

DEPTRAN

doxepin (as hydrochloride)

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about DEPTRAN.

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 DEPTRAN against the benefits it is expected to have for you.

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

Keep this leaflet with your medicine.

You may need to read it again.

What DEPTRAN is used for

DEPTRAN is used to treat depression.

DEPTRAN 10 mg and DEPTRAN25 mg capsules can be used at any stage in the treatment of depression. However, the

higher strength, DEPTRAN50 mg tablets, is approved only for the maintenance treatment of depression (after your symptoms have improved).

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.

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.

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

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.

Before you take DEPTRAN

When you must not take it

Do not take DEPTRAN if you have an allergy to:

- any medicine containing doxepin hydrochloride

- any other tricyclic antidepressants such as amitriptyline and imipramine
- any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction to DEPTRAN may include:

- shortness of breath
- wheezing or difficulty breathing
- skin rash, itching or hives on the skin
- swelling of the face, lips, tongue or other parts of the body
- increased sensitivity of the skin to the sun.

Do not take DEPTRAN if you are taking a medicine called a monoamine oxidase inhibitor (MAOI) or have been taking it within 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 (Nardil), tranylcypromine (Parnate), moclobemide (e.g. Aurorix, Arima) and selegiline (Eldepryl, Selgene).

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.

Do not take DEPTRAN if you have:

- glaucoma, a condition where the pressure in the eye is increased, including a type of glaucoma called angle closure glaucoma
- urinary retention (difficulty in passing urine)

Do not take DEPTRAN if 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.

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

Before you start to take it

You must tell your doctor if you are allergic to:

- any other medicines
- any other substances such as foods, dyes or preservatives.

Tell your doctor if you are not well or have any other health problems or a history of, including:

- any mental illness
- heart disease
- liver or kidney problems
- diabetes

Tell your doctor if you are pregnant or intend becoming pregnant.

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

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

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including:

- all prescription medicines
- all medicines, vitamins, herbal supplements or natural therapies you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may be affected by DEPTRAN or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines. Your doctor will advise you.

Tell your doctor or pharmacist if you are taking any of the following:

- 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 (e.g. Prozac, Lovan), sertraline (e.g. Zoloft) and paroxetine (e.g. Aropax, Paxtine)
- cimetidine (e.g. Tagamet, Magicul), a medicine used to treat reflux and stomach ulcers
- medicines for diabetes (e.g. Daonil, Minidiab)
- anti-anxiety medicines (e.g. diazepam, Valium, Serepax)
- medicines containing atropine (e.g. Atropt, Atropine eye drops, Atropine Sulphate injection) or medicines for irritable bowel syndrome (e.g. Pro-banthine, Buscopan)
- tranquillisers such as Risperdal, or Largactil
- medicines for controlling abnormal heart beats e.g. Durules, Tambocor

- medicines for epilepsy e.g. Dilantin, Tegretol, Teril
- 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)

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

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

How to 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 it

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

When to take it

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 it

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 it

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, then go back to taking it as you would normally.

Do not try to make up for missed doses by taking more than one dose at a time.

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 (overdose)

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

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

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

You may need urgent medical attention.

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 slow breathing, confusion, convulsions, depression (including coma), abnormal heartbeat and low blood pressure.

While you are taking DEPTRAN

Things you must 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 become pregnant while taking DEPTRAN, tell your doctor immediately.

If you are a woman of childbearing age, you should avoid becoming pregnant while taking DEPTRAN.

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

If you 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:

- 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 agitation
- 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.

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.

Things you must not do

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

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

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 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.

Things to be careful of

Be careful driving or operating machinery 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.

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 doxepin overdose. 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.

Side effects

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

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

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.

Do not be alarmed by the list of side effects.

You may not experience any of them.

Ask your doctor or pharmacist any questions you may have.

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

- drowsiness, dizziness, light-headedness
- difficulty in sleeping, bad dreams
- dry mouth
- blurred vision
- difficulty in passing urine
- feeling sick, vomiting, indigestion
- constipation, diarrhoea
- changes in taste or taste sensitivity
- loss of appetite or increase in appetite
- mouth ulcers
- numbness.

These side effects are usually mild.

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

- anxiety, nervousness, aggressive behaviour
- fast or irregular heart beat
- 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 immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- seizures or fits.
- symptoms of high fever, drowsiness, sweating, fast heart beat 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

These symptoms are usually rare but may be serious and need urgent medical attention.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Other side effects not listed above 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.

After taking DEPTRAN

Storage

Keep DEPTRAN where children cannot reach them.

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

Keep DEPTRAN 10 (containing 10mg of doxepin) in a cool, dry place where the temperature stays below 25°C.

Keep DEPTRAN 25 (containing 25mg of doxepin) in a cool, dry place where the temperature stays below 25°C.

Keep DEPTRAN 50 (containing 50mg of doxepin) in a cool, dry place where the temperature stays below 30°C.

Do not store it or any other medicine, in the bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep your capsules in their blister pack until it is time to take them.

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

Disposal

If your doctor tells you to stop taking DEPTRAN, or the capsules or tablets have passed their expiry date, ask your pharmacist what to do with any left over.

Product description

What it looks like

- DEPTRAN 10 - Size 3 capsule with a white body and white cap, printed in black ink DP 10 on the cap. Each pack contains 50 capsules.
- DEPTRAN 25 - Size 3 capsule with white body and blue cap. Each pack contains 50 capsules.
- DEPTRAN 50 - 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.

Ingredients

The active ingredient in DEPTRAN is doxepin (as doxepin hydrochloride).

Each DEPTRAN 10 capsule contains 10 mg of doxepin.

The 10 mg capsules also contain:

- lactose monohydrate
- sodium starch glycolate
- purified talc
- magnesium stearate
- empty Hard Gelatin Capsule White Opaque/White Opaque 10000368 (ARTG PI: 111127)
- tekPrint SW-9008 Black Ink (ARTG PI: 2328)
- tekPrint SW-9009 Black Ink (ARTG PI: 2343)

Each DEPTRAN 25 capsule contains 25 mg of doxepin.

The 25 mg capsules also contain:

- lactose monohydrate
- sodium starch glycolate
- purified talc

- magnesium stearate
- sodium lauryl sulfate
- colloidal anhydrous silica
- gelatin
- titanium dioxide
- brilliant blue FCF
- erythrosine

Each DEPTRAN 50 tablet contains 50 mg of doxepin.

DEPTRAN 50 tablets also contain:

- lactose monohydrate
- microcrystalline cellulose
- povidone
- purified talc
- sodium starch glycollate
- magnesium stearate
- carnauba wax
- hypromellose
- diethyl phthalate

- erythrosine
- indigo carmine

DEPTRAN capsules and tablets are gluten free.

Supplier

DEPTRAN is supplied in Australia by:

Alphapharm Pty Ltd

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.mylan.com.au

Australian registration numbers:

DEPTRAN 10 - AUST R 308999

DEPTRAN 25 - AUST R 60448

DEPTRAN 50 - AUST R 17637

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