

Stesolid® Rectal Solution
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 this leaflet. See section 4.

What is in this leaflet:

- 1. What Stesolid is and what it is used for**
- 2. What you need to know before you use Stesolid**
- 3. How to use Stesolid**
- 4. Possible side effects**
- 5. How to store Stesolid**
- 6. Contents of the pack and other information**

1. What Stesolid is and what it is used for

Stesolid rectal solution contains diazepam which belongs to a group of medicines called benzodiazepines. Diazepam is used to treat:

- severe anxiety and agitation
- epilepsy or febrile convulsions
- tetanus

Stesolid rectal solution may also be used to cause relaxation and sleepiness before an operation or dental procedure, or in other circumstances where a rapid effect is required but where intravenous injection is impracticable or undesirable.

Your doctor may prescribe Stesolid for other uses. Please follow your doctor's instructions.

2. What you need to know before you use Stesolid

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

- are **allergic** to diazepam, to other benzodiazepine or to any of the other ingredients of this medicine (listed in section 6)
- **have severe breathing problems or have difficulty 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 **myasthenia gravis** (a condition which causes muscle weakness)
- 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 below 'Pregnancy, breast-feeding and fertility').
- **suffer from sleep apnoea** (a condition where you stop breathing whilst asleep)

Warnings and precautions

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

- have a history of **alcoholism** or **drug abuse**

- have someone **close to you** who has recently died
- are **elderly** (as there is an increased risk of side effects)
- have a **personality disorder**
- have **liver** disease
- suffer from **depression**
- have **suicidal thoughts**

• **Mental side effects** – contact your doctor if you experience side effects such as agitation, irritability, delusions, rage, hyperactivity, restlessness, aggressiveness, nightmares or hallucinations. These side effects are more likely to occur in children or the elderly (see section 4).

• **Amnesia** – you could experience amnesia when using this medicine. Amnesia is more likely to occur when taking high doses of diazepam and should not be used in cases of loss or bereavement as psychological adjustment may be inhibited.

• **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. Therefore, you should use Stesolid for as short 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.

Warnings about stopping treatment

• **Withdrawal symptoms**- Treatment should be gradually withdrawn. Withdrawal symptoms occur with Stesolid even when normal doses are given for short periods of time. See Section 3, ‘**If you stop using Stesolid**’.

• **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 (see section 3 ‘If you stop taking Stesolid’).

Other medicines and Stesolid

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

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- **antipsychotics** such as clozapine (to treat mental problems)
- **hypnotics** (to help you sleep)
- **antihistamines** (to treat allergies)
- **lofexidine** (to help relieve symptoms when you stop using opioids)
- **antidepressants** (e.g. fluvoxamine, fluoxetine)
- **sedatives** (used to give calming effects)
- **general anaesthetics**
- **muscle relaxants** (e.g. suxamethonium, tubocurarin, baclofen, tizanidine)
- **strong analgesics** (drugs used to treat severe pain) such as morphine (opioids).
- barbiturates such as **phenobarbital** (to treat epilepsy and mental disorders).
- **St John’s wort (*Hypericum perforatum*)** (used to treat depression)

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

- **anti-epileptics** (phenytoin and carbamazepine), as these can reduce the effect of Stesolid. Furthermore, Stesolid can affect how phenytoin works.
- **cimetidine, omeprazole or esomeprazole** (medicines used to reduce acid in your stomach), as these can cause Stesolid to be removed from the body more slowly than usual.

- **anti-viral agents** (e.g. atazanavir, ritonavir, delavirdine, efavirenz, indinavir, nelfinavir or saquinavir) and **anti-fungal agents** (e.g. fluconazole, itraconazole, ketoconazole or voriconazole) as these medicines can cause Stesolid to be removed from the body more slowly than usual and therefore increase the risk of side effects.
- **rifampicin** (an antibiotic) as this medicine can cause Stesolid to be removed from the body more quickly than usual. The effect of Stesolid can be weakened.
- **theophylline** (to treat asthma and other breathing disorders), as it can weaken the effect of Stesolid.
- **sodium oxybate**, avoid concomitant use (enhanced effects of sodium oxybate).
- **disulfiram** (to treat alcohol addiction). Taking this medicine with Stesolid could make you very sleepy and can cause Stesolid to be removed from the body more slowly than usual. A reaction may occur as long as two weeks after cessation of disulfiram.
- **isoniazid** (used to treat tuberculosis), as it can cause Stesolid to be removed from the body more slowly than usual.
- **oral contraceptives**, as they can slow down the removal of Stesolid from the body and increase its effect. Breakthrough bleeding can occur when taking Stesolid and oral contraceptives together, but the contraceptive protection is not reduced.
- **cisapride** (used to treat stomach problems), as it can cause Stesolid to be removed from the body more slowly than usual.
- **corticosteroids** (medicines used to treat inflammation in the body) as they can weaken the effect of Stesolid.
- **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). Stesolid can reduce the effect of levodopa.
- **valproic acid** (used to treat epilepsy and mental disorders) as it can slow down the removal of Stesolid from the body and increase its effect.
- **ketamine** (an anaesthetic) as Stesolid increases the effect of ketamine.

