

PACKAGE LEAFLET: INFORMATION FOR THE USER

DiazepamRecTubes® 2.5mg Rectal Solution

DiazepamRecTubes® 5mg Rectal Solution

DiazepamRecTubes® 10mg Rectal Solution

(referred to as Diazepam RecTubes® in this leaflet)

Read all of this leaflet carefully before you start to take this medicine.

- Keep this leaflet. You may need to read it again while administering the treatment.
- If you have any further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Diazepam RecTubes® are and what they are used for
2. Before using Diazepam RecTubes®
3. How to use Diazepam RecTubes®
4. Possible side effects
5. How to store Diazepam Rec Tubes®
6. Further information

1. What Diazepam RecTubes® are and what they are used for

The name of your medicine is Diazepam RecTubes®. The active ingredient is diazepam. Diazepam belongs to a group of medicines known as benzodiazepines, which are used as sedatives and anticonvulsants (to control fits) or to relax tense muscles.

DiazepamRecTubes® are used in adults and children above one year:

- to treat severe anxiety or agitation
- to treat epileptic and feverish convulsions (fits)
- to relieve muscle spasm
- before minor surgical or dental procedures
- in circumstances where a rapid effect is required and where injection may be impracticable or undesirable.

2. Before using DiazepamRecTubes®

You should not be given Diazepam RecTubes® if you:

- are allergic (hypersensitive) to diazepam or any of the other ingredients in Diazepam RecTubes® (see section 6, Further information)
- suffer from sleep apnoea (stopping breathing during sleep)
- suffer from severe breathing difficulties
- have severe liver problems
- suffer from any fears (phobias) or obsessions
- suffer from depression, with or without anxiety
- are suffering and being treated for any long standing mental illness
- have experienced recent loss or bereavement
- have a head injury

Diazepam RecTubes® should not be given to patients who are in a coma, or used to treat anxiety in children without careful prior assessment.

If you are elderly or severely unwell speak to your doctor first before using Diazepam RecTubes®. If you are elderly, long term use of this medicine may increase your risk of developing dementia.

Talk to your doctor or pharmacist before using Diazepam RecTubes® if you:

- suffer from any kidney or liver disease
- suffer from severe muscle weakness (myasthenia gravis)
- suffer from epilepsy
- suffer from a rare blood disorder (porphyria)
- have difficulty with breathing
- suffer from poor blood supply to the brain or any brain damage
- suffer from any kind of personality disorder
- have suicidal tendencies
- are prone to aggressive outbursts harming either yourself or others
- have had problems with addiction to drugs or alcohol
- currently smoke or drink alcohol.
- If you have a low level of protein in the blood (hypoalbuminaemia)

Taking other medicines

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

The following medicines can affect or can be affected by Diazepam Rec Tubes®:

- medicines used to reduce pain (e.g. codeine)
- medicines used before surgery (general anaesthetics)
- medicines used to treat depression (e.g. fluvoxamine, fluoxetine and mirtazapine)
- medicines used to treat mental illness (e.g. clozapine, zotepine)
- medicines used to treat bacterial infection (e.g. isoniazid, rifampicin)
- medicines used to treat hayfever or other allergic conditions
- medicines used to treat high blood pressure (alpha blockers e.g. moxonidine, beta-blockers, ACE inhibitors, calcium channel blockers, vasodilators e.g. hydralazine)
- medicines used to treat viral infections (e.g. amprenavir, saquinavir and ritonavir)
- medicines used to treat anxiety or insomnia (e.g. other drugs of benzodiazepine group)
- medicines used for asthma and bronchitis (e.g. theophylline, aminophylline)
- medicines used to treat heart failure (e.g. digoxin)
- medicines used to treat alcohol dependence (e.g. disulfiram)
- medicines used to treat heroin withdrawal (e.g. lofexidine)
- medicines used to treat vomiting due to cancer therapy (e.g. nabilone)
- medicines used to treat parkinsons disease (e.g. levodopa)
- medicines used to relax the muscles (e.g. baclofen, tizanidine)
- medicines used to treat stomach ulcers (e.g. cimetidine, omeprazole and esomeprazole)
- oral contraceptives ("The Pill")
- medicines used to treat epilepsy (e.g. phenytoin, phenobarbital and carbamazepine).

