman of childbearing age, you should avoid becoming pregnant while taking DEPTRAN.
- have any suicidal thoughts or other mental/mood changes.
- or someone you know is demonstrating any of the following warning signs of suicide while taking

DEPTRAN, contact your doctor or a mental health professional right away or go to the nearest hospital for treatment:

- o thoughts or talk of death or suicide
- o thoughts or talk of self-harm or harm to others
- o any recent attempts of self-harm
- o increase in aggressive behaviour, irritability or agitation
- o worsening of depression.

Occasionally, the symptoms of depression may include thoughts of suicide or self-harm. 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 24 years of age.

All mentions of suicide or violence must be taken seriously.

Remind any doctor, dentist or pharmacist you visit that you are taking DEPTRAN.

Things you should not do

- **Do not stop taking DEPTRAN, or change the dose, without first checking with your doctor.**

Suddenly stopping DEPTRAN may make you feel tired, sick in the stomach and give you a headache. To prevent this, your doctor may want to gradually reduce the amount you take each day before stopping the medicine completely.

- **Do not let yourself run out of DEPTRAN over the weekend or on holidays.**
- **Do not give DEPTRAN to anyone else, even if they have the same condition as you.**
- **Do not take DEPTRAN to treat any other complaints unless your doctor tells you to.**

Driving or using machines

Be careful before you drive or use any machines or tools until you know how DEPTRAN affects you.

DEPTRAN may cause drowsiness and affect coordination in some people.

If this occurs, do not drive, operate machinery or do things that may be dangerous if you are not alert.

Drinking alcohol

Tell your doctor if you drink alcohol.

Be careful when drinking alcohol while taking DEPTRAN.

Combining DEPTRAN and alcohol can make you more sleepy, dizzy or light-headed. It should be borne in mind that consuming alcohol may increase the danger of DEPTRAN overdosage. This is especially important in patients who may use alcohol excessively.

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 DEPTRAN.

The effects of DEPTRAN may last for some days after you have stopped taking it.

Looking after your medicine

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

If you take your capsules or tablets out of their container they may not keep well.

- Store DEPTRAN 10 mg and DEPTRAN 25 mg below 25°C.
- Store DEPTRAN 50 mg below 30°C.

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

Store it in a cool dry place 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.

Getting rid of any unwanted medicine

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

Do not take this medicine after the expiry date.

6. Are there any side effects?

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.

It can be difficult to tell whether side effects are the result of taking DEPTRAN, effects of your condition or side effects of other medicines you may be taking. For this reason, it is important to tell your doctor of any change in your condition.

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 the list of side effects. You may not experience any of them.

Less serious side effects

Less serious side effects	What to do
• drowsiness, dizziness, light-headedness • difficulty sleeping, bad dreams • dry mouth • blurred vision • difficulty in passing urine • feeling sick, vomiting, indigestion • constipation, diarrhoea	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
• changes in taste or taste sensitivity • loss of appetite or increase in appetite • mouth ulcers • numbness	These side effects are usually mild.

Serious side effects

Serious side effects	What to do
• anxiety, nervousness, aggressive behaviour • fast or irregular heartbeat • chest pain • bruising or bleeding more easily than normal, reddish or purple blotches under the skin • signs of frequent or worrying infections such as fever, severe chills, sore throat or mouth ulcers • yellowing of the skin and eyes (also called jaundice) • agitation, confusion • symptoms of tiredness, abdominal pain, jaundice and history of gallstones • symptoms of sunburn (such as redness, itching, swelling, blistering) which may occur more quickly than normal • unsteadiness, stiffness, shakiness or unwanted movements	Tell your doctor as soon as possible if you notice any of these serious side effects.

Very serious side effects

Very serious side effects	What to do
• seizures or fits • symptoms of high fever, drowsiness, sweating, fast heartbeat and muscle stiffness • symptoms of allergy such as a skin rash, increased sweating, swelling of the face or tongue • thoughts of suicide or attempting suicide or self-harm • sudden pain or ache in or around your eye • eyes becoming red, or feeling hard or tender • vision worsening, becoming blurred or starting to see circles (haloes) around lights	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects. These symptoms are usually rare but may be serious and need urgent medical attention.

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 people.

Some of these side effects (e.g. changes in blood pressure, liver function or glucose control) can only be found when your doctor does tests from time to time to check your progress.

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 DEPTRAN contains

DEPTRAN 10

Active ingredient (main ingredient)	doxepin (as hydrochloride) 10 mg
Other ingredients (inactive ingredients)	• lactose monohydrate • sodium starch glycolate • purified talc • magnesium stearate • empty Hard Gelatin Capsule White Opaque/White Opaque 10000368 (ID: 111127) • tekPrint SW-9008 Black Ink (ID: 2328) • tekPrint SW-9009 Black Ink (ID: 2343)
Potential allergens	sulfites, galactose and sugars as lactose

DEPTRAN 25

Active ingredient (main ingredient)	doxepin (as hydrochloride) 25 mg
Other ingredients (inactive ingredients)	• lactose monohydrate • sodium starch glycolate • purified talc • magnesium stearate • sodium lauryl sulfate • colloidal anhydrous silica • gelatin • titanium dioxide • brilliant blue FCF • erythrosine

Potential allergens	sulfites, galactose and sugars as lactose
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DEPTRAN 50

Active ingredient (main ingredient)	doxepin (as hydrochloride) 50 mg
Other ingredients (inactive ingredients)	• lactose monohydrate • microcrystalline cellulose • povidone • purified talc • sodium starch glycollate • magnesium stearate • carnauba wax • hypromellose • diethyl phthalate • erythrosine • indigo carmine
Potential allergens	sulfites, galactose and sugars as lactose

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

What DEPTRAN looks like

DEPTRAN 10 mg is a size 3 capsule with a white body and white cap, printed in black ink DP 10 on the cap. Each pack contains 50 capsules (AUST R 308999).

DEPTRAN 25 mg is a size 3 capsule with white body and blue cap. Each pack contains 50 capsules (AUST R 60448).

DEPTRAN 50 mg is 8mm, hexagonal, normal convex, light violet, filmcoated tablet debossed DN over 50 on one side and " α " on the other. Each pack contains 50 tablets (AUST R 17637).

Who distributes DEPTRAN

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

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