DIAZEPAM RECTUBES®
DIAZEPAM RECTAL SOLUTION

PATIENT INFORMATION LEAFLET

INFORMATION FOR PATIENTS

If you are the patient, parent or carer, please read this leaflet carefully before you have to use this medicine. It gives a brief outline of the more important things you should know. If you want to know more about this medicine, or you are not sure about anything, ask your doctor or pharmacist.

THE NAME OF YOUR MEDICINE IS DIAZEPAM RECTUBES®

The active ingredient in Diazepam RecTubes® is diazepam. The tubes are available in four strengths: 2.5mg, 5mg, 10mg and 20mg. Other ingredients include: benzoic acid, benzyl alcohol, sodium benzoate, ethanol, propylene glycol and purified water.

The presentation consists of a white polythene rectal tube in alufoil wrap in a printed outer carton of 2 or 5 tubes.

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.

Marketing Authorisation Holder: Wockhardt UK Limited, Ash Road North, Wrexham, LL13 9UF, UK.
Manufacturer: CP Pharmaceuticals Limited, Ash Road North, Wrexham, LL13 9UF, UK.

HOW DOES YOUR MEDICINE WORK?

Diazepam belongs to a group of medicines known as benzodiazepines, which are used as sedatives and anticonvulsants (to control fits), or to relax muscles.

WHAT IS DIAZEPAM FOR?

Diazepam can be used for severe anxiety or agitation, for the control of epileptic or feverish convulsions (fits), for sedation before minor surgical or dental procedures and to relieve muscle spasm. Diazepam RecTubes® are for use in adults and children over the age of one year.

BEFORE ADMINISTERING THE MEDICINE

Diazepam should not be given to you if:
• you are pregnant or breast feeding (unless your doctor decides it is essential). Tell your doctor straight away if you think you may be pregnant or intend to start a pregnancy.
• you are allergic to diazepam, or any other benzodiazepines or any of the ingredients. Check by reading the list of ingredients above.
• you are suffering from phobias (fears) or obsessions
• you are suffering from depression, with or without anxiety, or other long-standing mental illness, for which you are not being treated.
• you are suffering from severe breathing difficulties
• you have experienced recent loss or bereavement
• you have serious liver problems
• you suffer from sleep apnoea syndrome (stopping breathing during sleep)

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

ADVICE WHEN DIAZEPAM RECTUBES® ARE ADMINISTERED
Special care will be necessary if you

- are elderly or run down
- have kidney or liver problems, myasthenia gravis (very weak muscles), difficulty with breathing, poor blood supply to the brain or any brain damage, or porphyria (a rare blood disorder)
- have a personality disorder, suicidal tendencies, are prone to aggressive outbursts or self-harm
- have had problems with addiction to drugs or alcohol or if you currently smoke or drink alcohol

If you are using Diazepam Rec Tubes® on a daily basis, early checks should be made to ensure that the dose is not too high.

If you are supposed to control the amount of sodium in your diet you should be aware that this medicine contains sodium and that the amount of sodium in each dose is 0.42mmol for Rec Tubes 2.5mg, 0.85mmol for Rec Tubes 5mg and 10mg and 1.7mmol for Rec Tubes 20mg.

Your memory may be affected a few hours after inserting Diazepam Rec Tubes®, so ideally you need to be able to have a period of 7-8 hours uninterrupted sleep after use of this medicine.

If given continuously for too long, there is a risk of becoming dependent on diazepam or having problems with withdrawal symptoms when you stop. The dose should be reduced gradually to reduce the risk of withdrawal symptoms, or "rebound symptoms" whereby the problem for which you were being given diazepam recurs.

Smoking can affect how diazepam works.

Taking another medicine whilst you are taking Diazepam Rec Tubes® can affect how it or the other medicine works. Make sure that your doctor knows what other medicines you are taking. This includes medicines you may have bought yourself.

Examples of medicines that can affect Diazepam Rec Tubes® are:

- Drugs used for mental illness (e.g. zotepine and clozapine), anxiety (other benzodiazepines) or depression (e.g. fluvoxamine)
- Some painkillers, such as codeine.
- Sleeping tablets.
- Anaesthetics
- Erythromycin, used to treat infections.
- Baclofen and tizanidine, used to relax the muscles.
- Drugs used for epilepsy such as phenytoin, carbamazepine and sodium valproate.
- Isoniazid and rifampicin, used in the treatment of tuberculosis
- Ritonavir and amprenavir, used to treat virus infections.
- Disulfiram, a drug used for alcohol dependence.
- Cimetidine or omeprazole, drugs used to treat stomach ulcers.
- Oral contraceptives.
- Levodopa, a drug used in the treatment of Parkinson’s disease.
- Theophylline, a drug used for asthma and bronchitis.
- Some antihistamines (used for hayfever and other allergic conditions)
- Lofexidine, used to treat heroin withdrawal
- Nabilone, used to treat vomiting due to cancer therapy
- Antihypertensives, used to lower blood pressure, such as moxonidine and doxazosin
- Digoxin, used in heart failure

