

Anexate[®]

flumazenil

Consumer Medicine Information

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 you being given ANEXATE injection against the benefits they expect it will have for you.

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

Keep this leaflet.

You may need to read it again.

What ANEXATE is used for

ANEXATE is used to reverse benzodiazepine overdose, both suspected and known.

It is given 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.

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

Before you are given ANEXATE

When you must not be given it

Do not use 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 for control of a potentially life-threatening condition**

Before you are given it

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

You must tell your doctor if:

1. **you are allergic to any other medicines or any other substances such as foods, preservatives or dyes**
2. **you suffer from epilepsy**
3. **you have severe liver disease**
4. **you suffer from panic disorder**
5. **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.

Taking other medicines

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

Some medicines may interfere with Anexate or affect how well it works. These medicines include:

- Benzodiazepines eg diazepam, (Valium, Ducene), bromazepam (Lexotan), temazepam (Temaze, Normison) etc
- Anticonvulsants
- Antidepressants

How ANEXATE is given

ANEXATE is given as an injection into a vein. ANEXATE 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.

While you are using ANEXATE

Things to be careful of

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

ANEXATE may cause drowsiness or dizziness in some people and therefore may affect alertness. This is 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.

There is also a possibility of other benzodiazepine effects such as difficulty in breathing, within the first 24 hours after administration.

Storage

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.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well after you have been given ANEXATE.

ANEXATE helps most people who experience an overdose with 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:

- nausea with or without vomiting
- dizziness, lightheadedness
- feeling anxious or fearful
- rapid or irregular heart beat

- depression, tearfulness with or without agitation

These may be related to the reversal of anaesthetic.

Product Description

What ANEXATE looks like

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

Ingredients

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

Active ingredients

Each 5 mL ANEXATE ampoule contains:

- 0.5 mg flumazenil

Inactive ingredients

- Disodium edetate
- Glacial acetic acid (260)
- Sodium chloride
- Sodium hydroxide
- water for injections

ANEXATE comes in a pack of 5 ampoules.

Distributor

ANEXATE is distributed by:

Roche Products Pty Limited
ACN 000 132 865

ABN 70 000 132 865

4 - 10 Inman Road

Dee Why NSW 2099

Customer enquiries: 1 800 233 950

Please check with your pharmacist for the latest Consumer Medicine Information.

Australian Registration Number

- AUST R 13706

This leaflet was prepared in January 2005.