

New Zealand Consumer Medicine Information

Stesolid[®] diazepam

(pronounced die-az-e-pam)

Rectal tubes containing 5mg or 10mg diazepam

What is in this leaflet?

This leaflet answers some common questions about Stesolid[®].

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of your taking Stesolid[®] against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Stesolid[®] is used for

Stesolid[®] rectal tubes contain a medicine called diazepam (die-az-e-pam) and are used for the treatment of fits or seizures caused by fever (called febrile convulsions).

Your doctor may have prescribed Stesolid[®] for another reason. Ask your doctor or pharmacist if you have any questions about why Stesolid[®] has been prescribed for you.

Before you use Stesolid[®]

When you must not use it

- If you are sensitive (allergic) to diazepam (or the group of medicines to which it belongs, called benzodiazepines) or any of the ingredients of Stesolid[®] (listed at the end of this leaflet).
- If you have severe breathing problems or have difficulty breathing.
- If you have a condition called myasthenia gravis which causes muscle weakness.
- If you have a condition called sleep apnoea where you stop breathing temporarily whilst asleep.

- If you are breast feeding.
- If you have severe liver problems.
- If the packaging is torn or shows signs of tampering.

Before you start to use it

Tell your doctor or pharmacist if:

- you are pregnant or plan on becoming pregnant. Your doctor will discuss the risks and benefits of using Stesolid[®] with you.
- you suffer from anxiety or depression
- you are using any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop. **Many medicines interact with diazepam.** Your doctor will be able to provide you with more information.
- you have a history of drug or alcohol abuse.
- you have epilepsy or have experienced seizures

What else you should know

There is a risk of becoming dependent on Stesolid[®], particularly with 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.**

Withdrawal symptoms include: anxiety, panic, fast or irregular heartbeat, headaches, muscle spasms, sweating, trembling, irritability, stomach upsets, aggression, loss of appetite, sensitivity to light, noise or touch, paranoid psychosis (mental illness causing severe suspiciousness), severe confusion and fits.

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

How to use Stesolid[®]

How to take it

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

The tubes are inserted into the back passage (anus) using the nozzle provided. Instructions for inserting the tubes are on the folded label on each bag. Please read the instructions carefully before using Stesolid[®].

How much to use

Your doctor will tell you how much to use. In general the following dosages apply:

Adults: 10-20mg

Children (7-12 years): 10mg

Children (1-6 years): 5mg

The medicine should start to work within 5 minutes. If necessary, these doses may be repeated once only, after five minutes.

The maximum recommended dose is 30mg unless adequate medical supervision is available.

If the fit or seizure is not brought under control by the dose of Stesolid[®] advised by your doctor, contact your doctor for further information.

If you use too much (overdose) or if you swallow it

If Stesolid[®] rectal tube contents are accidentally swallowed or if you think you or anyone else may have used too much of this medicine you should:

- consult your doctor immediately *or*
- telephone the New Zealand Poisons Information Centre 0800 POISON (0800 764 766) for advice, *or*
- go to Accident and Emergency at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. Urgent medical attention may be required.

While you are using Stesolid[®]

Things you must do

Tell your doctor or pharmacist if you become pregnant while using Stesolid[®].

If you are about to be started on any new medicine, tell your doctor or pharmacist that you are using Stesolid[®].

Tell your doctor if for any reason you have not used Stesolid[®] exactly as directed.

Otherwise your doctor may think that it was not effective and change your treatment unnecessarily.

Things you must not do

Avoid drinking alcohol while you are using Stesolid[®] rectal tubes as it can make you feel drowsy or dizzy.

Avoid drinking grapefruit juice while you are using Stesolid[®] rectal tubes as it can increase the amount of diazepam in your blood.

Speak to your doctor if you require more information.

Do not drive or operate machinery while taking Stesolid[®] as the medicine can make you feel drowsy and affect your concentration.

Do not give Stesolid[®] to anyone else, even if they have the same condition as you.

Do not use Stesolid[®] to treat any other complaints unless your doctor or pharmacist tells you to.

Side Effects

Tell your doctor or pharmacist if you do not feel well while you are using Stesolid[®].

Like other medicines Stesolid[®] can cause some side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and require medical attention.

Ask your doctor or pharmacist to answer any questions you may have.

You must get urgent medical help if you have any of the following symptoms:

- You have difficulty breathing
- Your lips, face or throat swell or you have difficulty swallowing
- Your skin develops a severe rash or becomes itchy

You may be having an allergic reaction.

Tell your doctor or pharmacist if you notice any of the following side effects and they worry you:

Common side effects

- Drowsiness, dizziness, unsteadiness, tremor, tiredness, confusion, lack of co-ordination, withdrawal symptoms if treatment is not stopped gradually (see “Before you use Stesolid[®]”).

Uncommon side effects

- Concentration or memory difficulties, headache, difficulty breathing, difficulty speaking, stomach upsets, increased production of saliva, allergic skin reactions, muscle weakness.

Rare side effects

- Difficulty sleeping, loss of consciousness, yellowing of the skin and/or eyes (jaundice), heart problems (slow heart beat, heart failure), low blood pressure, dry mouth, increased appetite, coughing and bringing up phlegm, breast

enlargement in men, impotence or libido changes, difficulty passing urine or uncontrolled passing of urine, decreased alertness, emotional withdrawal, depression, mental disturbances and paradoxical reactions (excitement instead of sedation).

Stesolid[®] may also occasionally cause disturbances to vision.

Some people may get other side effects while using Stesolid[®]. Tell your doctor if you notice any unwanted side effect, especially if severe or persistent, or if there is a change in your health that you think might be caused by Stesolid[®].

Do not be alarmed by this list of side effects. You may not experience any of them.

After Using Stesolid[®]

Storage

Stesolid[®] rectal tubes must be stored in a cool dry place away from light where the temperature stays below 25°C.

Do not store it in the bathroom, near a sink or in a car on hot days.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

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

Disposal

If your doctor or pharmacist tells you to stop using Stesolid[®] or it has passed its expiry date, ask your pharmacist what to do with any that is left over.

Further Information

If you have any further questions about Stesolid[®] rectal tubes please consult your doctor or pharmacist.

Product Description

What it looks like

Stesolid[®] rectal tubes contain a clear, colourless to yellowish liquid in a yellow polyethylene tube. A single tube is packed into an aluminum bag.

Stesolid[®] is available in boxes of 5 x 5mg/2.5ml rectal tubes and 5 x 10mg/2.5ml rectal tubes.

Ingredients

Stesolid® rectal tubes contain diazepam (5mg or 10mg), benzoic acid, ethanol, propylene glycol, sodium benzoate, benzyl alcohol and purified water.

Sponsor

Stesolid® is supplied in New Zealand by:

Teva Pharma (New Zealand) Limited
PO Box 128 244
Remuera
Auckland 1541
Telephone: 0800 800 097

Date of Preparation

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