

ANTEN

Doxepin (as hydrochloride) 10mg, 25mg and 50mg Capsules



What is in this leaflet

This leaflet answers some common questions about ANTEN. It does not contain all the information available on this medicine. It does not take the place of talking to your doctor or pharmacist. All medicines have risks and benefits. Your doctor has weighed the risks of you taking ANTEN against the benefits they expect it will have for you. If you have any concerns about using this medicine, ask your doctor or pharmacist. Keep this leaflet. You may want to read it again.

What ANTEN is used for and how it works

Your ANTEN capsules contain doxepin hydrochloride. It belongs to a group of medicines known as tricyclic antidepressants (TCAs).

ANTEN is used to treat depression. Depression is thought to be caused by a chemical imbalance in parts of the brain. This affects your whole body and can cause emotional and physical symptoms such as feeling low in spirit, loss of interest in activities, being unable to enjoy life, poor appetite or overeating, disturbed sleep, often waking up early, loss of sex drive, lack of energy and feeling guilty over nothing. ANTEN works by correcting this chemical imbalance and may help relieve the symptoms of depression.

Your doctor may, however, prescribe ANTEN for another reason. Ask your doctor if you have any questions about why ANTEN has been prescribed for you.

ANTEN is not recommended for use in children 12 years of age and under. ANTEN is not recommended for use in

adolescents (13-18 years of age) for the treatment of depression, unless under the supervision of a specialist.

ANTEN is available on prescription from your doctor.

Before you take ANTEN

When you must not take it

Do not take ANTEN if:

- **You are allergic to doxepin, other tricyclic antidepressants or any other ingredients listed at the end of this leaflet**
- **You are taking another medicine for depression called a monoamine oxidase inhibitor (MAOI) or have been taking a MAOI within the last 14 days. Ask your doctor or pharmacist if you are unsure as to whether or not you are taking a MAOI**
- **You suffer from mania (mood of excitement, over-activity and uninhibited behaviour)**
- **You have severe liver disease**
- **You are breastfeeding**
- **You suffer from raised pressure in the eye (glaucoma)**
- **You have difficulty passing urine (urinary retention).**

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.

Before you take it

Tell your doctor if:

- You have had an allergic reaction to any medicine that you have taken previously to treat your current condition
- You have heart, liver or kidney problems
- You have epilepsy, fits or convulsions (or a condition such as alcoholism, brain damage or a recent head injury which might make fits more likely to occur)
- You are pregnant, plan to become pregnant or are breastfeeding
- You have suicidal thoughts or have attempted suicide in the past
- You have allergies to any other medicines, foods, preservatives or dyes.

If you are pregnant or plan to become pregnant you need to discuss with your doctor the risks and benefits of taking amitriptyline during pregnancy. The general condition of your newborn baby might be affected by the medicine. If your baby has been exposed to this medicine during the last three months of pregnancy it may suffer withdrawal symptoms such as trouble with breathing, fits, feeding difficulties, vomiting, stiff or floppy muscles, vivid reflexes, tremor, jitteriness, irritability, constant crying, and sleepiness. If your newborn baby has any of these symptoms, please contact your doctor immediately.

Taking other medicines

If you are taking any other medicines, including any you get without a prescription from a pharmacy, supermarket or health food shop, tell your doctor or pharmacist.

Medicines that may interfere with ANTEN include:

- **Monoamine Oxidase Inhibitors** (e.g. moclobemide, phenelzine, tranylcypromine)
- **Other antidepressants** (e.g. SSRIs and tricyclic antidepressants)
- **Antianxiety Medication**
- **Antihypertensive Medication** (e.g. guanethidine, debrisoquine)
- **Sympathomimetics, such as nasal decongestants** (used for colds or hay fever)
- **Cimetidine** (used to treat ulcers and other stomach complaints)
- **Central Nervous System Depressants** (e.g. barbiturates)
- **Tolazamide**
- **Thyroid Hormone Medication**
- **Anaesthetics**
- **Medicines used to treat epilepsy** (e.g. phenytoin, carbamazepine)
- **Anticholinergics** (found in some medicines to relieve stomach cramps, travel sickness).

These medicines may be affected by ANTEN or may affect how well ANTEN works. You may need different amounts of your medicines or you may need to take different medicines.

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

How to take ANTEN properly

How much to take

Your doctor will tell you how much ANTEN you need to take each day. It is important that you take ANTEN as directed by your doctor. Do not take more than the recommended dose.

It may take up to 2 to 3 weeks before any response to ANTEN is noticeable.

The usual starting dose is 75 mg of doxepin daily. If necessary, your doctor may increase the dose up to

a maximum of 300 mg daily, in three divided doses.

If you are elderly you may be started on a dose of 10-50 mg daily. If necessary, your doctor may increase the dose.

Your doctor may tell you to take different doses to these. If so, follow their instructions.

The capsule(s) should be swallowed whole with a glass of water.

How long to take it

For depression, the treatment is usually continued for at least six months to prevent potential recurrence. You may not feel better immediately as most antidepressants take time to work. Do not stop taking ANTEN even if you begin to feel better, unless your doctor tells you to do so. Make sure you do not run out of tablets.

If you forget a dose

If you forget a dose, just take the next dose when it is due. Do not take more than one dose at a time to make up for missed doses.

