Package leaflet: Information for the user

Epistatus 10 mg/ml oromucosal solution

midazolam

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Epistatus is and what it is used for

Epistatus oromucosal solution contains the medicine midazolam, which belongs to a group of medicines known as benzodiazepines.

Epistatus is used to stop a prolonged, acute convulsive seizure (‘fit’) in infants, toddlers, children and adolescents aged from 3 months to less than 18 years.

In infants from 3 months to less than 6 months, this medicine should only be used in a hospital setting where monitoring is possible and resuscitation equipment is available (see “Warnings and precautions” for more information).

2. What you need to know before you use Epistatus

Do not give Epistatus if the patient has
- an allergy to midazolam, any other benzodiazepine (such as diazepam or nitrazepam), or any of the other ingredients of this medicine (listed in section 6).
- an illness called ‘myasthenia gravis’ (which causes muscle weakness).
- a severe breathing problems (Epistatus can make breathing difficulties worse).
- a sleep apnoea syndrome (which causes breathing to be frequently interrupted during sleep).
- a severe liver problems.

Warnings and precautions
Talk to the doctor or pharmacist before using Epistatus if the patient:
- has a lung condition causing breathing problems as this medicine could make your breathing worse.
- has kidney, liver or heart problems.
- is taking any other medication with sedative effects and feels very weak, run down and is short of energy because this medicinal product affects the central nervous system (CNS).
- regularly drinks large amounts of alcohol or has had problems with alcohol use in the past (see ‘Epistatus contains ethanol (alcohol)’).
- regularly takes recreational drugs or has had problems with drug use in the past.

This medicine may affect the patient's memory of the period after they have been given it (temporary memory loss). Patients should be carefully observed by the parents or caregivers after being given this medicine. See also section 4 (possible side effects).

Since delayed severe breathing problems (such as breathing more slowly or weakly than expected) cannot be excluded in younger children, infants aged from 3 months to less than 6 months should only be treated in a hospital setting where monitoring is possible and resuscitation equipment is available.

If you are not sure whether any of the above applies to the patient, please speak to a doctor or pharmacist before giving this medicine.

Children and adolescents
This medicine should not be given to children younger than 3 months since there is not enough information in this age group.

Other medicines and Epistatus
Tell the doctor or pharmacist if the patient is taking, has recently taken, or might take any other medicines. If you have any doubt about whether any medicine the patient is taking may affect the use of Epistatus, please speak to your doctor or pharmacist.
This is extremely important, as using more than one medicine at the same time can strengthen or weaken the effect of the medicines involved.

The effects of Epistatus may be intensified by medicines such as:
- antiepileptics, (for treating epilepsy) e.g. phenytoin
- antibiotics, e.g. erythromycin, clarithromycin
- antifungals, e.g. ketoconazole, voriconazole, fluconazole, itraconazole, posaconazole
- anti-ulcer medicines, e.g. cimetidine, ranitidine and omeprazole
- medicines used to treat blood pressure, e.g. diltiazem, verapamil
- some medicines used to treat HIV and AIDS, e.g. saquinavir, lopinavir/ritonavir combination
- narcotic analgesics (very strong pain killers), e.g. fentanyl
- medicines used to reduce fat in the blood, e.g. atorvastatin
- medicines used to treat nausea, e.g. nabilone
- hypnotics (sleep inducing medicines)
- sedative antidepressants (medicines used to treat depression that make you sleepy)
- sedatives (medicines that relax you)
- anaesthetics (for pain relief)
- antihistamines (to treat allergies).

The effects of Epistatus may be reduced by medicines such as:
- rifampicin (used to treat tuberculosis)
- xanthines (used to treat asthma)
- St John's Wort (a herbal medicine). This should be avoided in patients taking Epistatus.

Epistatus may increase the effect of some muscle relaxants e.g. baclofen (causing increased drowsiness). This medicine may also stop some other medicines from working as well, e.g. levodopa (used to treat Parkinson's disease).

Concomitant use of Epistatus and opioids (strong pain killers, medicines for substitution therapy and some cough medicines) increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible.
However if your doctor does prescribe Epistatus together with opioids the dose and duration of concomitant opioid treatment should be limited by your doctor.

Please tell your doctor about all opioid medicines you are taking, and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

Epistatus contains a small amount of alcohol and therefore should not be co-administered with disulfiram.

Talk to your doctor or pharmacist about medicines the patient should avoid whilst taking Epistatus.

Operations
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.

Epistatus with food, drink and alcohol
The patient must not drink alcohol if they have been given Epistatus. Alcohol may increase the sedative effects of Epistatus and make them very sleepy.

The patient must not drink grapefruit juice while taking Epistatus. Grapefruit juice may increase the sedative effect of Epistatus and make them more sleepy.

Pregnancy, breast-feeding and fertility
Pregnancy
If the patient is pregnant, thinks she might be pregnant or is planning to have a baby, ask a doctor for advice before giving this medicine.

Midazolam may be used during pregnancy if clearly necessary. Frequent doses of this medicine during the last 3 months of pregnancy or during childbirth can cause problems for the baby; these can include abnormal heart rhythms, hypothermia (low body temperature), poor suckling, breathing difficulties and poor muscle tone at birth.

Breast-feeding
Tell a doctor if the patient is breast-feeding. Even though small amounts of this medicine may pass into breast milk, it may not be necessary to stop breast-feeding. The doctor will advise if the patient should temporarily stop breast-feeding after being given Epistatus.

Driving and using machines
Epistatus has a major influence on the ability to drive and use machines.