This product contains more than 10% alcohol as well as diazepam so sedation may be enhanced. You should not drink alcohol while using Diazepam Rec Tubes®. Diazepam also affects concentration and muscle function, so you should not drive or operate machinery while you are being treated with Diazepam Rec Tubes®.
If you have any doubts about whether you should use these rectal tubes then discuss things more fully with your doctor BEFORE using them.

ADMINISTERING THIS MEDICINE

These tubes are for rectal use only. The usual dose is 0.5mg/kg body weight but the dose will vary according to the patient’s weight, age and state of health. They should not be used for children under one year old.

Your doctor will decide the dose, which is best for you. Your doctor’s instructions must be followed completely and any special instructions or warnings, which appear on the label which the pharmacist, has put on the package. If you do not understand, or are in any doubt, ask your doctor or pharmacist.

If used continuously for too long, there is a risk of becoming dependent on diazepam or of having problems when stopping it (withdrawal symptoms). 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 tapering off period during which the dose will be reduced gradually.

When the medicine is withdrawn, especially if it is stopped suddenly, the following symptoms may occur: headache, muscle pain, extreme anxiety, tension, restlessness, depression, confusion and irritability. Sometimes, anxiety symptoms return after the medicine is stopped, or you could have problems with mood changes or difficulty sleeping.

If too much diazepam is accidentally inserted you should contact your doctor or nearest Casualty Department immediately.

AFTER ADMINISTERING THIS MEDICINE

Like many medicines diazepam RecTubes® may cause side effects in some patients, particularly when you start using them. The side-effects that some other patients have had with diazepam are sedation, drowsiness, headaches, muscle weakness, dizziness (with risk of falls in the elderly), unsteadiness, confusion, slurred speech, trembling hands, numbed emotions, reduced alertness, tiredness, forgetfulness and a hangover effect. Elderly or run down patients are more likely to have side effects and may need lower doses.

Other effects which may occur rarely are dry mouth, stomach or bowel upsets, problems with your vision, changes in the liver, jaundice (yellow skin), problems passing water, incontinence, low blood pressure, slow pulse, changes in sexual desire, skin rashes and other allergic reactions (with swelling of the face and eyes and difficulty breathing in severe cases), blood problems, chest pain and breathing problems. Diazepam may uncover depression in susceptible individuals.

Rarely, instead of feeling sleepy, some patients, particularly if they are children or elderly, may become irritable, aggressive, overexcited, “high”, uninhibited, overanxious or have difficulty sleeping. If this happens, tell your doctor so that the medicine can be discontinued under his/her direction.

The benzoic acid in Rectubes may cause stinging.

If any of these side effects are troublesome or if you experience any side effects other than the ones mentioned here, tell your doctor or pharmacist.

There may be a slight increase in abnormalities, particularly hare lip, in babies born to mothers given benzodiazepines during the first three months of pregnancy. Babies exposed to benzodiazepines during pregnancy may be slow developers. If a mother has received diazepam towards the end of pregnancy or during labour, the baby may be affected, with feeling cold, floppiness, difficulty breathing and suckling, or withdrawal symptoms.

SAFE KEEPING FOR YOUR MEDICINE
Do not use the tubes if the expiry date on the tube has passed or if they show signs of deterioration. These tubes should be kept at room temperature (but not above 25°C) in the package or container in which they were given to you. Do not transfer them to another container.

KEEP THEM IN A SECURE PLACE OUT OF THE REACH AND SIGHT OF CHILDREN

REMEMBER, this medicine is for YOU only. NEVER give it to anyone else. It may harm them, even if their symptoms are the same as yours. Unless your doctor tells you to, do not keep the tubes that you no longer need. Give them back to the pharmacist.
INFORMATION FOR YOUR CARER
HOW TO ADMINISTER THE MEDICINE

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 Rec Tubes®. If you think this may be a problem we recommend 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 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. Once the foil is opened, the shelf life is reduced to 6 months.

12. Do I need to keep Diazepam RecTubes® in the fridge?
    - No - they can be stored at room temperature (but not above 25°C).