

ANTENEX

diazepam

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about ANTENEX.

It does not contain all of 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 ANTENEX against the benefits expected for you.

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

Keep this leaflet with your medicine.

You may need to read it again.

What ANTENEX is used for

ANTENEX is used to:

- manage anxiety
- relieve symptoms associated with alcohol withdrawal such as acute agitation and tremor
- relax muscles.

ANTENEX contains the active ingredient diazepam, which belongs to a group of medicines called benzodiazepines. These medicines are thought to work by their action on brain chemicals.

ANTENEX is not recommended as first choice of treatment in patients with depression, and/or psychosis as it can increase your risk of suicide.

Benzodiazepines are not recommended as the only treatment

of severe mental illnesses and should not be used alone to treat depression.

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

Your doctor may have prescribed ANTENEX for another reason.

In general, benzodiazepines such as ANTENEX should be taken for short periods only (for example 2 to 4 weeks). Continuous long-term use is not recommended unless advised by your doctor. The use of benzodiazepines may lead to dependence on the medicine.

Anxiety and tension associated with the normal stress of everyday life usually does not require treatment with medicines.

ANTENEX is not recommended for use in children under 6 months of age.

ANTENEX is available only with a doctor's prescription.

Before you take ANTENEX

When you must not take it

Do not take ANTENEX if you are allergic to:

- diazepam or any other benzodiazepine medicine
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itching or hives; swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing; wheezing or shortness of breath.

Do not take ANTENEX if you have:

- severe and chronic lung or airways disease
- severe liver disease
- sleep apnoea
- severe muscle weakness
- drug or alcohol dependence

Do not take this medicine after the expiry date printed on the pack 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 this medicine, talk to your doctor.

Before you start to take it

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

Tell your doctor if you are pregnant or plan to become pregnant.

ANTENEX may affect your unborn baby if you take it during pregnancy.

ANTENEX may cause complications to newborn infants. It may cause low blood pressure, poor muscle tone, reduced respiratory function and low body temperature in the newborn infant. Continuous treatment during pregnancy and administration of high doses in connection with delivery should be avoided. Withdrawal symptoms in newborn infants have been reported with prolonged use of this class of drug. Your doctor will discuss the risks and benefits of taking ANTENEX during pregnancy.

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

Tell your doctor if you are breastfeeding or plan to breastfeed.

ANTENEX is not recommended for use in breastfeeding. ANTENEX may pass into breast milk and may cause drowsiness and/or feeding difficulties in your baby.

Tell your doctor if you have or have had any of the following medical conditions:

- lung, liver or kidney problems
- high or low blood pressure
- depression, schizophrenia or other mental illness
- glaucoma (increased pressure in the eye)
- epilepsy (fits).
- history of alcohol or drug abuse

Tell your doctor if you drink alcohol regularly.

Combining ANTENEX and alcohol may cause severe sedation, difficulties breathing and/or heart problems (respiratory and/or cardiovascular depression), coma and death.

Tell your doctor if you take Central Nervous System (CNS) depressants

Combining ANTENEX and CNS depressants may cause severe sedation, difficulties breathing and/or heart problems (respiratory and/or cardiovascular depression), coma and death.

Tell your doctor if you plan to have surgery.

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

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may be affected by ANTENEX, or may affect how well it works. These include:

- other sleeping tablets, sedatives or tranquillisers
- medicines for depression
- other medicines for anxiety
- medicines used to treat epilepsy, fits or convulsions (e.g. phenytoin)
- antihistamines, medicines for allergies, hayfever, colds or travel sickness
- muscle relaxants
- cimetidine and omeprazole, medicines used to treat reflux or stomach ulcers
- pain relievers
- disulfiram, a medicine used to deter alcohol consumption
- cisapride, a medicine used to treat gastric reflux
- ketoconazole, a medicine used to treat fungal infections.
- opioids, medicine used to treat severe pain e.g. morphine, pethidine

Your doctor can tell you what to do if you are taking any of these medicines.

Tell your doctor if you take opioids.

Combining ANTENEX and opioids may cause severe sedation, difficulties in breathing (respiratory depression), coma and may be life-threatening.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

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

How to take ANTENEX

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

They may differ from the information contained in this leaflet.

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

How much to take

The dose varies from person to person. This depends on your age, the condition being treated, and whether or not you are taking any other medicines.

Your doctor will tell you how many tablets you need to take each day and when to take them.

The usual adult dose is between 5 mg and 40 mg daily.

Elderly people, children and those with kidney or liver problems may need smaller doses.

ANTENEX is not recommended for children below 6 months of age.

How to take it

Swallow the tablets with a glass of water.

ANTENEX can be taken with or without food.

How long to take it for

Take ANTENEX only for as long as your doctor recommends.

