

Antenex

contains the active ingredient 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.

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
- * myasthenia gravis - a condition where there is severe muscle weakness
- * drug or alcohol dependence
- * depression, anxiety associated with depression, or any other mental illness which is not being treated with another medicine.

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.

The safe use of Antenex in pregnant women has not been established. Like other benzodiazepine medicines, Antenex may cause unwanted effects in the newborn baby if used during pregnancy. Your doctor will discuss the risk and benefits of taking Antenex during pregnancy.

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

Antenex is not recommended for use in breastfeeding. Antenex passes into breast milk and may cause drowsiness and feeding difficulties in

your baby. Your doctor will discuss the risks and benefits of taking Antenex when breastfeeding.

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

- * epilepsy, fits or convulsions
- * liver or kidney problems
- * lung or breathing problems
- * low blood pressure
- * depression, psychosis or schizophrenia
- * glaucoma (increased pressure in the eye)
- * drug or alcohol dependence or a history of these problems
- * hereditary problems of galactose intolerance (the Lapp lactase deficiency or glucose-galactose malabsorption).

Tell your doctor if you drink alcohol regularly.

Alcohol may increase the effects of Antenex.

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:

- * sleeping tablets, sedatives or tranquillisers
- * medicines for mental illnesses such as depression (eg. fluvoxamine and fluoxetine) and schizophrenia
- * other medicines for anxiety
- * medicines to treat epilepsy, fits or convulsions (eg. phenytoin)
- * antihistamines, medicines for allergies, hayfever, colds or travel sickness

- * medicines used to treat stomach cramps
- * some medicines used to treat Parkinson's disease
- * other muscle relaxants
- * cimetidine, cisapride and omeprazole, medicines to treat reflux or stomach ulcers
- * strong pain relievers
- * disulfiram, a medicine used to deter alcohol consumption
- * ketoconazole, a medicine used to treat fungal infections.

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

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.

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.

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 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
- * tremor, unsteadiness, muscle weakness
- * loss of memory, lack of concentration
- * headache
- * nausea (feeling sick), constipation
- * loss of bladder control, passing little or no urine
- * slurred speech
- * blurred vision
- * unpleasant dreams
- * changes in sex drive.

The above list includes the mild side effects of Antenex.

See your doctor immediately if you notice any of the following:

- * confusion
- * depression
- * anxiety, restlessness, agitation, irritability, aggressiveness
- * hallucinations, delusions
- * sudden rage or increased excitement

- * severe sleep disturbances
- * yellowing of the skin and/or eyes
- * signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers.

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

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

- * fainting
- * chest pain
- * severe 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.

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

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 degrees 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 - round, white tablet marked DM/2 on one side and G on the other
- * Antenex 5 - round, yellow tablet marked DM/5 on one side and G on the other.

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
- * maize starch
- * magnesium stearate
- * pregelatinised maize starch [Antenex 2 only]
- * quinoline yellow CI47005 (E104) [Antenex 5 only].

The tablets are gluten free.

Manufacturer

Antenex is made in Australia by:

Alphapharm Pty Limited

(ABN 93 002 359 739)

Chase Building 2

Wentworth Park Road

Glebe NSW 2037

Phone: (02) 9298 3999

Medical Information

Phone: 1800 028 365

www.alphapharm.com.au

Australian registration numbers:

Antenex 2

AUST R 17582 (bottle)

Antenex 5

AUST R 17583 (bottle)

This leaflet was prepared on
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