From the leaflet:

**What Stesolid rectal tubes are and what they are used for**

Diazepam is used to treat:

- severe anxiety and agitation
- muscle spasms
- epilepsy or febrile convulsions
- symptoms of alcohol withdrawal

Stesolid rectal tubes can also be used to provide sedation before operations (premedication).

Your doctor may prescribe Stesolid rectal tubes for other uses. Please follow your doctor’s instructions.

**Before you use**

Do not use Stesolid rectal tubes and tell your doctor if you:

- are allergic (hypersensitive) to diazepam or to other benzodiazepine medicines or to any of the other ingredients (see section 6)
- have acute respiratory depression (slow and/or shallow breathing)
- suffer from depression (with or without anxiety) or hyperactivity

- have a phobia (a fear of a particular object or situation) or other mental illness
- have a condition called myasthenia gravis which causes muscles to weaken and tire easily
- suffer from sleep apnoea (a sleep disorder where you have abnormal pauses in breathing during sleep)
- have severe liver disorders
- have porphyria (an inherited condition causing skin blisters, abdominal pain and brain or nervous system disorders)
- planning a pregnancy or are pregnant (see Pregnancy and breast-feeding)

Check with your doctor or pharmacist before using Stesolid rectal tubes if you:

- have someone close to you who has recently died
- are elderly. Stesolid rectal tubes can cause confusion and have effects on muscles causing falls and injuries
- have a personality disorder
- have liver disease
- suffer from depression
- have suicidal thoughts

**Warnings about stopping treatment**

- Psychiatric side effects – contact your doctor if you experience side effects such as agitation, irritability, delusions, rage, inappropriate behaviour, restlessness, aggressiveness, nightmares or hallucinations. These side effects are more likely to occur in children or the elderly.
- Dependence – when taking this medicine there is a risk of dependence, which increases with the dose and duration of treatment and also in patients with a history of alcoholism and drug abuse or personality disorder. Therefore, you should take Stesolid rectal tubes for as short a period of time as possible.
- Tolerance – if after a few weeks you notice that this medicine is not working as well as they did when first starting treatment, you should speak to your doctor.
- Withdrawal – treatment should be gradually withdrawn. Withdrawal symptoms occur with Stesolid rectal tubes even when normal doses are given for short periods of time. See Section 3, ‘If you stop taking Stesolid rectal tubes’.
- Rebound sleeplessness and anxiety

When you stop taking this type of medicine, some of the symptoms that led to treatment can return more intensely than before, such as sleep disturbances, anxiety, restlessness or mood changes. The risk of this is greater if you stop suddenly.

To avoid these things happening, treatment should be stopped gradually, under the advice of a doctor.

Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

- antidepressants (e.g. fluoxetine, fluoxetine)
- antipsychotics such as clozapine (to treat mental problems)
- antihistamines (to treat allergies)
- lofexidine (to help relieve symptoms when you stop taking opioids)
- general anaesthetics
- sedatives (used to give calming effects)
- hypnotics (to help you sleep)
- sodium oxybate (to treat narcolepsy)
- muscle relaxants (e.g. suxamethonium, tubocurarin, baclofen, tizanidine)
- some strong pain killers such as morphine (opoids)
- barbiturates such as phenobarbital (to treat epilepsy and mental disorders)
- st John’s wart (h.p) (used to treat depression)

Taking these medicines with diazepam can affect your mental status, make you very sleepy and suppress your breathing and blood pressure.

- disulfiram (to treat alcohol addiction).
- medicines for epilepsy e.g. phenytoin and carbamazepine, as these can reduce the effect of diazepam. Diazepam can furthermore affect how phenytoin works.
- theophylline (to treat asthma and other breathing disorders), as it can weaken the effect of diazepam.
- cimetidine, omeprazole or esomeprazole (stomach acid reducing medicines), as these can cause diazepam to be removed from the body more slowly than usual.
- medicines for Parkinson’s disease). Diazepam can reduct the effect of levodopa.
- valproic acid (used to treat epilepsy and mental disorders) as it can slow down the removal of diazepam from the body and increase its effect.
- ketamine (an anaesthetic) as diazepam increases the effect of ketamine.

**Taking Stesolid with food and drinks**

Do not drink alcohol while you are taking diazepam. Alcohol may increase the sedative effects of Stesolid rectal tubes and make you very sleepy. You should not drink grapefruit juice while taking diazepam as it causes diazepam to be removed from the body more slowly and increases the risk of side effects.

Drinks containing caffeine may reduce the effects of diazepam.

**Alcohol**

Do not drink alcohol while you are using Stesolid rectal tubes. Alcohol may increase the sedative effects of diazepam and make you very sleepy.

**Pregnancy and breast-feeding**

Ask your doctor or pharmacist for advice before taking any medicine.

You should not take Stesolid rectal tubes if you are pregnant, planning to become pregnant or are breast-feeding. If you take Stesolid rectal tubes late in pregnancy or during labour your baby might have a low body temperature, floppiness and breathing difficulties. If taken regularly during late pregnancy, your baby may develop withdrawal symptoms.

