Read all of this leaflet carefully before you start using this medicine because it contains important information about your treatment.

Be sure to read this leaflet every time you are about to give Epistatus and before you give any further doses until you become familiar with its use. This also applies to any other patient who is to be given this medicine in the future. It contains directions on how to give and how to administer this medicine. Your doctor or pharmacist may have further information on non-medicinal ingredients that may affect some people (see Section 6).

What is Epistatus and is it used for?

Epistatus is a liquid oral medicinal preparation which belongs to a group of medicines known as benzodiazepines.

Epistatus is supplied as a transparent, disposable, single-use (10 ml) oral syringe. Each pre-filled oral syringe contains midazolam maleate corresponding to 10 mg midazolam.

What do you need to know before you use Epistatus

Do not give Epistatus:

- to a child or adolescent under 10 years of age or to a child or adolescent aged 10 to less than 18 years if you are not sure.
- to a patient who is severely overactive.
- to a patient with a history of drug abuse.
- to a patient with a history of alcoholism.
- to a patient who has signs of drug or alcohol withdrawal.
- to a patient who has had alcohol or drug withdrawal within the past 12 months.

The dosage and administration of this medicine should be reviewed by the doctor or pharmacist.

How to give this medicine

Ask a doctor, pharmacist or nurse to show you how to take or administer this medicine. Always check with your doctor or pharmacist before giving this medicine to another person.

How to give Epistatus

- Ask a doctor, pharmacist or nurse to show you how to take or administer this medicine. Always check with your doctor or pharmacist before giving this medicine to another person.
- Pull the tamper evident tab on the side of the plastic outer case, open it and take the syringe out.
- Do not use this medicine after the expiry date which is stated on the label and orange carton after EXP. 
- Do not use this medicine if you are not sure what it is used for or how to use it. Never give your medicine to another person unless you have been given specific instructions to do so by your doctor or pharmacist. Do not pass it on to others unless they have the same illness as you do.
- Do not use this medicine if the expiry date has passed. Do not use this medicine if the bottle is broken or the syringe plunger is stuck or does not move freely or if there is any other problem with the syringe.


Step 1
- Pull the tamper evident tab on the side of the plastic outer case, open it and take the syringe out.

Step 2
- Grasp your patient's face or head, gently pinch and pull back the patient's cheeks, tip the lip of the buccal cavity into the back of the space between the cheek and the lower gum (buccal cavity).

Step 3
- Grasp your patient's face or head, gently pinch and pull back the patient's cheeks, tip the lip of the buccal cavity into the back of the space between the cheek and the lower gum (buccal cavity).

Step 4
- Grasp your patient's face or head, gently pinch and pull back the patient's cheeks, tip the lip of the buccal cavity into the back of the space between the cheek and the lower gum (buccal cavity).

When giving this medicine

To administer Epistatus, open the pre-filled oral syringe and pour the contents directly into the buccal cavity.

The recommended dose for children and adolescents aged 10 to less than 18 years of age is 10 mg. The dose must be administered by the nurse according to the doctor's instructions.

Care must be taken when administering the product to avoid the risk of the patient choking.

The patient must not drink alcohol if they have been given Epistatus. Alcohol may increase the sedative effects of Epistatus.

If the patient is going to have an inhaled anaesthetic (one that the patient breathes in) for an operation or for dental treatment, it is important to tell the doctor or dentist that they have been given Epistatus.

This medicine may also stop some other medicines from working as well, e.g. levodopa (used to treat Parkinson's disease).

Parkinson's disease.

This medicine may affect the patient's memory of the period after they have been given it (temporary memory loss). This is extremely important, as using more than one medicine at the same time can strengthen or weaken the effect of the medicines involved.

Ask your doctor or pharmacist if you need further advice.

Talk to the doctor or pharmacist before giving this medicine to another person if you are not sure. They may give you some instructions on how to give Epistatus.

If the patient gets side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

Keep the syringe to show to the ambulance staff or doctor.

Seek emergency medical assistance – telephone for an ambulance immediately – if the patient's seizure does not stop shortly after administering Epistatus.

The effects of Epistatus may be increased by medicines such as:

- alcohol.
- sleeping tablets.
- other medicines to treat anxiety.
- other medicines to treat insomnia.
- other medicines to treat nervousness.
- antidepressants.
- anticonvulsants.
- other medicines used in epilepsy.
- other medicines used in depression (including some types of antidepressant).
- some medicines used in the treatment of psychosis (e.g. clozapine)
- other medicines used to treat epilepsy.
- other medicines that may increase the effect of midazolam, e.g. MAO inhibitors, sedatives.
- other medicines that may reduce the effect of midazolam, e.g. rifampicin.
- other medicines that may increase the effect to midazolam, e.g. nitrofurantoin.
- other medicines that may increase the effect of midazolam, e.g. other benzodiazepines.
- other medicines that may reduce the effect of midazolam, e.g. barbiturates.
- other medicines that may reduce the effect of midazolam, e.g. lorazepam.
- other medicines that may increase the effect of midazolam, e.g. benzodiazepines.
- other medicines that may reduce the effect of midazolam, e.g. carbamazepine.
- other medicines that may increase the effect of midazolam, e.g. methadone.
- other medicines that may reduce the effect of midazolam, e.g. chloral hydrate.
- other medicines that may increase the effect of midazolam, e.g. diazepam.
- other medicines that may reduce the effect of midazolam, e.g. phenytoin.
- other medicines that may increase the effect of midazolam, e.g. phenobarbital.
- other medicines that may reduce the effect of midazolam, e.g. primidone.
- other medicines that may increase the effect of midazolam, e.g. pyrazole.
- other medicines that may reduce the effect of midazolam, e.g. phe
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- other medicines that may increase the effect of midazolam, e.g. phenobarbital.
- other medicines that may reduce the effect of midazolam, e.g. cloza
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