

Supply Disruption Alert

SDA/2021/013

Issued: 11/10/2021

Diazepam RecTubes® 2.5mg Rectal Solution

Summary

- Diazepam RecTubes® 2.5mg have been discontinued in the UK.
- Remaining supplies are expected to be exhausted by March 2022.
- Diazepam RecTubes® are licensed in acute severe anxiety and agitation, epileptic and febrile convulsions, tetanus and as a sedative in minor surgical and dental procedures or in other circumstances where rapid effect is required and where intravenous injection is not appropriate.
- Diazepam RecTubes® 2.5mg are mainly used in the management of status epilepticus and convulsions in neonates (off-label) to deliver doses of 1.25mg- 2.5mg doses and repeated if required.
- Clinicians across healthcare settings should review all patients prescribed Diazepam RecTubes® 2.5mg and relevant local guidelines/ protocols which recommend the use of Diazepam RecTubes® 2.5mg to consider alternative preparations where appropriate.
- Diazepam 5mg/ 2.5mL rectal solution remain available and can support an uplift in demand.
- Alternative parenteral and non-parenteral preparations remain available.

Action

All healthcare professionals in primary and secondary care including Ambulance Services should be aware of the following advice and should:

- not initiate new patients on Diazepam RecTubes® 2.5mg; and
- update patient's epilepsy passport/ child's emergency care plans **immediately** if any changes to treatment are required (see supporting information below).

Primary care:

Prescribers should identify all patients prescribed Diazepam RecTubes 2.5mg® and;

- review on-going need for a rapidly acting benzodiazepine, taking into consideration the patients age and medical history; and
- where on-going treatment is required, make early contact with specialists in secondary care for advice on management options/ referral if required; or
- prescribe an alternative preparation;
- ensure additional counselling is provided to confirm parents/carers are confident in administering the new prescribed regime;
- ensure patients have sufficient supplies of their medicine in the event urgent administration is required;
- review patients to ensure the switch has been successful in managing symptoms.

GP Practices who keep Diazepam RecTubes® 2.5mg for emergency administration should:

- review local practice for emergency treatment of seizures and select an appropriate alternative preparation, ensuring any associated guidelines, local protocols etc are updated to reflect the change ([see CQC guidance for further information](#));
- provide appropriate education and training to staff on administration of alternative preparations in an emergency.

Secondary care:

Pharmacy teams, specialist clinicians and Medication Safety Officers should:

- ensure local guidance and formularies are reviewed and amended to replace Diazepam RecTubes® 2.5mg with an alternative preparation and provide appropriate education and training to staff where required; and
- ensure patients currently prescribed Diazepam RecTubes® 2.5mg (including those referred from primary care) are reviewed in a timely manner and prescribed an alternative preparation with individualised management plans agreed, enacted, and communicated to the patients GP; and
- parents/carers are counselled appropriately on the new treatment regimen including when to access emergency assistance where required.

Ambulance Services:

Ambulance services who administer Diazepam 2.5mg RecTubes® in an emergency setting, should:

- pro-actively review and amend local guidelines where Diazepam RecTubes® 2.5mg are indicated and update protocols to administer an alternative preparation, taking into account factors such regulatory exemptions and legal frameworks; and
- provide appropriate education and training to ambulance service staff on administration of alternative preparations.

Product details

Diazepam RecTubes® 2.5mg Rectal Solution (Wockhardt UK Ltd)

Background

Wockhardt UK Ltd, have discontinued Diazepam RecTubes® 2.5mg Rectal Solution due to manufacturing issues with stocks expected to be exhausted by March 2022.

Diazepam RecTubes® 2.5mg are licensed for use in patients aged 1 year and above for the treatment of epileptic and febrile convulsions, acute severe anxiety and agitation, tetanus and as a sedative in minor surgical and dental procedures or other circumstances where a rapid effect is required but where intravenous injection is not appropriate.

Diazepam RecTubes® 2.5mg are used off-label in children under 1 year old.

Alternate preparations for consideration for use in neonates

Alternate non-parenteral preparations which can be considered are:

- Midazolam (2.5mg/ 0.5mL, 5mg/ 1mL, 7.5mg/ 1.5mL, and 10mg/ 1mL, 10mg/2mL) oromucosal solution pre-filled syringes- licensed for the treatment of prolonged, acute, convulsive seizures in infants, toddlers, children and adolescents (from 3 months to < 18 years). It is used off label in

younger children, including neonates. Please refer to [BNFC](#) or local guidelines for dosing information in this younger age group.

