

Consumer Medicine Information (CMI) summary

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

1. Why am I taking ANTENEX?

ANTENEX contains the active ingredient diazepam. ANTENEX is used for anxiety, to relax muscles, to treat trembling, confusional states or anxiety associated with alcohol withdrawal, and to treat panic attacks. For more information, see Section [1. Why am I taking ANTENEX?](#) in the full CMI.

2. What should I know before I take ANTENEX?

Do not take ANTENEX if you have ever had an allergic reaction to diazepam, any other benzodiazepine medicine, or any of the ingredients listed at the end of the CMI. The use of ANTENEX may lead to dependence on the medicine. **Talk to your doctor if you have any other medical conditions, have drug or alcohol addiction, drink alcohol, 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 ANTENEX?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ANTENEX 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 ANTENEX?

- Take ANTENEX exactly as your doctor has prescribed. Your doctor will tell you how many ANTENEX tablets to take each day.
- The usual adult dose is between 5 and 40 mg daily. Children, elderly and very ill patients may need to take less.
- ANTENEX should be taken for short periods only (for example, 2-4 weeks), unless advised by your doctor.

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

5. What should I know while taking ANTENEX?

| | |
|------------------------------------|---|
| Things you should do | <ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist visit that you are taking ANTENEX.• Call your doctor straight away if you become pregnant while taking ANTENEX.• Call your doctor straight away if you have any suicidal thoughts or other mental/mood changes. |
| Things you should not do | <ul style="list-style-type: none">• Do not take ANTENEX for a longer time than your doctor has prescribed.• Do not stop taking ANTENEX or lower the dose without first checking with your doctor, especially if you have epilepsy.• Do not take any other medicines without first telling your doctor.• Do not let yourself run out of medicine over the weekend or on holidays. |
| Driving or using machines | <ul style="list-style-type: none">• 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. |
| Drinking alcohol | <ul style="list-style-type: none">• Alcohol may increase the effects of ANTENEX. Your doctor may suggest that you avoid alcohol or reduce the amount of alcohol you drink while you are taking ANTENEX. |
| Looking after your medicine | <ul style="list-style-type: none">• Store ANTENEX in a cool, dry place below 30°C, where children cannot reach it.• Keep your tablets in the original packaging until it is time to take them. |

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

6. Are there any side effects?

Some of the less side effects include drowsiness, tiredness, dizziness, unsteadiness, loss of memory, inattentiveness, confusion, lack of concentration, headache, hangover feeling in the morning, slurred speech, or unpleasant dreams. Serious side effects include sudden anxiety or excitation, restlessness, agitation, irritability, anger, abnormal behaviour, hallucinations, delusions, severe sleep disturbances, or difficulties in breathing, choking or coughing. 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.

ANTENEX®

Active ingredient: *diazepam*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking ANTENEX. **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 ANTENEX.**

Where to find information in this leaflet:

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

1. Why am I taking ANTENEX?

ANTENEX contains the active ingredient diazepam.

ANTENEX belongs to a group of medicines called benzodiazepines, which are thought to work by their action on brain chemicals.

ANTENEX is used to:

- **manage anxiety**

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

- **relieve symptoms associated with alcohol withdrawal such as acute agitation and tremor**
- **relax muscles**
- **treat panic attacks.**

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.

2. What should I know before I take ANTENEX?

Warnings

Do not take ANTENEX if:

- you are allergic to diazepam, any other benzodiazepine medicine, or 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.

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

- you have severe and chronic lung or airway disease
- you have severe liver disease
- you have temporary stops in breathing during sleep (sleep apnoea)
- you suffer from severe muscle weakness
- you have drug or alcohol addiction.

Check with your doctor if you:

- have any other medical conditions, including:
 - o liver, kidney or lung disease
 - o high or low blood pressure
 - o glaucoma (high pressure in the eye)
 - o depression, schizophrenia or other mental illness
 - o epilepsy (fits)
 - o history of alcohol or drug abuse.
 - take any medicines for any other condition
 - drink alcohol. Alcohol may increase the effects of ANTENEX
 - 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.
- are allergic to any other medicines, foods, dyes or preservatives
 - plan to have surgery.

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.

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 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.

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.

Use in children

Do not give ANTENEX to children under the age of six months.

Dependence

The use of benzodiazepines (such as ANTENEX) may lead to dependence on the medicine.

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 ANTENEX and affect how it works, and some medicines may be affected by ANTENEX. These include:

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

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

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

4. How do I take ANTENEX?

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

How much to take

- Take ANTENEX exactly as your doctor has prescribed. Your doctor will tell you how many ANTENEX tablets to take each day and when to take them. The dose varies from person to person depending on age, the

condition being treated and whether or not you are taking any other medicines.

