

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. There may be an increased risk of miscarriage from benzodiazepine exposure during pregnancy.

- you suffer from anxiety or depression
- you have a history of drug or alcohol abuse
- you have epilepsy or have experienced seizures
- you take medicines for any other conditions.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop. Some medicines may interfere with Diazepam and affect how it works, and some medicines may be affected by Diazepam. These medicines include:

- other sleeping tablets, sedatives or tranquillisers
- medicines to treat depression or mental illness
- medicines to treat epilepsy (fits and convulsions), such as carbamazepine, phenobarbital, phenytoin
- pain relievers
- muscle relaxants
- cimetidine and omeprazole- medicines used to treat ulcers
- disulfiram - a medicine used in alcohol abuse
- some medicines to treat Parkinson's disease e.g. levodopa
- some treatments for tuberculosis, such as isoniazid

- theophylline, a medicine used to treat chronic obstructive pulmonary disease and asthma
- certain medicines used to treat fungal infections such as fluconazole, itraconazole, ketoconazole
- antiviral agents used to treat HIV
- certain oral contraceptives

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Stesolid®

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: mood changes, extreme 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), sleep disturbances, restlessness, severe confusion and fits.

If you have epilepsy or have a history of seizures, sudden discontinuation of treatment with diazepam can result in convulsions or prolonged seizures.

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 immediately or go to Accident and Emergency at your nearest hospital.

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

Check with your doctor if you are pregnant or intend to become pregnant. If there is a need to use Stesolid when you are pregnant your doctor will discuss the risks and benefits to you and the unborn baby. There may be an increased risk of miscarriage from benzodiazepine exposure during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed. Diazepam may pass into the breast milk and cause drowsiness and/or feeding difficulties in the baby. Stesolid is not recommended for use while breastfeeding.

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.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>Neurological or brain-related:</p> <ul style="list-style-type: none">• drowsiness, tiredness• dizziness, unsteadiness• loss of memory, inattentiveness, confusion, lack of concentration• uncoordinated movement• headache, hangover feeling in the morning• slurred speech• unpleasant dreams• blurry or distorted vision• changes in sex drive <p>Skin related:</p> <ul style="list-style-type: none">• itching or skin rash <p>Gastrointestinal related:</p> <ul style="list-style-type: none">• stomach upset	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Immune system disorders</p> <ul style="list-style-type: none">• swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing <p>Neurological or brain-related:</p> <ul style="list-style-type: none">• sudden anxiety or excitement• restlessness, agitation, irritability, anger, abnormal behaviour• severe confusion, drowsiness, loss of reflexes or muscle weakness• hallucinations or delusions• severe sleep disturbances• thoughts of harming yourself or thoughts of suicide <p>Liver or gall bladder related</p> <ul style="list-style-type: none">• yellowing of the skin and eyes <p>Renal and urinary disorders</p> <ul style="list-style-type: none">• difficulty urinating <p>Respiratory or breathing-related:</p> <ul style="list-style-type: none">• Difficulties in breathing or choking or coughing	<p>Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

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.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to <https://pophealth.my.site.com/carmreportnz/s/>. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

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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