- Diazepam 5mg/ 2.5mL RecTubes® - If the above option is not considered appropriate, clinicians can consider a part dose to be extracted via a syringe or rectal straw (off-label). *Clinicians should refer to local guidance for consideration.*

Refer to local and/or [NICE guidance](#) for consideration of parenteral therapy should the above options not be considered appropriate.

Supporting Information

Clinical resources and SmPC's:

NICE Guidance;

- [NICE Guidance: Protocols for treating convulsive status epilepticus in adults and children.](#)

SmPC's:

- [SmPC Diazepam RecTubes 2.5mg rectal Solution](#)
- [SmPC Diazepam 5mg & 10mg Rectal Solution](#)
- [SmPC Midazolam oromucosal pre-filled syringe \(various strengths\)](#)

Misc. support resources;

- [Royal College of Paediatrics and Child Health: Epilepsy Passport overview](#)
- [National Ambulance Patient Group Directions](#)

Distribution

If you are responsible for cascading these alerts in your organisation, these are our suggested distribution lists.

Trusts (NHS boards in Scotland)

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- A&E consultants
- A&E departments
- A&E directors
- A&E nurses
- All departments
- All staff
- All wards
- Ambulance services directors
- Ambulance staff
- Anaesthesia, directors of
- Anaesthetic medical staff
- Anaesthetic nursing staff
- Anaesthetists
- Chief pharmacists
- Clinical governance leads
- Clinical Procurement Specialists

- Community children's nurses
- Community dental practices
- Community hospitals
- Community midwives
- Community nurses
- Day surgery units
- Dental departments
- Dental nurses
- Dentists
- District nurses
- Emergency Preparedness and Response officer
- General surgeons
- General surgery
- General surgical units, directors of
- Health and safety managers
- Health visitors
- Hospital pharmacies
- Hospital pharmacists
- Intensive care medical staff/paediatrics
- Intensive care nursing staff (adult)
- Intensive care nursing staff (paediatric)
- Intensive care units
- Intensive care, directors of
- IV nurse specialists
- Maintenance staff
- Minor injury units
- Maternity units
- Maxillofacial departments
- Medical directors
- Midwifery departments
- Midwifery staff
- Neonatal nurse specialists
- Neonatology departments
- Neonatology directors
- Neurology specialists
- NHS walk-in centres
- Nursing executive directors
- Outpatient clinics
- Outpatient theatre managers
- Outpatient theatre nurses
- Paediatric intensive care units
- Paediatric medicine, directors of
- Paediatric nurse specialists
- Paediatric oncologists
- Paediatric surgeons
- Paediatric surgery, directors of
- Paediatric wards
- Paediatricians
- Paediatrics departments
- Palliative care teams
- Paramedics
- Pharmaceutical advisors

- Pharmacists
- Purchasing managers
- Resuscitation officers and trainers
- Risk managers
- School nurses
- Special care baby units
- Supplies managers
- Theatre managers
- Theatre nurses
- Theatres
- Walk-in centres

UK Health Security Agency

Directors for onward distribution to:

- Safety officers

NHS England and NHS Improvement Regional teams

CAS liaison officers for onward distribution to all relevant staff including:

- Community pharmacists
- General dental practitioners

General Practice

For onward distribution to all relevant staff including

- General practitioners
- General practice managers
- General practice nurses

Social services

For onward distribution to all relevant staff including:

- Children's disability services
- Community care staff
- Education departments for equipment held in schools
- Schools with hoists

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)

- Clinics
- Hospices
- Hospitals in the independent sector
- Independent treatment centres
- Nursing agencies
- Private medical practitioners

Establishments registered with OFSTED Children's services

- Educational establishments with beds for children
- Residential special schools

Enquiries

England

Enquiries from NHS Trusts in England should in the first instance be directed to your trust pharmacy team who will escalate issues to the Regional Pharmacy Procurement Specialist and national teams if required.

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All other organisations should send enquiries about this notice to the DHSC Medicine Supply Team, quoting reference number SDA/2021/013

Email: DHSCmedicinesupplyteam@dhsc.gov.uk