Concomitant use of Diazepam 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 Diazepam 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.

Stesolid with food and drink

Grapefruit juice may increase the amount of diazepam in your blood. If you are elderly, suffer from cirrhosis or any of the conditions listed in section 2, this could possibly increase the sedative effects of Stesolid and you should speak to your doctor or pharmacist.

Drinks containing caffeine may reduce the effects of diazepam.

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, breastfeeding and fertility

If you are pregnant or breast-feeding, think you might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Stesolid rectal solution **must not be used** if you are pregnant or might become pregnant. 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.

There are no data on the effects of Stesolid on fertility in humans.

Driving and using machines

Stesolid can make you feel sleepy, forgetful, have poor co-ordination and affect your concentration along with other side effects that can possibly affect everyday activities (see Section 4, 'Possible side effects'). It may also affect how your muscles work. You **should not** drive, operate machinery or take part in such activities where, if affected, you could put yourself or others at risk. The effects of Stesolid may continue for several days after discontinuation of the product.

Stesolid rectal solution contains 10 % w/v ethanol, benzoic acid, sodium benzoate and propylene glycol

Each dose contains up to 0.25 mg of alcohol. The alcohol may be harmful for those suffering from liver disease, alcoholism, epilepsy, brain injury or diseases as well as for pregnant women. The alcohol may modify or increase the effects of other medicines.

Benzoic acid and sodium benzoate are mild irritants to the skin, eyes and mucous membranes.

Propylene glycol may cause skin irritation.

3. How to use Stesolid

Always use Stesolid rectal solution exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

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

The recommended doses are:

- **Adults:** 0.5mg per kg body weight
- **Children and adolescents 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 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 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 fit are not brought under control with Stesolid rectal solution, contact a doctor for advice. Further doses should only be given after consulting a doctor. The maximum dose is 30 mg.

If you use more Stesolid rectal solution than you should

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 clumsiness and loss of coordination, feeling sleepy or deep sleep, speech problems, irregular or slow heartbeat, uncontrolled eye movement, muscle weakness or excitement. An extreme overdose may lead to coma (unrousable unconsciousness), reflex problems and 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 taking Stesolid

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 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, 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.

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.

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

Some side effects can be serious and may require immediate medical attention:

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 (affect 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.

Other side effects:

Very common (affects more than 1 user in 10)

- Drowsiness

Common (affects 1 to 10 users in 100)

- Confusion
- Uncoordinated muscle movements (ataxia), tremor, impaired movements
- Fatigue, sedation
- Withdrawal symptoms (for possible symptoms see section 3 'If you stop taking Stesolid')

Uncommon (affects 1 to 10 users in 1,000)

- Memory impairment (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), concentration difficulties, balance disorders, dizziness, headache, slurred speech
- Nausea, vomiting, constipation, diarrhoea, increased salivary secretion
- Allergic skin reactions such as itching, skin redness and swelling and skin rash
- Muscle weakness

Rare (affects 1 to 10 users in 10,000)

- Mental side effects such as excitation, agitation, restlessness, irritability, aggressiveness, hallucinations, memory loss, delusion, rages, psychoses and nightmares. Decreased alertness, depression. May be or become serious. These side effects are more likely to occur in children or the elderly.
- 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 (incontinence)
- Abnormal breast enlargement in males (gynaecomastia)
- Inability to have an erection (impotence), changes in sexual drive (libido)
- Blood disorders (you may develop sore throat, nosebleeds or infections)

Very rare (affect less than 1 user in 10,000)

- Low levels of white blood cells (leukopenia)
- High levels of certain enzyme in the blood (transaminases)

Not known (frequency cannot be estimated from the available data)

- Reversible disorders of vision such as blurred vision, double vision (diplopia) and involuntary eye movements (nystagmus)
- Uncovering of depression with suicidal thoughts and dependence or abuse of this medicine or similar medicines.
- Abnormal pauses in breathing

Use of Stesolid may lead to the development of physical or psychic dependence.

Reporting of side effects

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 HPRA

Pharmacovigilance, Website: www.hpra.ie.

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

5. How to store Stesolid

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

Do not store above 25°C.

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

Do not throw away any medicine 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 Stesolid contains:

- The active substance is diazepam. Each rectal tube contains either 5 mg or 10 mg of diazepam.
- The other ingredients are benzoic acid, ethanol, propylene glycol, sodium benzoate, benzyl alcohol, water.

What Stesolid looks like and contents of the pack

Stesolid rectal solution is 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 Ireland Ltd,
Euro House,
Euro Business Park,
Little Island,
Cork T45 K857,
Ireland

Manufacturer

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

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

This leaflet was last revised in October 2020