- medicines used to remove water from the body (diuretics)
- medicines used in the treatment of angina (nitrates)
- medicines used to prevent episodes of sudden onset of sleep (narcolepsy) with muscle weakness (sodium oxybate)

You should avoid smoking whilst taking this medicine.

Some of the ingredients of coffee (caffeine) will affect the way Diazepam RecTubes® work.

Pregnancy and breast-feeding

You should not take this medicine if you are pregnant or breast-feeding unless your doctor specifically recommends you to.

If you are using this medicine and planning to get pregnant or think you are pregnant speak to your doctor immediately.

Driving and using machinery

Diazepam RecTubes® may affect your muscles or make you feel sleepy or forgetful (especially if you don't have enough sleep). If you are affected in this way, do not drive or use any tools or machinery.

Important information regarding some of the ingredients in Diazepam RecTubes®

Diazepam RecTubes® contains Benzoic acid and sodium benzoate which may cause mild irritation to the skin, eyes and mucous membrane.

The propylene glycol may cause skin irritation.

Diazepam RecTubes® contains alcohol and diazepam, so you should not drink alcohol as sedation may be enhanced or you may experience slowed breathing or heart rate.

3. How to use Diazepam RecTubes®

This medicine is for rectal use only.

The tubes are for single use only.

Always use Diazepam RecTubes® as your doctor has told you. Your doctor will decide the right dose for you according to your weight, age and state of health. The dose will be on the pharmacist's label.

This medicine is not to be used in children under one year old.

Children above 1 year old:

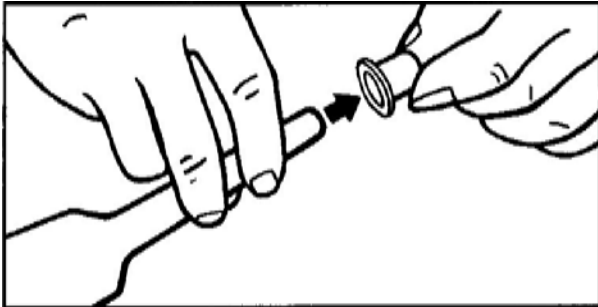
the usual dose is 0.5mg/kg.

Adults:

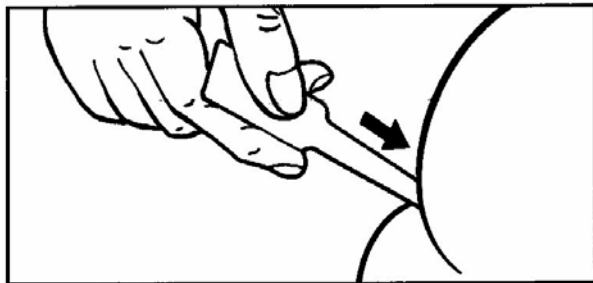
- the usual dose is 0.5mg/kg body weight
- if Diazepam RecTubes® are being prescribed for anxiety, your doctor will normally recommend that you do not use them for more than 8-12 weeks, including a period during which the dose will be reduced gradually.

Step by Step instruction on how to administer the Diazepam RecTubes®:

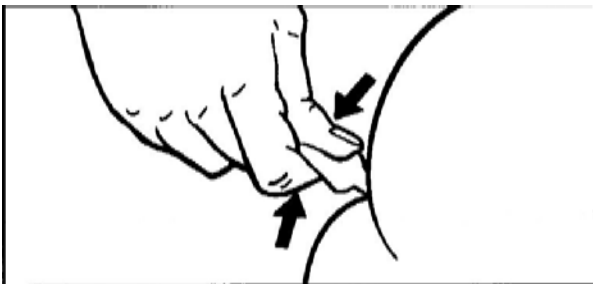
1. If possible turn adults to lie on their side, or front for a child.
2. Tear open the foil pack
3. Remove the tube cap