Taking your medicine at the same time each day may help you to remember to take it regularly. If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

While you are taking ANTEN

Things you must do

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

Tell your doctor or pharmacist that you are taking ANTEN before you start any new medicine.

Tell your doctor if you develop a skin rash or hives, or you become pregnant while taking ANTEN.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking ANTEN.

If you are going to have any blood tests, tell your doctor that you are taking ANTEN.

Keep all appointments you and your doctor have scheduled so that your progress can be followed.

Tell your doctor if you notice any of the following, especially if they are severe, abrupt in onset, or were not part of your presenting symptoms: anxiety, agitation, panic attacks, insomnia (difficulty sleeping), irritability, hostility (aggressiveness), impulsivity, akathisia (restlessness or difficulty sitting still), hypomania, mania (mood of excitement, over-activity and uninhibited behaviour), worsening of depression.

Tell your doctor immediately if you have any distressing thoughts (thought of suicide or self-harm) or experiences during this initial period or at any other time.

Things you must not do

Do not take ANTEN to treat any other complaints unless your doctor tells you to.

Do not stop taking ANTEN or lower the dose without first checking with your doctor.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Things to be careful of

ANTEN may cause drowsiness in some people. Be careful when driving, operating machinery or performing jobs that need you to be alert, until you are certain that ANTEN does not affect your performance.

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

Be careful drinking alcohol while taking ANTEN.

Side effects

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

All medicines can have some unwanted 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.

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

- Stomach or bowel problems (e.g. nausea, diarrhoea, constipation)
- Drowsiness
- Dry mouth or taste change
- Increased sweating
- Loss of appetite
- Shakiness or tremor
- Changes in your sex drive
- Dizziness
- Headache
- Weakness
- Impaired concentration or thought processes
- Vision problems
- Irregular heart beats, also called palpitations
- Difficulty in passing urine
- Trouble sleeping, nightmares.

These are the more common side effects of ANTEN.

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

- Fast heart beat
- Signs of frequent infections such as fever, chills, sore throat or mouth ulcers
- Unusual bruising or bleeding
- Yellowing of the eyes or skin (jaundice)
- Ongoing difficulty in passing urine
- Hallucinations, agitation, confusion
- Sudden switch of mood to one of excitement, overactivity, talkativeness and uninhibited behaviour
- Aggressive behaviour, nervousness
- Tingling or numbness of the hands or feet
- Uncontrolled movements, including trembling and shaking of the hands and

fingers, twisting movements of the body, shuffling walk and stiffness of the arms and legs.

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

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

- Skin rash or itching, swelling of the face, severe sunburn, blistering or swelling of the skin
- Seizures or fits.

The side effects listed above are very serious and require urgent medical attention or hospitalisation.

See your doctor if you experience any of the following when you stop ANTEN treatment:

- Insomnia (difficulty sleeping)
- Irritability
- Excessive sweating.

These symptoms are generally not serious and disappear within a few days.

An increased risk of bone fractures has been observed in patients taking this type of medicine.

The list of side effects mentioned above is not complete. If you should suffer from any of these side effects or any other undesired effect please tell your doctor or pharmacist.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

In case of overdose

You should only take the number of capsules that you have been told. Signs and symptoms of mild overdose include drowsiness, blurred vision and excessive dryness of the mouth. Severe overdose may cause loss of consciousness, reduced breathing rate, convulsions, low blood pressure, and irregular heart beats.

Immediately contact your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) or go to the Emergency department at your nearest hospital, if you think that you may have taken too much, or if anyone else has taken any ANTEN by mistake. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Take the pack of ANTEN with you if you can.

Keep telephone numbers for these places handy.

Storage conditions

Do not take this medicine after the expiry date shown on the pack/blister strip or if the packaging shows signs of tampering.

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

Store below 25°C and out of reach of children. Avoid exposure to heat, light and moisture.

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

Disposal

If your doctor tells you to stop taking ANTEN or if the capsules have passed the expiry date, ask your pharmacist what to do with the remaining medicine.

Product Description

What ANTEN capsules look like

ANTEN 10 mg capsules: white powder encapsulated in a blue body and a scarlet cap.
ANTEN 25 mg capsules: white powder encapsulated in a flesh body and a scarlet cap.
ANTEN 50 mg capsules: white powder encapsulated in a flesh body and a scarlet cap.

ANTEN is available in blister packs of 100 capsules.

Ingredients

Each ANTEN 10mg capsule contains 11.31 mg of the active ingredient, doxepin hydrochloride, equivalent to 10mg doxepin.

Each ANTEN 25mg capsule contains 28.27 mg of the active ingredient, doxepin hydrochloride, equivalent to 25mg doxepin.

Each ANTEN 50mg capsule contains 56.54 mg of the active ingredient, doxepin hydrochloride, equivalent to 50 mg doxepin.

Each capsule also contains lactose, maize starch, colloidal silicon dioxide, and magnesium stearate. The capsule shell consists of gelatine and the colorants titanium dioxide, erythrosine, red iron oxide (10 mg & 25 mg), yellow iron oxide (10 mg & 50 mg), brilliant blue FCF (10 mg) and sunset yellow FCF (50 mg).

If you want to know more

Should you have any questions regarding this product, please contact your doctor or pharmacist.

Who supplies this medicine

Distributed in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland.

Telephone: (09) 579 2792

Date of information

17 August 2011
(Based on datasheet 5 August 2011)