

## Green plus information leaflet – paraldehyde 50% in olive oil rectal solution

### Background information

Paraldehyde in olive oil rectal solution is used in the treatment of status epilepticus resistant to treatment with buccal midazolam and rectal diazepam.

Paraldehyde is not licensed for this indication and there is no licensed product available in the UK so it has to be made as a “special” or imported from abroad.

Although it is unlicensed, its use is nationally recognised and included in the Children’s BNF:

<https://bnfc.nice.org.uk/drug/paraldehyde.html>

It is an amber-coloured solution with a strong unpleasant smell.

### Sunderland joint formulary status

Green Plus.

Must be started by a specialist but on-going prescribing can be continued by a GP

### Related NICE guidance

N/A.

### Licensed indication

Unlicensed product and indication.

### Dosage and administration

By rectum: 0.8ml/kg for one dose.

Parents and carers receive full training on the administration of the enema. The following is an outline:

1. Do not give paraldehyde enema if the liquid is brownish in colour or if it has a vinegar-like smell.
2. Put on a pair of gloves
3. Lay your child on their left side
4. Draw up the required dose from the bottle using a syringe
5. Attach the tube to the end of the syringe
6. Insert the tube a few centimetres into the rectum
7. Gently push the plunger on the syringe until the entire dose is given.
8. Remove the tube and hold the buttocks together for a few minutes
9. Throw away the syringe, tube and gloves

Due to the nature of paraldehyde, special handling measures should be followed:

- Paraldehyde can melt plastic, however, if the solution is drawn up and given within 10 minutes, the plastic syringe is unlikely to be affected.
- Gloves must be worn when giving the enema.
- If the solution gets onto the skin or into the eyes wash with cold running water for 5 to 10 minutes.
- The products is flammable, store below 25C and keep away from sources of ignition.

A nationally approved information leaflet can be accessed from the following link:

[https://www.medicinesforchildren.org.uk/sites/default/files/content-type/leaflet/pdf/20140822133207\\_0.pdf](https://www.medicinesforchildren.org.uk/sites/default/files/content-type/leaflet/pdf/20140822133207_0.pdf)

### Contraindications

Hypersensitivity to paraldehyde or olive oil

Lung disease

Colitis

Liver disease

<p><b>Cautions</b></p> <p>Bronchopulmonary disease. Hepatic impairment</p>
<p><b>Drug interactions</b></p> <p>Disulfram</p>
<p><b>Side effects</b></p> <p>Sedation. Irritation and rash around the anus. Breath smelling of paraldehyde after administration.</p>
<p><b>Monitoring</b></p> <p>No specific monitoring is required. If frequent prescription requests please inform the patient's consultant.</p>
<p><b>GP and specialist responsibilities</b></p> <p>The specialist and secondary care team are responsible for ensuring that the carer/parents are fully trained in all aspects of use of the rectal solution and management of the child after administration.</p> <p>Gloves, quill and syringes are provided by the senior specialist nurse at STSFT.</p>
<p><b>Cost</b></p> <p><b>Further information about supply.</b> The product is available as a drug tariff listed special order product – prescribe as, “Paraldehyde 50% in olive oil rectal solution” 10ml. The cost is £106.02 per 10ml pack. It is available from Stepping Hill hospital (Stockport pharmaceutical) who supply to retail pharmacies. The pharmacy will need to go through a verification process prior to ordering therefore there will be a delay in obtaining the first supply.</p>