This medicine may make the patient sleepy, forgetful or affect their concentration or coordination. This may affect their ability to perform skilled tasks such as driving, riding a bicycle or operating machinery. After receiving this medicine, the patient should not drive, ride a bicycle or operate machinery until they are completely recovered.

Please discuss with the doctor if you need further advice.

Epistatus contains maltitol
If the patient has been told by their doctor that they have an intolerance to some sugars, tell the doctor before you give this medicine.

Epistatus contains ethanol (alcohol)
Each ml of Epistatus contains 197 mg of alcohol (ethanol). This amount of medicine is equivalent to less than 5 ml beer, or 2 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.

Epistatus contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially ‘sodium-free’.

3. How to give Epistatus

The dose is individual and depends on age and kidney and liver function. The general doses are:

Age range	Dose
from 3 to 6 months hospital setting	2.5 mg (0.25 ml)
from 6 months to less than 1 year	2.5 mg (0.25 ml)
from 1 year to less than 5 years	5 mg (0.5 ml)
from 5 years to less than 10 years	7.5 mg (0.75 ml)
from 10 years to less than 18 years	10 mg (1 ml)

Children aged from 3 months to less than 6 months should only be treated in a hospital setting where monitoring is possible and resuscitation equipment is available.

The patient will be kept under supervision after he/she has been given Epistatus.

Preparing to give this medicine
If the patient is having a seizure (‘fit’), allow their body to move freely and do not try to restrain them. Only move the patient if they are in danger from the surroundings, for example, a road, open water, hot cooking appliances, fire or sharp objects.
Support the patient’s head with something soft, such as a cushion or your lap.

How to give this medicine
Epistatus is for oromucosal use only which means that it is only to be used in the mouth. It should be administered by trained healthcare professionals only. Care will be taken when giving the medicine to avoid the risk of the patient choking.

If the patient’s condition does not improve
If the patient’s seizure does not stop shortly after administering Epistatus, patient’s clinical status will be reassessed and a second dose may be considered. This assessment may include contacting emergency medical services.

If the patient’s condition improves but the seizure (‘fit’) then starts again
If the patient’s seizure starts again after initial improvement, patient’s clinical status will be reassessed and a second dose may be considered. This assessment may include contacting emergency medical services.

If you give more Epistatus than you should
If the patient is outside of a hopistal setting, contact emergency medical services.
Signs that a patient has been given too much Epistatus may be:
- drowsiness, tiredness, fatigue
- confusion or feeling disorientated
- losing their co-ordination
- developing muscle weakness
- low blood pressure – this can make them feel dizzy and faint
- breathing difficulties

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects

If the patient is outside of the hospital, call emergency services straight away if any of the following side effects occur:
- Severe breathing difficulties e.g. slow or shallow breathing or blue lips. In very rare cases breathing might stop.
- Cardiac arrest (heart stopped) reported in very rare cases. Signs include loss of consciousness associated with no pulse.
- Swelling of the face, lips, tongue or throat which makes it difficult to swallow or breathe, or a pale skin, a weak and rapid pulse, or feeling of loss of consciousness. You may be having a serious allergic reaction.

Other side effects
Common side effects (may affect up to 1 in 10 people):
- Sleepiness or losing consciousness, muscle spasms and muscle tremors (shaking of your muscles that you cannot control), reduced alertness, headache, dizziness
- Feeling and being sick
- Tiredness

Uncommon side effects (may affect up to 1 in 100 people):
- Agitation, hallucinations (seeing and possibly hearing things that are not really there)
- Temporary memory loss
- Rash, hives (lumpy rash), itchiness

Very rare side effects (may affect up to 1 in 10,000 people):
- Aggression, difficulty co-ordinating muscles, physical assault
- Fits (convulsions), restlessness
- Low blood pressure, slow heart rate, or redness of the face and neck (flushing)
- Breathlessness
- Constipation
- Dry mouth
- Hiccups

Frequency not known (cannot be estimated from the available data):
- Rage, confusion, hostility, euphoria (an excessive feeling of happiness or excitement)
- Thrombosis (local coagulation or clotting of the blood in a part of the circulatory system), laryngospasm (tightening of the vocal cords causing difficult and noisy breathing)

Reporting of side effects
If the patient gets side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Epistatus

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and bottle label after EXP. The expiry date refers to the last day of that month.

The cap must be replaced and closed tightly after use to prevent evaporation of the solution. Once open use it within 1 year.

Do not store above 25°C.
Do not refrigerate or freeze.
Store in the original package in order to protect from light.

Do not give this medicine if you notice that the solution is not clear (e.g. cloudy or white particles are present).

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Epistatus contains

- The active substance is midazolam (as midazolam maleate). Each ml of Epistatus contains 10 mg midazolam.
- The other ingredients are ethanol, saccharin sodium (E954), glycerol (E422), purified water, sodium hydroxide (E524) (for pH adjustment) and liquid maltitol (E965).

What Epistatus looks like and contents of the pack

Epistatus oromucosal solution is a slightly viscous, clear, colourless to pale yellow solution, practically free from visible particles. It is presented as 5 ml of oromucosal solution in a multidose amber glass bottle with a tamper-evident, child-resistant polyprolylene (PP) screw cap with low density polyethylene (LDPE) integral neck adaptor.

The bottle is packaged in a carton with 4 x 1 ml oral syringes, each syringe intended for single patient use. The oral syringes are marked with 0.05 ml as minor graduation and 0.25 ml as major graduation.

Marketing Authorisation Holder

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