- The usual adult dose is between 5 and 40 mg daily. Children, elderly, those with kidney or liver problems and very ill patients may need to take less.
- Follow the instructions provided and take ANTENEX until your doctor tells you to stop

When to take ANTENEX

- ANTENEX can be taken up to three times a day. Your doctor will tell you how much you need to take.

How to take ANTENEX

- Tablets should be swallowed whole with a glass of water.
- The tablets can be taken with or without food.

How long to take ANTENEX 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.

If you forget to take ANTENEX

ANTENEX should be used regularly at the same time each day.

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 ANTENEX

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

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.

5. What should I know while taking ANTENEX?

Things you should do

- Tell all doctors, dentists and pharmacists who are treating you that you are taking ANTENEX.
- If you plan to have surgery that requires 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.

- Be sure to keep all of your appointments with your doctor so that your progress can be checked.

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 of any problems or difficulties during or after taking ANTENEX.

Call your doctor straight away if you:

- become pregnant while taking ANTENEX
- for any reason, have not taken your medicine exactly as prescribed

Otherwise your doctor may think that it was not effective and change your treatment unnecessarily.

- feel the tablets are not helping your condition
- have any suicidal thoughts or other mental/mood changes.

All thoughts of suicide must be taken seriously. Tell your doctor or a mental health professional.

Things you should not do

- Do not take any other medicines whether they require a prescription or not without first telling your doctor.
- Do not take ANTENEX for a longer time than your doctor has prescribed. ANTENEX should be taken for short periods only (for example, 2-4 weeks) unless advised by your doctor.
- Do not stop taking ANTENEX or lower the dose without first checking with your doctor. Stopping this medicine suddenly may cause some unwanted effects. Your doctor will explain how you should slowly reduce your dose of ANTENEX before you can stop taking it completely.
- Do not let yourself run out of medicine over the weekend or on holidays.
- Do not suddenly stop taking ANTENEX if you suffer from epilepsy. Stopping this medicine suddenly may make your epilepsy worse.
- Do not give ANTENEX to anyone else even if their symptoms seem similar to yours.
- Do not use ANTENEX to treat other complaints unless your doctor says so.

Things to be careful of

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.

Avoid drinking grapefruit juice as it may affect the absorption of ANTENEX.

Driving or using machines

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

ANTENEX may cause drowsiness, dizziness or loss of concentration in some people and therefore may affect alertness. Make sure you know how you react to ANTENEX before you drive a car or operate machinery or do anything else that could be dangerous if you are drowsy, dizzy or not alert. Children should be careful when riding bicycles or climbing trees.

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol may increase the effects of ANTENEX. Your doctor may suggest that you avoid alcohol or reduce the amount of alcohol you drink while you are taking ANTENEX.

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

Looking after your medicine

- Keep your tablets in the original packaging until it is time to take them.
- Store below 30°C.

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 use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date or if the packaging is torn or shows signs of tampering.

6. Are there any side effects?

All medicines can have side effects. You may not experience any of them. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

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

Less serious side effects

| Less serious side effects | What to do |
|--|--|
| Neurological or brain-related: <ul style="list-style-type: none"> drowsiness, tiredness dizziness, unsteadiness loss of memory, inattentiveness, confusion, lack of concentration headache, hangover feeling in the morning slurred speech unpleasant dreams | Speak to your doctor if you have any of these less serious side effects and they worry you. |

Serious side effects

| Serious side effects | What to do |
|--|---|
| Neurological or brain-related: <ul style="list-style-type: none"> sudden anxiety or excitation restlessness, agitation, irritability, anger, abnormal behaviour hallucinations or delusions severe sleep disturbances Respiratory or breathing-related: <ul style="list-style-type: none"> difficulties in breathing or choking or coughing | 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. Serious side effects are rare. |

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.

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 ANTENEX contains

| | |
|--|----------------------------------|
| Active ingredient (main ingredient) | diazepam 2 mg or 5 mg per tablet |
|--|----------------------------------|

| | |
|---|---|
| Other ingredients (inactive ingredients) | <ul style="list-style-type: none"> lactose monohydrate maize starch magnesium stearate pregelatinised maize starch (ANTENEX 2 only) quinoline yellow aluminium lake (ANTENEX 5 only) |
| Potential allergens | sulfites, galactose and sugars as lactose |

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

What ANTENEX looks like

ANTENEX 2 is an 8 mm, flat bevelled edged, white tablet marked "DM/2" on one side, "G" on reverse (AUST R 17582).

ANTENEX 5 is an 8 mm, flat bevelled edged, very pale yellow tablet marked "DM/5" on one side, "G" on reverse (AUST R 17583).

Who distributes ANTENEX

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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