

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 using ANEXATE?

ANEXATE contains the active ingredient flumazenil. ANEXATE is used to arouse people after surgery or benzodiazepine overdose. For more information, see Section [1. Why am I using ANEXATE?](#) in the full CMI.

2. What should I know before I use ANEXATE?

Do not use if you have ever had an allergic reaction to ANEXATE or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, 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 use ANEXATE?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ANEXATE 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 use ANEXATE?

- ANEXATE is given as an injection into a vein and must only be given by an anaesthetist or experienced physician.
- Your doctor will decide what dose of ANEXATE you will receive. This depends on your condition.
- Usually only a single dose of ANEXATE is required.

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

5. What should I know while using ANEXATE?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Anexate.• Inform your doctor prior to using Anexate if you have other medical conditions especially the ones listed in section 2 of the full CMI.• Inform your doctor prior to using Anexate if you have been taking high doses of benzodiazepines and/or you have been taking benzodiazepines for a long time.
Things you should not do	<ul style="list-style-type: none">• Do not use this medicine if you are allergic to flumazenil, or any of the ingredients listed at the end of the full CMI.• Do not use this medicine if you are taking a benzodiazepine for control of a potentially life-threatening condition.
Driving or using machines	<ul style="list-style-type: none">• This medicine may cause drowsiness or dizziness in some people. This can be due to the possibility of re-sedation within the first 24 hours after administration of ANEXATE.• Do not drive, operate machinery or do anything else that could be dangerous within 24 hours after administration of ANEXATE.
Looking after your medicine	<ul style="list-style-type: none">• ANEXATE will be stored in the pharmacy or on the ward. It is kept in a cool dry place where the temperature stays below 30°C.

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

6. Are there any 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.

ANEXATE®

Active ingredient(s): *flumazenil*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ANEXATE. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ANEXATE.**

Where to find information in this leaflet:

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

1. Why am I using ANEXATE?

ANEXATE contains the active ingredient flumazenil. ANEXATE is used to reverse benzodiazepine overdose, both suspected and known.

ANEXATE is used to arouse people after surgery or benzodiazepine overdose.

Your doctor may have prescribed ANEXATE for another reason.

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

2. What should I know before I use ANEXATE?

Warnings

Do not use ANEXATE if:

- you are allergic to flumazenil, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- you are taking a benzodiazepine for control of a potentially life-threatening condition

Check with your doctor if you:

- have any other medical conditions such as:
- epilepsy
- severe liver disease
- suffer from panic disorder
- you have been taking high doses of benzodiazepines and /or you have been taking benzodiazepines for a long time.

If you have not told your doctor about any of the above, tell them before you are given ANEXATE.

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

Check with your doctor if you are pregnant or intend to become pregnant. The safety of flumazenil in human pregnancy has not been established.

Talk to your doctor if you are breastfeeding or intend to breastfeed. It is not known whether flumazenil is excreted in human milk.

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 ANEXATE. These medicines include:

- Benzodiazepines, e.g. diazepam (Valium), bromazepam (Lexotan), temazepam (Temaze, Normison) etc.
- anticonvulsants
- antidepressants

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

4. How do I use ANEXATE?

How ANEXATE is given

- as an injection into a vein. ANEXATE must only be given by an anaesthetist or experienced physician.

How much ANEXATE is given

- Your doctor will decide what dose of ANEXATE you will receive. This depends on your condition.
- Usually only a single dose of ANEXATE is required.

If you are given too much ANEXATE

Overdose of ANEXATE is unlikely to occur since it is administered by an experienced physician. If too much ANEXATE is administered, the doctor will monitor your vital signs and keep you under observation.

If you think that too much ANEXATE has been given to you

For information on the management of overdose you should:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using ANEXATE?

Things you should do

Call your doctor straight away if you:

- Do not feel well after you have been given ANEXATE.

Remind any doctor, dentist or pharmacist you visit that you are using ANEXATE.

Things you should not do

- Do not take any other medicines whether they require a prescription or not without first telling your doctor.

Driving or using machines

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

ANEXATE may cause dizziness or drowsiness in some people. This can be due to the possibility of re-sedation within the first 24 hours after administration of ANEXATE.

Do not drive, operate machinery or do anything else that could be dangerous within the first 24 hours after administration of ANEXATE.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- ANEXATE will be stored in the pharmacy or on the ward.
- It is kept in a cool dry place where the temperature stays below 30°C.

6. Are there any side effects?

All medicines can have side effects. 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.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> nausea with or without vomiting dizziness, lightheadedness feeling anxious or fearful rapid or irregular heartbeat depression, tearfulness with or without agitation 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Some allergic reactions may be life-threatening, pay attention to the below symptoms which can indicate drug allergy:</p> <ul style="list-style-type: none"> 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 <p>These may be related to the reversal of anaesthetic.</p>	<p>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.</p>

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 available only with a doctor's prescription and must be administered by an anaesthetist or experienced physician.

What ANEXATE contains

Active ingredient (main ingredient)	Flumazenil Each 5 mL ANEXATE ampoule contains 0.5 mg flumazenil as the active ingredient.
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> disodium edetate glacial acetic acid (260) sodium chloride sodium hydroxide water for injections
Potential allergens	This medicine does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

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

What ANEXATE looks like

ANEXATE is available as a clear, solution at a concentration of 0.1 mg per mL in 5 mL glass ampoules.

ANEXATE comes in a pack of 5 ampoules. (Aust R 13706).

Who distributes ANEXATE

Pharmaco (Australia) Ltd

Level 13, 465 Victoria Avenue

Chatswood NSW 2067

Australia

Phone: 1800 201 564

Under license of CHEPLAPHARM Arzneimittel GmbH,
Germany

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