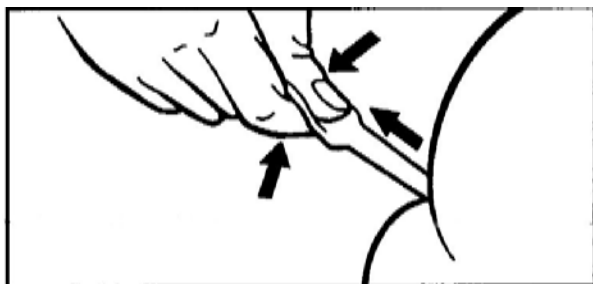
4. Insert the nozzle completely into the rectum, pointing it downwards
- NOTE: In children under 15kgs (33 lbs) insert the nozzle only halfway



5. Empty the tube by pressing firmly between the thumb and index finger



6. Keep the tube completely pressed together until you have withdrawn it out of the rectum.
- Note: A small amount of the solution is intended to be left in the tube after the dose is given.
7. Maintain the patient's position and hold the buttocks together for a few minutes to prevent seepage



If you accidentally insert too much of the medicine

If you (or anybody else, including a child) has accidentally had an overdose of this medicine, then you should contact your nearest hospital casualty department or your doctor immediately. Always take the container and this leaflet with you.

The symptoms of mild overdose may include confusion, loss of consciousness with a sleep-like state, abnormally slow breathing, slurred speech, difficulty in controlling movements, loss of muscle co-ordination, difficulty in breathing, low blood pressure and muscular weakness.

The symptoms of severe overdose include deep coma and severe depression of breathing.

Stopping Diazepam Treatment

If Diazepam RecTubes® are given continuously for too long, there is a risk of becoming dependent on diazepam or developing withdrawal symptoms when stopped or “rebound phenomenon” whereby the problem for which you were being treated recurs. Withdrawal symptoms include: anxiety, depression, insomnia, headache, dizziness, tinnitus, loss of appetite, tremor, stomach cramps, muscle aches and cramps, nausea vomiting and sweating. Rare and more serious symptoms include muscle twitching, confusion, convulsions, hallucinations and delirium. **You should not stop the treatment suddenly** and it is recommended that the dose is decreased gradually.

4. Possible side effects

Like all medicines, Diazepam RecTubes® can cause side effects in some patients, especially the elderly, although not everybody gets them. As can happen with any medicine, a few people may develop an allergic reaction. If you experience any of the following, tell your doctor immediately:

- Rash, itching, swelling of the face and eyes, difficulty breathing.
- If you feel restless, have nightmares, convulsions or notice behavioural changes after applying Diazepam.
- Blood disorders (you may develop a sore throat, nose bleeds or infections).
- Chest pain, slow pulse, slow heart rate, stopping breathing during sleeping, yellow skin (jaundice).

Rarely instead of feeling sleepy, opposing effects may be seen in some patients especially in children or elderly which include aggressive behaviour, irritability, overexcitement, increased anxiety, feeling “high” and difficulty sleeping.

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

- drowsiness (feeling sleepy)
- vertigo
- muscle weakness
- slurred speech
- low blood pressure
- changes to blood cells
- trembling hands
- problems with vision

- hallucinations (seeing or hearing things that are not there)
- dry mouth or increased production of saliva
- changes in sexual desire
- inhibition of female orgasm
- production of breast milk in females
- fatigue or tiredness
- enlargement of breasts in males
- erectile dysfunction
- headache with hangover effect
- forgetfulness
- difficulty in controlling movements
- restlessness and agitation
- sleep problems (nightmares)
- loss of coordination or reduced alertness
- confusion
- increased liver enzymes, jaundice
- loss of memory with inappropriate behaviour
- stomach or bowel upset
- problems in passing urine
- inability to control flow of urine (incontinence)
- hypothermia
- difficulty in breathing
- pain or burning at the site of application (rectum)
- skin rash or other allergic symptoms such as Stephen-Johnson Syndrome

Withdrawal symptoms often include anxiety, depression, loss of concentration, sleeplessness, headache, dizziness, ringing noise in the ears, loss of appetite, trembling hands, perspiration, irritability, nausea, vomiting, abdominal cramps, abnormal heart rate.

