Diazepam Desitin® Rectal Solution Abbreviated Prescribing Information.

Prescribers should consult the Summary of Product Characteristics before prescribing Diazepam Desitin® Rectal Solution. Diazepam available as Diazepam Desitin Rectal Solution 5 and 10 mg in 2.5 ml solution. Indications: For use when rapid effect is required in the following conditions but i.v injection impracticable or undesirable: epileptic and febrile convulsions (may be of particular value in children); muscle spasm caused by tetanus; sedative in minor and dental surgery; initial use in anxiety and agitation when severe, disabling or causing extreme distress. **Dosage and administration:** For rectal administration only. Usual dose is 0.25–0.5 mg/kg depending on age, weight and response. Obtain dose by rounding upward to next available dose. Adults: two 10 mg tubes. Children: Under 10 kg (under 1 year): not recommended; 10-15 kg (1-3 years): one 5 mg tube, insert tube half way to mark on nozzle; > 15 kg (over 3 years): one 10 mg tube. Elderly and debilitated: no more than half usual adult dose. Renal/hepatic impairment: dosage reduction may be required. If no effect is seen after 10 minutes, repeat dose in children or give an additional 10 mg tube to adults. The dose can be repeated every 12 hours. In case of initially higher doses or repeated administration, monitor respiration. If convulsions still not controlled institute other anticonvulsive measures. Treatment should be as short as possible. Use lowest dose that can control symptoms. Reassess patient regularly and evaluate the need for continued treatment. Tubes for single use only. **Contraindications:** Hypersensitivity to benzodiazepines or any of the excipients. Myasthenia gravis. Severe respiratory insufficiency. Sleep apnoea syndrome. Severe hepatic insufficiency. Contains benzyl alcohol: do not use in premature babies. **Special warnings and precautions for use:** Use with caution in renal/hepatic dysfunction, chronic pulmonary insufficiency, closed angle glaucoma or organic brain changes, particularly arteriosclerosis. May enhance effects of CNS depressants, avoid concurrent use. May be associated with anterograde amnesia, should not be used in cases of loss or bereavement. Not recommended for primary treatment of psychotic illness. Do not use in phobic or obsessional states, or in the treatment of depression or anxiety associated with depression due to risk of suicide being precipitated. Extreme caution in patients with a history of alcohol or drug abuse or in patients with personality disorders. Do not give to children without careful assessment of the need to do so; keep the duration of treatment to a minimum. Reduce dose in elderly and chronic respiratory insufficiency. Do not use in severe hepatic insufficiency. Dependence potential is low when limited to short-term use. Withdrawal symptoms, sometimes severe, may occur following normal use of therapeutic doses for only short periods: consider when treating patients for more than a few days. Rebound insomnia and anxiety may occur on withdrawal and may be accompanied by other reactions including mood changes, anxiety or sleep disturbances and restlessness. Decrease dose gradually as risk of withdrawal/rebound phenomena greater after abrupt discontinuation. Some loss of efficacy to the hypnotic effects may develop after repeated use for a few weeks. Warn against changing to short-acting benzodiazepine, as withdrawal symptoms may develop. Discontinue if psychiatric or paradoxical reactions occur, more likely in children and elderly. Contains more than 10% alcohol. **Interactions:** Enhanced sedation or respiratory and cardiovascular depression may occur if given with other CNS depressants. Narcotic analgesics: enhancement of the euphoria may also occur leading to an increase in psychic dependence. Cimetidine and omeprazole reduce clearance of benzodiazepines and potentiate their action. Hepatic enzyme inducers e.g. rifampicin may increase clearance of benzodiazepines. Sedative effect may be enhanced with alcohol. This affects the ability to drive or use machines. Concomitant intake with alcohol not recommended. Diazepam metabolism is accelerated by theophylline and smoking. May interact with other hepatically metabolised drugs, causing inhibition (levodopa) or potentiation (phenytoin, muscle relaxants). **Pregnancy and lactation:** Should not be used in pregnancy especially in the first and third trimesters, unless benefit outweighs risk. Women of childbearing potential should be warned to contact their physician if they intend or suspect that they are pregnant. Risk of physical dependence and development of withdrawal symptoms in infants born to mothers who took benzodiazepines chronically during latter stages of pregnancy. Use during lactation should be avoided as diazepam is excreted in breast milk. Benzyl alcohol in Diazepam Desitin may cross the placenta; consider possible toxicity for premature babies after administration before or during labour. **Effects on ability to drive or use machines**: Patients should not drive or operate machines for at least 24 hours after last dose. **Undesirable effects:** Elderly or debilitated patients are particularly susceptible to side effects and may require lower doses. Common side effects: double vision, muscle weakness, reduced alertness, numbed emotions, confusion, anterograde amnesia, paradoxical reactions (more likely in children and elderly), sedation, drowsiness, headaches, dizziness (risk of falls in elderly), ataxia, slurred speech, tremor, fatigue, hangover effect. In susceptible patients an unnoticed depression may become evident. Physical dependence can develop even at therapeutic doses (see warnings and precautions). Psychic dependence may occur. Abuse of benzodiazepines has been reported. **Pack sizes and NHS price:** Packs of 5, 5 mg rectal solution £5.85 [PL14040/0001]; Packs of 5, 10 mg rectal solution £7.35 [PL14040/0002]. **Legal category:** POM. **Marketing Authorisation Holder:** Desitin Arzneimittel GMBH, Wegbeim Jäger 214, 22335 Hamburg, Germany. **Prepared in**: Jan 2017. For further information on Diazepam Desitin® please contact Medical Information on MedInfo@desitin.co.uk.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Desitin Pharma Limited on MedInfo@desitin.co.uk.