

Stesolid® Rectal Tubes

5 mg and 10 mg diazepam

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.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in the leaflet. See section 4.

What is in this leaflet:

- 1 What Stesolid rectal tubes are and what they are used for
- 2 What you need to know before you use Stesolid rectal tubes
- 3 How to use Stesolid rectal tubes
- 4 Possible side effects
- 5 How to store Stesolid rectal tubes
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1 What Stesolid rectal tubes are and what they are used for

Stesolid rectal tubes contain diazepam which belongs to a group of medicines called benzodiazepines. 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.

2 What you need to know before you use Stesolid rectal tubes

Do not use Stesolid rectal tubes if you

- are **allergic** to diazepam or to other benzodiazepine medicines or to any of the other ingredients of this medicine (listed in 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)

Warnings and precautions

Talk to your doctor or pharmacist before using Stesolid rectal tubes if you

- have a history of **alcoholism** or **drug abuse**
- 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 using 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 use 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 it 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 using Stesolid rectal tubes'.
- **Rebound sleeplessness and anxiety** When you stop using 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.

Other medicines and Stesolid rectal tubes

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

- **antidepressants** (e.g. fluvoxamine, fluoxetine)
- **antipsychotics** such as clozapine (to treat mental problems)
- **antihistamines** (to treat allergies)
- **lofexidine** (to help relieve symptoms when you stop using 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** (opioids)
- barbiturates such as **phenobarbital** (to treat epilepsy and mental disorders)
- **St John's wort (h.p)** (used to treat depression)

Concomitant use of Stesolid rectal tubes 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 Stesolid rectal tubes together with opioids the dose and duration of concomitant 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.

- Taking these medicines with diazepam could affect your mental status, make you very sleepy and suppress your breathing and blood pressure.
- **disulfiram** (to treat alcohol addiction). Using this medicine with diazepam could make you very sleepy and can cause diazepam to be removed from the body more slowly than usual.
- **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.
- **rifampicin** (an antibiotic) as this can cause diazepam to be removed from the body more

quickly than usual. The effect of diazepam can be weakened.

- **atazanavir, ritonavir, delavirdine, efavirenz, indinavir, nelfinavir or saquinavir** (antivirals), **fluconazole, itraconazole, ketoconazole or voriconazole** (anti-fungal medicines) as these can cause diazepam to be removed from the body more slowly than usual and therefore increase the risk of side effects.
- **isoniazid** (used to treat tuberculosis), as it can cause diazepam to be removed from the body more slowly than usual.
- **oral contraceptives**, as they can slow down the removal of diazepam from the body and increase its effect. Breakthrough bleeding can occur when using diazepam and oral contraceptives together, but the contraceptive protection is not reduced.
- **corticosteroids** (medicines used to treat inflammation in the body) as they can weaken the effect of diazepam.
- **medicines to lower high blood pressure, diuretics** (water tablets), **nitrates** (for heart conditions), hydralazine, minoxidil, sodium nitroprusside as these could lower your blood pressure too much.
- **levodopa** (used to treat Parkinson's disease). Diazepam can reduce 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.

Stesolid rectal tubes with food and drink

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

You should not drink **grapefruit juice** while using 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.

Pregnancy and breast-feeding

You should not use Stesolid rectal tubes if you are pregnant, planning to become pregnant or are breast-feeding. If you use Stesolid rectal tubes late in pregnancy or during labour your baby might have a low body temperature, floppiness and breathing difficulties. If used 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 Section 4, '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 using 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 used 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 using this medicine.

Stesolid rectal tubes contains benzoic acid, sodium benzoate and propylene glycol

These may cause mild irritation to the skin and/or mucous membranes.

3 How to use Stesolid rectal tubes

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

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.

The recommended dose is

Adults: 0.5mg per kg of body weight.

Elderly: 0.25mg per kg of body weight.

Children and adolescents above 1 year of age: 0.5mg per kg of body weight.

If you have breathing problems, you may also be given a lower dose. After inserting 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 use 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 fits are not brought under control with Stesolid rectal tubes, contact a doctor for advice. Further doses should only be given after consulting a doctor. The maximum dose is 30mg.

If you use 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, controlled eye movement and muscle weakness. An extreme overdose would lead to coma (unrousable 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 a dose, use Stesolid as soon as you remember it. If you are about to use the next dose, skip the missed dose. Do not use a double dose to make up for a forgotten dose.

If you stop using Stesolid rectal tubes

Do not stop using your medicine without talking to your doctor. You should gradually reduce the number or strength of rectal tubes you use before stopping them completely. If you stop using 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 using 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 using Stesolid rectal tubes.

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

4 Possible side effects

Like all medicines, this medicine 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)

Rare: affects 1 to 10 users in 10,000

- Respiratory arrest (cessation of breathing)
- Unconsciousness
- Jaundice (yellowing of your skin or the white of your eyes)

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

- Anaphylaxis (severe allergic reaction) with symptoms such as sudden wheezing, swelling of your lips, tongue and throat or body, rash, fainting or difficulties to swallow

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

Very common: affects more than 1 user in 10

- Drowsiness

Common: affects 1 to 10 users in 100

- Fatigue, sedation
 - Withdrawal symptoms (for possible symptoms please see Section 3, '**if you stop using Stesolid rectal tubes**')
 - Confusion
 - Loss of coordination of muscle movements (ataxia) and other movement disorders, tremor
- Uncommon: affects 1 to 10 users in 1,000
- Muscle weakness
 - Memory loss (which may be experienced several hours after using diazepam. If possible, to reduce the risk allow 7 to 8 hours of uninterrupted sleep after using)
 - Difficulty in concentrating
 - Balance disorders, dizziness, headache
 - Slurred speech
 - Stomach and intestinal problems such as feeling or being sick, constipation, diarrhoea
 - Increased salivation

Rare: affects 1 to 10 users in 10,000

- Psychiatric side effects such as excitation, agitation, restlessness, irritability, inappropriate behaviour, aggressiveness, memory loss, delusion, rages, psychoses, nightmares or hallucinations. May be or become serious. These side effects are more likely to occur in children or the elderly.
- Decreased alertness
- Depression
- Emotional withdrawal
- 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 using diazepam)
- Uncovering of depression with suicidal thoughts and dependence or abuse of this medicine or similar medicines.
- Abnormal pauses in breathing

5 How to store Stesolid rectal tubes

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 or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5 How to store Stesolid rectal tubes

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 protect the environment.

6 Contents of the pack and other 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 benzoic acid, ethanol, propylene 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.

Marketing Authorisation Holder:

Accord Healthcare Limited
Sage House, 319 Pinner Road
North Harrow, Middlesex
HA1 4HF, United Kingdom

Manufacturers

Balkanpharma - Dupnitsa AD
3 Samokovsko Shosse Str.
Dupnitsa 2600, Bulgaria

Merckle GmbH
Graf-Arco-Str. 3, 89079 Ulm, Germany

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