Usually, ANTENEX should be taken for short periods only (for example 2 to 4 weeks). Continuous long-term use is not recommended unless advised by your doctor. The use of benzodiazepines may lead to dependence on the medicine.

If you forget to take it

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 your tablets 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 take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much ANTENEX. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much ANTENEX, you may feel drowsy, tired, confused, dizzy, have difficulty breathing, feel weak or become unconscious.

Benzodiazepines increase the effect of CNS depressants. When ANTENEX is combined with other CNS depressants, the effects of overdose are likely to be severe and may prove fatal.

While you are taking ANTENEX

Things you must do

Take ANTENEX exactly as your doctor prescribed.

Before starting any new medicine, tell your doctor or pharmacist that you are taking ANTENEX.

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

If you become pregnant while taking ANTENEX, tell your doctor immediately.

If you plan to have surgery that requires a general anaesthetic, tell your doctor or dentist that you are taking ANTENEX.

If you have a thyroid function test, tell your doctor that you are taking ANTENEX.

ANTENEX may affect the results of this test.

Visit your doctor regularly so they can check on your progress.

You may need to have tests to check your blood and liver function. Also, your doctor can advise you on whether you need to keep taking ANTENEX.

Tell your doctor if you feel ANTENEX is not helping your condition.

Tell your doctor of any problems or difficulties during or after taking ANTENEX.

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.

All thoughts of suicide must be taken seriously. Tell your doctor or a mental health professional immediately if you have any suicidal thoughts or other mental/mood changes.

Things you must not do

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

Stopping ANTENEX suddenly may cause some unwanted effects. Your doctor may want you to gradually reduce the amount of ANTENEX you are taking before stopping completely.

Do not drive or operate machinery until you know how ANTENEX affects you.

ANTENEX may cause drowsiness, dizziness or loss of concentration in some people. If any of these occur, do not drive, operate machinery or do anything else that could be dangerous. Children should be careful when riding bicycles or climbing trees.

Do not suddenly stop taking ANTENEX if you suffer from epilepsy.

Stopping this medicine suddenly may make your epilepsy worse.

Do not take ANTENEX for a longer time than your doctor has prescribed.

ANTENEX should be taken for short periods only (for example 2 to 4 weeks) unless advised otherwise by your doctor.

Do not use ANTENEX to treat any other conditions unless your doctor tells you to.

Do not give ANTENEX to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful drinking alcohol while taking ANTENEX.

Combining alcohol with ANTENEX can make you more drowsy or dizzy. Your doctor may suggest that you avoid alcohol or reduce the amount of alcohol that you drink while you are taking ANTENEX.

Be careful if you are elderly, unwell or taking other medicines.

You may have an increased chance of getting side effects such as drowsiness, confusion, dizziness and unsteadiness, which may increase the risk of a fall.

Side effects

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

ANTENEX helps most people, 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.

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

You may not experience any of them.

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

Some people, such as children and the elderly, may have an increased chance of getting some side effects.

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

- drowsiness, tiredness
- dizziness, unsteadiness
- loss of memory, inattentiveness, confusion, lack of concentration
- headache, hangover feeling in the morning
- slurred speech
- unpleasant dreams

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

- sudden anxiety or excitation
- restlessness, agitation, irritability, anger, abnormal behaviour
- Hallucinations or delusions
- severe sleep disturbances
- difficulties in breathing or choking or coughing

The above list includes serious side effects which may require medical attention. Serious side effects are rare.

Tell your doctor if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After taking ANTENEX

Storage

Keep ANTENEX 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 your tablets in a cool dry place where the temperature stays below 30°C.

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

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

Heat and dampness can destroy some medicines.

Disposal

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

Product description

What it looks like

ANTENEX tablets are available in 2 strengths:

- ANTENEX 2 - 8 mm, flat bevelled edged, white tablet marked "DM/2" on one side, "G" on reverse
- ANTENEX 5 - 8 mm, flat bevelled edged, very pale yellow tablet marked "DM/5" on one side, "G" on reverse

ANTENEX tablets are packed in bottles containing 50 tablets.

Ingredients

The active ingredient in ANTENEX is diazepam.

- Each ANTENEX 2 tablet contains 2 mg of diazepam.
- Each ANTENEX 5 tablet contains 5 mg of diazepam.

The tablets also contain the following inactive ingredients:

- lactose monohydrate
- maize starch
- magnesium stearate

- pregelatinised maize starch [ANTENEX 2 only]
- quinoline yellow aluminium lake [ANTENEX 5 only].

ANTENEX tablets contain sugars (as lactose) and traces of galactose and sulfites.

Manufacturer

ANTENEX is made in Australia by:

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

Australian registration numbers:

ANTENEX 2

AUST R 17582 (bottle)

ANTENEX 5

AUST R 17583 (bottle)

This leaflet was prepared in April 2023.

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