

STESOLID RECTAL TUBE 5MG

Diazepam (5mg)

What is in this leaflet

1. What Stesolid is used for
2. How Stesolid works
3. Before you use Stesolid
4. How to take Stesolid
5. While you are using Stesolid
6. Side Effects
7. Storage and Disposal of Stesolid
8. Product description
9. Manufacturer and Product Registration Holder
10. Date of Revision

What Stesolid is used for

Stesolid rectal tubes are enemas containing the active ingredient diazepam. Diazepam is a type of medicine called a benzodiazepine.

Benzodiazepines are used for their sedative, anxiety-relieving and muscle-relaxing effects.

Stesolid is used in controlling convulsions, or seizures associated with fever in children (febrile convulsions).

How Stesolid work

Diazepam works by acting on receptors in the brain called GABA receptors. This causes the release of a neurotransmitter called GABA in the brain.

Neurotransmitters are chemicals that are stored in nerve cells in the brain and nervous system. Diazepam helps control convulsions because the increased activity of GABA that it causes in the brain helps to calm excessive electrical nerve activity that is responsible for causing seizures.

As diazepam increases the activity of GABA in the brain, it increases its calming effect and results in sleepiness, a decrease in anxiety and relaxation of muscles.

Stesolid rectal tubes are administered into the rectum. The diazepam is absorbed rapidly into the bloodstream from the rich supply of blood vessels in this area. Rectal administration is used when a rapid effect is needed, but an injection is impractical or undesirable.

Before you use Stesolid

-When you must not take it

Do not use Stesolid if you are:

- allergic (hypersensitive) to diazepam, other benzodiazepine medicines or to any of the other ingredients in Stesolid
- have severe breathing problems or have difficulty breathing
- have myasthenia gravis (a condition which causes muscle weakness)
- suffer from sleep apnoea (a condition where you stop breathing whilst asleep)
- have porphyria (a rare hereditary disease in which the blood pigment hemoglobin is abnormally metabolized)
- planning a pregnancy or are pregnant (see below 'Pregnancy and Breastfeeding')
- suffer from depression (with or without anxiety) or hyperactivity
- have severe liver disorders

-Before you start to take it

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

- have a phobia (a fear of a particular object or situation) or other mental illness
- have a history of complex sleep-related behaviors which may include sleep driving, making phone calls, preparing and eating food while asleep
- are elderly (as there is an increased risk of side effects).

Pregnancy and Breastfeeding

You should not use Stesolid if you are pregnant, planning to become pregnant or are breast feeding. If your doctor has decided you should receive Stesolid rectal solution during late pregnancy or during labour, your baby might have a low body temperature, floppiness, and breathing difficulties. If Stesolid rectal solution is used regularly in late pregnancy, your baby might develop withdrawal symptoms. Stesolid rectal solution must not be used if you are breast-feeding as diazepam enters breast milk and may affect the

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

Driving and using machines

Stesolid can make you sleepy, have poor co-ordination along with other side effects that can affect everyday activities. You should not drive, operate machinery or take part in such activities where, if affected, you could put yourself or others at risk.

-Taking other medicines

It is important to tell your doctor or pharmacist what medicines you are already taking, including those bought without a prescription and herbal medicines, before you start treatment with this medicine. Similarly, check with your doctor or pharmacist before taking any new medicines with this one, to make sure that the combination is safe.

There may be an increased risk of drowsiness and sedation if diazepam is used with any of the following (which can also cause drowsiness):

- alcohol
- hypnotics (sleeping pills)
- neuroleptics (antipsychotic medications used in the treatment of mental illness)
- antihistamines (anti-allergy medicine)
- morphines and its analogues (pain-killers)

Taking Stesolid with an opioid medicine (medicine to relieve pain) can depress your central nervous system. Inform your doctor if you are currently taking any opioid medicine.

Seek medical attention immediately if you or the person taking this medication experience(s) symptoms of unusual dizziness or light-headedness, extreme sleepiness, slowed or difficult breathing, or unresponsiveness.

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The following medicines may increase the blood level of diazepam and its sedative effects:

- cimetidine (medicine to treat heartburn and peptic ulcers)
- disulfiram (medicine to treat chronic alcoholism)
- omeprazole (medicine to treat conditions caused by excess stomach acid).

Rifampicin (an antibiotic) decrease the blood level of diazepam. As this could make it less effective, your doctor may need to prescribe you a larger than normal dose of diazepam.

How to take Stesolid

-How much to take

Adults: 10-20mg

Children 6-12 years: 10mg

Children 1-5 years: 5mg

The dosage may be repeated if necessary.

-When to take it

The time to give rectal diazepam should be individualised for each patient. Check with your doctor when to use Stesolid.

-How long to take it

If your symptoms or the fits are not brought under control with Stesolid, contact a doctor for advice. Further doses should only be given after consulting a doctor.

-If you forget to take it

If you forget to use a dose, use it as soon as you remember it and then use the next dose at the right time. Do not use a double dose to make up for a forgotten dose.

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

-If you take too much (overdose)

If you (or someone else) use a lot of medicine at the same time, 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 hypotension (low blood pressure), respiratory depression (breathing difficulties), and coma.

While you are using Stesolid

-Things you must do

Always use Stesolid 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 folded label on each bag. Please read the instructions very carefully before using your medicine.

-Things you must not do

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

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

-Things to be careful of

There is a risk of anaphylaxis (severe allergic reaction) and angioedema (severe facial swelling) which can occur as early as the first time the product is taken.

You may also become dependent on this medicine, particularly with high doses, continued use or if you have a history of alcoholism or drug abuse.

If dependence has developed, withdrawal symptoms will occur if you suddenly stop treatment. To avoid these things happening, treatment should be stopped gradually under the advice of a doctor.

Side Effects

Medicines and their possible side effects can affect individual people in different ways. The following are some of the side effects that are known to be associated with this medicine. Just because a side effect is stated here does not mean that

all people using this medicine will experience that or any side effect.

- drowsiness.
- difficulties with concentration
- confusion.
- uncoordinated muscle movements (ataxia).
- mental side effects such as excitation, hallucination and aggressiveness (paradoxical aggression).
- dizziness.

Elderly patients are especially susceptible to these side effects. If you get any of the above side effects, or notice any other side effects not listed in this leaflet, tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to The National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.moh.gov.my (Consumers → Reporting → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage and Disposal of Stesolid

-Storage

Store at room temperature below 30°C, away from light.

-Disposal

Do not use after the expiry date stated on the label.

Take any unused tubes back to your pharmacist to be destroyed. Only keep the tubes if the doctor tells you to. Do not throw them away with your normal household water or waste. This will help to protect the environment.

Product Description

-What it looks like

Stesolid Rectal Tube 5mg contains a clear, colourless to yellowish liquid in a yellow polyethylene tube.

-Ingredients

Active Ingredient

Each tube contains Diazepam 5mg

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Diazepam (5mg)

Inactive ingredients

Benzoic acid, sodium benzoate, ethanol, propylene glycol, benzyl alcohol, alcohol and purified water.

-MAL Number

MAL16105030AZ

Manufacturer

PT Actavis Indonesia
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