Medicines & Healthcare products Regulatory Agency

DEVICE SAFETY INFORMATION (DSI)

Rectal catheters sold for personal use (gas and colic relievers): Do not use in infants, including for the treatment of colic, gas-related discomfort or constipation

(DSI/2026/008)

Specialisms: *General Practice, GI, hepatology and pancreatic disorders, Paediatrics and neonatology*

DEVICE DETAILS

Rectal catheters sold for personal use (gas and colic relievers)

AFFECTED LOT SERIAL NUMBERS

All manufacturers and models are affected

MANUFACTURED BY

All manufacturers and models are affected

Summary

Do not use rectal catheters sold for personal use (gas and colic relievers) in infants, including for colic, gas-related discomfort or constipation. Stop using these products immediately and dispose of any unused devices. The MHRA does not recommend their use because there is insufficient clinical evidence to demonstrate effectiveness, and the potential risks associated with these products are unknown.

Please note this advice is not applicable for rectal catheters that are used for specialist medical treatment for conditions such as Hirschsprung's, meconium ileus and gastroschisis where parents/ caregivers have been trained by healthcare professionals.

Rectal catheters sold for personal use (gas and colic relievers) are single use, hollow, plastic tubes with a stopper that are inserted into the infant's rectum (bottom) and are commonly used by parents and caregivers to attempt to provide relief from gas-related discomfort.

If parents or caregivers have any concerns about their baby, they should speak to their healthcare professional.

Advice for Healthcare Professionals:

- advise parents and caregivers not to use rectal catheters sold for personal use (gas and colic relievers) in infants, including to treat colic, gas, bloating, or constipation and dispose of any unused products
- the use of these devices may delay diagnosis of serious gastrointestinal conditions, such as bowel obstruction or volvulus, by temporarily alleviating symptoms like gas without addressing the root cause
- the risks of rectal trauma, perforation, bleeding or pain associated with the use of these devices in infants are unknown
- please refer to the NICE Clinical Knowledge Summary for information on the management of colic in infants
- report any incidents associated with the use of rectal catheters sold for personal use in infants to the MHRA via the Yellow Card Scheme or via local reporting routes. For more detailed reporting instructions please see 'Reporting advice' below.

Advice for Healthcare Professionals to Provide to Patients:

- do not use rectal catheters sold for personal use (gas and colic relievers) in your child, including to treat colic, gas, bloating, or constipation and dispose of any unused products
- the risks of injury to the infant's bottom (rectum), bleeding, pain or perforation (a hole in the bowel) associated with use of these devices in infants are unknown
- please refer to NHS guidance for the management of colic
- if you are concerned about your baby, it's best to speak to your health visitor, call NHS 111, see a GP, or call 999 in an emergency
- if you suspect that your child has had a side effect related to the use of rectal catheters sold for personal use (gas and colic relievers) report it to the MHRA via the Yellow Card website

Advice for Distributors:

- there is no advice for distributors related to this DSI

Explanation of identified safety issue

Rectal catheters sold for personal use (gas and colic relievers)

Rectal catheters sold for personal use (gas and colic relievers) are single use, hollow, plastic tubes with a stopper that are inserted into the infant's rectum and are commonly used by parents and caregivers to attempt to provide relief from gas-related discomfort. These products are available to purchase online and in-store, without a prescription or oversight from a healthcare professional. These are also known to be used by parents and caregivers to provide relief from colic and constipation in infants, although this is not the intended use of these devices.

Concerns with the use of rectal catheters sold for personal use (gas and colic relievers) in infants

An MHRA review was conducted following concerns raised by stakeholders and healthcare professionals about the use in a vulnerable patient population and the potential risks associated with the use of these devices by untrained parents and caregivers. The findings of this review were considered by the UK's independent Interim Devices Working Group (IDWG), who raised concerns about the potential risks associated with the use of these products and the lack of evidence of benefit. There was particular concern regarding these devices being used by non-healthcare professionals, especially to treat gas-related discomfort and colic in infants.

The concerns are outlined below:

- **Potential risk of physical harm:** Evidence is lacking to validate the designs of these devices and their associated instructions for use in preventing rectal trauma, perforation, bleeding, or pain when used by non-healthcare professionals. Consequently, an unacceptable risk of patient harm remains.

- **Potential to mask underlying symptoms:** Use of these devices may delay diagnosis of serious gastrointestinal conditions, such as bowel obstruction or volvulus, by temporarily alleviating symptoms like gas without addressing the root cause.

- **Lack of clinical evidence:** There is insufficient clinical evidence to both demonstrate the efficacy of these devices and to quantify the potential risks associated.

- **Reusability concerns and infection risks:** These devices are marketed as single use, however, there are reports of these devices being incorrectly reused. The reuse of these devices has the potential to introduce infection risks.

The MHRA has received no reports of rectal trauma, perforation, bleeding or pain in infants related to the use of rectal catheters sold for personal use (gas and colic relievers). However, significant residual concerns remain due to the lack of safety and

efficacy data. The MHRA will continue to review relevant evidence as it becomes available to assess the benefit-risk profile of these devices.

Advice for the treatment of gas-related discomfort, constipation and colic in infants

Following the conclusion of the MHRA's review into the current available evidence, rectal catheters sold for personal use (gas and colic relievers) are not recommended for use in infants, including to treat colic, gas-related discomfort and constipation. Parents and caregivers should cease use of all rectal catheters sold for personal use (gas and colic relievers) in infants immediately and dispose of any unused devices.

Please note this advice is not applicable for rectal catheters that are used for specialist medical treatment for conditions such as Hirschsprung's, meconium ileus and gastroschisis where parents/ caregivers have been trained by healthcare professionals.

Healthcare professionals, parents and caregivers should refer to existing information on the treatment of gas-related discomfort, constipation and colic in infants, Table 1 provides direct links.

However, if parents or caregivers are concerned about their baby, it's best to speak to their health visitor, call NHS 111, see a GP, or call 999 in an emergency.

Table 1: Information on the symptoms and management of constipation and colic in infants

Medical issue	**Information for Healthcare professionals**	**Information for Parents/ Caregivers**
Colic	• NICE Clinical Knowledge Summary on the management of colic in infants	• NHS guidance on symptoms and management of colic in infants
Constipation	• NICE Clinical Knowledge Summary on the management of constipation in children (birth to 18 years)	• Best Start in Life – NHS guidance on symptoms and management of constipation in infants

Reporting advice

Healthcare professionals should report incidents:

- in England and Wales to the Yellow Card website or via the Yellow Card app
- in Scotland to Incident Reporting & Investigation Centre (IRIC) and their local incident recording system
- in Northern Ireland to the Yellow Card website in accordance with your organisations medical device policies and procedures.

Additional information:

You can sign up to receive email updates on alerts and device safety information from the MHRA.

You can sign up to receive our monthly roundup of safety communications.

For any enquiries, please contact info@mhra.gov.uk

Stakeholder engagement:

- NHS England National Patient Safety team
- National Institute for Health and Care Excellence (NICE)
- Medical Device and Estates Safety (MDES) for Department of Health N. Ireland
- Incident Reporting & Investigation Centre (IRIC) for Scotland
- Welsh Government