**Driving and using machines**

Stesolid rectal tubes may make you feel sleepy, forgetful, have poor co-ordination and affect your concentration along with other side effects that can affect everyday activities (see Possible side effects). It may also affect how your muscles work. These effects may continue for several days after discontinuation of treatment with diazepam.
Do not drive, use any tools or machines, or take part in such activities where, if affected, you could put yourself or others at risk.

The medicine can affect your ability to drive as it may make you sleepy or dizzy.

- Do not drive while taking this medicine until you know how it affects you.
- It is an offence to drive if this medicine affects your ability to drive.
- However, you would not be committing an offence if:
  - The medicine has been prescribed to treat a medical or dental problem and
  - You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
  - It was not affecting your ability to drive safely

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

How to use

Always use Stesolid rectal tubes exactly as your doctor has told you.

The tubes are inserted into the anus using the nozzle provided. Instructions for inserting the tubes are on the foldable label on each bag. Please read the instructions very carefully before using your medicine.

Doses

Adults and children above 1 year of age: 0.5mg per kg of body weight

Elderly: 0.25mg per kg of body weight

If you have breathing problems you may also be given a lower dose.

After giving into the anus, the medicine is quickly absorbed and will start to take effect within 5 minutes.

Your doctor will decide the appropriate dose and for how long you need to take this medicine. The usual duration of treatment is not longer than 4 weeks. If needed, your doctor might increase the duration of treatment.

If you don’t feel better

If your symptoms or the fit are not brought under control with Stesolid rectal tubes, contact a doctor for advice. Further doses should only be given only after consulting a doctor. The maximum dose is 30mg.

If you take more Stesolid than you should

- If you have used too many rectal tubes (more than prescribed), or you think a child may have swallowed any, contact your nearest hospital casualty department or tell your doctor immediately.
- Signs of an overdose include loss of coordination of muscle movements, sleep-like drowsy state, confusion, slurred speech, irregular or slow heartbeat, uncontrolled eye movement and muscle weakness.

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An extreme overdose may lead to coma (unreassurable unconsciousness), low body temperature (hypothermia), low blood pressure, slow pulse and severe breathing difficulties.

If you forget to use Stesolid rectal tubes

If you forget to take a dose take it as soon as you remember it. If you are about to take the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Stesolid rectal tubes suddenly, you may experience withdrawal symptoms including anxiety, panic attack, palpitations (strong and pounding heartbeat), sweating, tremor, stomach problems, irritability, aggression, sensory disorder, muscle spasms, generally feeling unwell, loss of appetite, insomnia, mental side effects such as severe confusion and seizures. The likelihood and severity of withdrawal symptoms depends on the duration of treatment, dose strength and degree of dependency.

If you have epilepsy or history of seizures and suddenly stop taking Stesolid rectal tubes, there is a risk of convulsions or long-lasting epileptic seizure. There is also risk of seizures if you have an alcohol or drug abuse problem and suddenly stop taking Stesolid rectal tubes.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

Possible side effects

Like all medicines, Stesolid rectal tubes can cause side effects, although not everybody gets them.

Stop treatment and contact a doctor at once if you have the following symptoms of an allergic reaction: e.g. itchy skin, rash, swelling of the face, lips, tongue or throat, or difficulty breathing or swallowing.

Contact your doctor immediately, if you notice any of the following side effects or notice any other effects not listed:

Uncommon: affects 1 to 10 users in 1,000

- Respiratory depression (very slow and/or shallow breathing)
- Respiratory arrest (cessation of breathing)
- Insomnia (problems sleeping)
- Heart problems such as slow heartbeat (bradycardia), heart failure and cessation of heartbeat (cardiac arrest).
- Low blood pressure, fainting (syncope)
- Increased mucus in the lungs
- Dry mouth
- Increased appetite
- Changes in certain liver enzymes as seen in blood tests
- Lack of ability to urinate, loss of bladder control (leakage of urine)
- Breast enlargement in men
- Impotence, changes in sexual drive (libido)
- Blood disorders (you may develop sore throat, nose bleeds or infections)

Very rare: affects less than 1 user in 10,000

- Low levels of white blood cells (leukopenia)
- Higher level of a certain enzyme in the blood (transaminase) Not known frequency cannot be estimated from the available data
- Blurred vision, double vision and involuntary eye movements (these side effects disappear after you have stopped taking diazepam)

If you notice any side effects, they get worse, or if you notice any not listed, please tell your doctor or pharmacist.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

By reporting side effects you can help provide more information on the safety of this medicine.

How to store

Keep out of the sight and reach of children.

Do not store above 25°C. Do not use Stesolid rectal tubes after the expiry date stated on the label/carton/bottle. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Further Information

What Stesolid rectal tubes contain

- The active substance (the ingredient that makes the medicine work) is diazepam. Each rectal tube contains either 5mg or 10mg of diazepam.
- The other ingredients are benzaic acid, ethanol, polyethylene glycol, sodium benzoate, benzyl alcohol, water.

What Stesolid rectal tubes look like and contents of the pack

Stesolid rectal tubes contain a clear, colourless to yellowish liquid in a yellow polyethylene tube.

Pack size of 5 x 2.5ml, singly packed in aluminium foil.

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Colours

1. Black
2.
3.
4.
5.
6.

Non Printing Colours

1.
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3.