As can happen with any medicine, a few people may develop an allergic reaction. A severe form of allergic reaction (anaphylactic shock) is extremely rare but should be treated immediately.

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.

By reporting side effects you can help provide more information on the safety of this medicine. FREEPOST, Pharmacovigilance Section, Irish Medicines Board, Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2, Ireland Tel: 353 1 6764971, Fax +353 1 6762517, Website: www.imb.ie, email: imbpharmacovigilance@imb.ie.

5. How to store Diazepam RecTubes®

Keep out of the reach and sight of children.

Diazepam RecTubes® should be stored at room temperature (below 25°C). Store in the original container to protect from light; do not transfer to another container. Once foil is opened use immediately.

Do not use Diazepam RecTubes® after the expiry date which is stated on the tube and the carton. The expiry date refers to the last day of that month.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. Further information

What Diazepam RecTubes® contains:

The active ingredient is: diazepam

The other ingredients are: benzoic acid (E210), benzyl alcohol, sodium benzoate (E211), ethanol, propylene glycol and purified water.

What Diazepam RecTubes look like and the contents of the pack

The pack consists of 2 or 5 white polythene rectal tubes wrapped individually in alufoil packs and placed in an outer carton. The tubes have a nozzle attached for application. The rectal solution is a clear, colourless or almost yellow solution.

Diazepam RecTubes® are available in the following strengths:

Diazepam RecTubes 2.5mg in 1.25ml (2mg/ml)

Diazepam RecTubes 5mg in 2.5ml (2mg/ml)

Diazepam RecTubes 10mg in 2.5ml (4mg/ml)

Marketing Authorisation Holder: Wockhardt UK Ltd, Ash Road North, Wrexham, LL13 9UF, UK.

Manufacturer: CP Pharmaceuticals Ltd, Ash Road North, Wrexham LL13 9UF, UK.

Other formats: To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK Only). Please be ready to give the following information:

Product name	Reference number
Diazepam RecTubes 2.5mg in 1.25ml Rectal Solution	29831/0067
Diazepam RecTubes 5mg in 2.5ml Rectal Solution	29831/0068
Diazepam RecTubes 10mg in 2.5ml Rectal Solution	29831/0066

This is a service provided by the Royal National Institute of Blind People.

Leaflet Prepared: January 2014

Common questions and answers

1. How long does it take to work?

Usually it works within 10 minutes.

2. What if I give it and there's no change?

Your doctor would have told you what to do in these circumstances. If you are in doubt talk to your doctor.

3. What if I can't turn the patient on his/her side?

Under these circumstances it may be more difficult to administer Diazepam RecTubes®. If you think this may be a problem we recommend that you consult the doctor.

4. Do I need to lubricate the tube?

No, the plastic is very smooth and designed to be used without lubrication.

5. Can I give less than the whole tube to see what happens?

The whole dose should be given as prescribed.

6. Why do I have to maintain pressure on the tube?

To avoid the solution being sucked back into the tube as it is being withdrawn.

7. What if the solution leaks out of the patient's bottom?

If you hold the patient's buttocks together for a few minutes keeping the patient in the same position, this should not happen.

8. What if I find there is some solution left in the tube afterwards?

Perhaps you forgot to keep the tube compressed as you withdrew it. A small amount of solution is intended to be left in the tube after the dose has been given. If you are worried about how much you have been given, we recommend that you consult the doctor.

9. Will I hurt the patient?

No, using Diazepam RecTubes® should not hurt the patient.

10. How important is it to point the tube downwards?

Emptying the tube is easiest when pointing downwards. It is possible to empty it at other angles but this is usually more difficult.

11. Why do I have to keep the tube in the foil?

Diazepam RecTubes® have a shelf life of 36 months in the foil bag.

12. Do I need to keep Diazepam RecTubes® in the fridge?

No, they can be stored at room temperature (but not above 25°C).