Hydro-Caine Gel
Frequently Asked Questions

1. **What is Hydro-Caine Gel?**

   Hydro-Caine Gel is a Class III Sterile Aqueous Lubricating Gel.

   Hydro-Caine Gel is intended for urethral or suprapubic catheterisation, rectal or colonic procedures and for urethral dilatation and other instrumentation of the urethra

   It provides a protective layer to ensure the smooth passage of a catheter or instrument through narrow parts of the urethra. Hydro-Caine Gel reduces the risk of pain, infection and trauma by providing an effective lubricant with the additional benefits of antiseptics and local anaesthetic. Hydro-Caine Gel is a cost-effective solution produced to the highest quality standard, which helps healthcare professionals to improve patient outcomes.

2. **What classification of approval has Hydro-Caine Gel received in the UK?**

   Hydro-Caine Gel is a Class III Sterile Medical Device, according to MDD/93/42 /EEC Annex IX. Class III Rule 13.

   Hydro-Caine Gel is classified as a drug-device combination because it acts principally by physical means, as a lubricant to catheterisation, but also has an ancillary pharmacological mode of action that helps lower the risk of pain or infection.

   Class III is the most stringent category for medical device and as well as drug-eluting stents other examples of drug-device combinations include heparin coated catheters and bone cements that contain gentamicin.

3. **What is the difference between a medical device and medicinal product?**

   In brief
   The action of a medicinal product is typically achieved by pharmacological, immunological or metabolic means. In the case of a medical device, the principal intended action is typically fulfilled by physical means but it may be assisted in its function by pharmacological, immunological or metabolic means.

   Hydro-Caine Gel is a Class-III medical device, an approved drug-device combination similar in classification to coronary stents with anti-thrombotic coating. Hydro-Caine Gel is classified as a drug-device combination because it acts principally by physical means as a lubricant to catheterisation, with the additional benefit of antiseptics and local anaesthetic.

Please refer to the *Product Information For Use* sheet for further information.

Additional detail:

Further information is available in the *Important Product Information* sheet, but in summary:

Medical Device Definition:

Any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- Control of conception,

...which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means

Medicine Definition:

- Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or
- Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis

BACKGROUND – Historical note: Over time the classification of particular products has changed in accordance with changes in EC Legislation. Legislation on medicinal products predated the Medical Device Regulations (MDR).
This meant that when the MDR came into force or was subsequently amended, as with the change of definition of a medicinal product in Directive 2004/27/EC (amending Directive 2001/83/EC), which came into force on the 30th October 2005, a number of products were then regulated as Medical Devices.
The MDR have now been in place for over 10 years. However there may still be areas where the regulatory classification is unclear, particularly where products incorporate a medicinal product.

The classification of medicine or medical device does not reflect the level of efficacy, safety or quality of the product. The classification denotes that the action of a medicine is typically achieved by pharmacological, immunological or metabolic means. In the case of a medical device, the principal intended action is typically fulfilled by physical means.
Previously, the route available to register a lubricating gel with Lidocaine was to class it as a medicinal product. Changes in classification have allowed for

lubricating gels with Lidocaine, such as Hydro-Caine, to now be classed as a drug device combination.

As an approved drug device combination, Hydro-Caine Gel has a valid CE design examination certificate and has been reviewed and accepted by an accredited Notified Body regarding the quality, efficacy and safety of its ingredients. As a Good Manufacturing Practice (GMP) requirement we are obliged to batch test Hydro-Caine to confirm active ingredients and measured volume are consistent and the highest quality standard. Ongoing surveillance of Hydro-Caine Gel has reinforced the safety profile of the product.

4. **Will healthcare professionals be liable for any adverse events if Hydro-Caine Gel is used for its antiseptic and anaesthetic qualities?**

Hydro-Caine clearly states on its IFU that its primary action is a lubricating gel. It has the additional benefits of antiseptic and anaesthetic properties that help to reduce the risk of pain and infection. If the healthcare professional uses a lubricating gel (Hydro-Caine) for its primary action then they will not be liable should an adverse event occur.

Reference:

- *National Institute for Clinical Excellence Guidlines (2003);Pratt RJ et al: Epic 2 Guidelines (2007); Tenke et al (2008) European & Asian Guidelines on Management & Prevention of CAUTI Cited in Kyle G (2011) Lubrication and Female Catheterisation. BJN Vol 20 No 10*

- *Pratt RJ, Pellowe CM, Wilson JA, Loveday HP, Harper P, Jones SRLJ, McDougal C & Wilcox MH (2007) Epic 2: National Evidence Based Guidelines for Preventing Healthcare Associated Infections in NHS Hospitals in England. London: Thames Valley University*

5. **What levels of Lidocaine and Chlorhexidine are found in Hydro-Caine Gel? Do these accurately match the levels stated on the packet?**

   Each 100 gram gel contains:
   - Chlorhexidine Gluconate Solution 20% Antiseptic (w/v) 0.250g
   - Methyl Hydroxybenzoate (E218) Preservative 0.060g
   - Propyl Hydroxybenzoate (E216) Preservative 0.025g
   - Lidocaine Hydrochloride Anaesthetic 2.000g

   These are the product specification, which are adhered to for every batch. This has been confirmed in the Manufacturers Safety Data Sheet. As a Good Manufacturing Practice (GMP) requirement we are obliged to batch test Hydro-Caine to confirm active ingredients and measured volume are consistent and the highest quality standard. Ongoing surveillance of Hydro-Caine Gel has reinforced the safety profile of the product.