

Consumer Medicine Information

Anexate[®]

Flumazenil

0.5 mg/5mL injection solution

What is in this leaflet

This leaflet answers some common questions about ANEXATE injection. It does not contain all the available information.

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 your being given ANEXATE injection against the benefits expected for you.

If you have any concerns about being given this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What ANEXATE is given for

ANEXATE contains the active ingredient flumazenil.

ANEXATE is used to reverse the effects of benzodiazepines, a class of anti-anxiety or sedative medicines.

Common benzodiazepines are:

- alprazolam (Arrow-Alprazolam[®], Xanax[®])
- clobazam (Frisium[®])
- clonazepam (Paxam[®], Rivotril[®])
- diazepam (D-Pam[®], Propam[®], Stesolid[®])
- lormetazepam (Noctamid[®])
- lorazepam (Ativan[®], Lorzem[®])
- midazolam (Hypnovel[®])
- nitrazepam (Insoma[®], Nitrados[®])
- oxazepam (Ox-Pam[®])
- temazepam (Euhypnos[®], Normison[®], Somapam[®])
- triazolam (Halcion[®], Hypam[®], Trycam[®])

ANEXATE is given to arouse people after surgery or in cases of suspected or known 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.**

ANEXATE is not addictive.

This medicine is available only with a doctor's prescription.

Before you receive ANEXATE

When you should not receive ANEXATE

You should not be given ANEXATE if:

- **you have had an allergic reaction to ANEXATE or any of the ingredients listed at the end of this leaflet**
- **you are taking a benzodiazepine to control a potentially life-threatening condition**
- **the package is torn or shows signs of tampering**
- **the expiry date (EXP) printed on the pack has passed**
If you take this medicine after the expiry date has passed, it may not work as well.

If you are not sure if you should receive ANEXATE, talk to your doctor.

Before you are given ANEXATE

Your doctor must know about all the following before you are given ANEXATE.

You must tell your doctor if:

- **you are allergic to any other medicines or any other substances such as foods, preservatives or dyes**
- **you suffer from epilepsy**
- **you have been taking a benzodiazepine for a long time or in high doses**
- **you have taken an overdose of one or more medicines or other substances**
- **you have had a recent head injury**
- **your liver function is impaired**
- **you are pregnant**
It is not known whether ANEXATE is harmful to an unborn baby when taken by a pregnant woman. If there is a need to take ANEXATE when you are pregnant your doctor will discuss the risks and benefits to you and the unborn baby.

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

Taking other medicines

Tell your doctor if you are taking any other medicines including any that you have bought from a pharmacy, supermarket or healthfood shop.

Some medicines that may interfere with ANEXATE are:

- zopiclone, used for treating insomnia (Apo-Zopiclone[®], Imovane[®])
- triazolopyridazines, a class of medicines similar to benzodiazepines

These medicines may be affected by ANEXATE, or may affect how well it works.

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

Ask your doctor or pharmacist if you are not sure about this list of medicines.

How ANEXATE is given

ANEXATE is given as an injection or an infusion (“drip”) into a vein. ANEXATE must only be given by an anaesthetist or an 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.

While you are receiving ANEXATE

Things you must do

Tell your doctor if you feel anxious or fearful, have an abnormal or rapid heart beat or have a seizure or convulsion while you are receiving ANEXATE.

Things to be careful of

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

Some people may become drowsy or dizzy after taking ANEXATE due to the possibility of re-sedation within the first 24 hours after administration. Make sure you know how you react to ANEXATE before you drive a car or operate machinery or do anything else that could be dangerous if you are drowsy, dizzy or not alert.

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

Some people may experience side effects such as drowsiness, confusion, dizziness and unsteadiness in the first 24 hours after administration 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 after receiving ANEXATE.

ANEXATE helps most people to reverse the effects of benzodiazepine medicines but it may have unwanted side effects in a few 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.

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

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

- feeling anxious or fearful
- abnormal or rapid heart beat
- seizures or convulsions
- rash, itching or hives on the skin
- swelling of your face, lips, tongue or other parts of the body
- shortness of breath, wheezing or trouble breathing

These may be related to reversal of the effects of the benzodiazepine medicines.

After receiving ANEXATE

Storage

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

Product Description

What ANEXATE looks like

ANEXATE is available as a clear solution in a 5(mL ampoule.

Ingredients

Active ingredients

Each 5 mL ANEXATE ampoule contains 0.5mg of flumazenil.

Inactive ingredients

Each ampoule also contains disodium edetate, glacial acetic acid, sodium chloride, sodium hydroxide and water for injection.

ANEXATE does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

Distributor

ANEXATE is distributed in NZ by:

Pharmaco (NZ) Ltd
PO Box 4079
Auckland 1140

Toll Free: 0800 804 079

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