

hameln pharmaceuticals Ltd.
Nexus, Gloucester Business Park
Gloucester, GL3 4AG
07 May 2019

Contact: Richard Wysocki
Tel.: 01452 621661
Email r.wysocki@hameln.co.uk
www.hameln.co.uk

Dear Customer

Re: Fentanyl 50 micrograms/ml injection (100 micrograms in 2 ml) – German stock

Thank you for your order.

In agreement with the NHS Commercial Medicines Unit you have been supplied with the German equivalent of hameln **Fentanyl 50 micrograms/ml injection 2 ml (100 micrograms in 2 ml)** ampoules.

Why have you received German stock?

Due to a national shortage of stock from the contracted suppliers of Fentanyl 50 micrograms/ml 2 ml (100 micrograms in 2 ml) injection, hameln were asked by the DHSC to support the UK market. As insufficient quantities of UK-licensed stock were available, hameln (with the approval of the DHSC and MHRA) are importing a small amount of stock of German licensed Fentanyl 50 micrograms/ml 2 ml injection – this is labelled as “Fentanyl-hameln 50 µg/ml Inj.lsg.” and approved in Germany under Marketing Authorisation number (49593.00.00).

Is the formulation of the German equivalent, the same as the UK product?

Yes – the formulation/ pharmaceutical composition is **identical** with the same active pharmaceutical ingredient and excipients obtained from the same source and with the product manufactured at the same manufacturing site. Please see below pictures of the two products:



German licensed pack



UK licensed pack

Are the licensed indications/route of administration for the German equivalent, the same as for the UK product?

This German licensed pack is approved by the German authorities, however the approved indications and routes of administration differ slightly from those of the UK product – please see Appendix 1 below. It is not unusual for the same product to have different approved indications in different markets, even when the formulation is exactly the same. These differences typically reflect the local (national) established clinical practice.

Prescribing Information

The German carton will contain a package leaflet in the German language, however due to the timescales involved it will not be possible to overlabel this product in English and a direct translation into English has not been provided. However, the Summary of Product Characteristics (SmPC) and Patient Information Leaflet (PIL) for the equivalent UK licensed product can be accessed via the electronic Medicines Compendium (eMC) or the “Products” section of the hameln website: <https://www.hameln.co.uk/Products/Product-Search/A-Z/Fentanyl-50-mcg-ml-100-mcg-in-2-ml>

Please note that as the German product is not licensed in the UK, hameln pharmaceuticals ltd are unable to make any corresponding prescribing recommendations for this product in the UK – any such use of this unlicensed medicine will be at the professional judgment and liability of the healthcare professional(s) concerned. The German product is a controlled drug but is not labelled as such.

Have the MHRA approved the import of this product?

The MHRA are aware of and have raised no objection to the importation of this product while the UK licensed pack is unavailable. NHSE and DHSC have been consulted about this substitution and have been closely involved in the preparation of this communication.

Should you require any additional information, please do not hesitate to contact our Medicines Information department directly.

Yours sincerely

A handwritten signature in blue ink, appearing to read 'R Wysocki'.

Richard Wysocki MRPharmS
Medical Affairs Director

Appendix 1: SmPC Comparison - Fentanyl 50 microgram/ml Injection (PL 01502/0062) and Fentanyl-hameln 50 Mikrogramm/ml Injektionslösung (49593.00.00)

	Fentanyl 50 microgram/ml Injection (PL 01502/0062)	Fentanyl-hameln 50 Mikrogramm/ml Injektionslösung (49593.00.00)
4.1 Therapeutic indications	<p>Fentanyl is an opioid analgesic used:</p> <ul style="list-style-type: none"> - in low doses to provide analgesia during short surgical procedures - in high doses as an analgesic/respiratory depressant in patients requiring assisted ventilation - in combination with a neuroleptic drug as part of the technique of neuroleptanalgesia - in the treatment of severe pain, such as the pain of myocardial infarction 	<p>Fentanyl is a short acting opioid used for neurolept analgesia and neurolept anaesthesia as an analgesic component in general anaesthesia with intubation and ventilation of the patient for analgesic treatment in the intensive care unit in patients under the condition of assisted ventilation</p>
4.2 Posology and method of administration	<p>Route of administration</p> <p>Intravenous administration either as a bolus or by infusion.</p> <p>Intramuscular administration.</p>	<p>Method of administration</p> <p>Fentanyl should be administered slowly (1 – 2 minutes) by intravenous injection (see also "Special warnings and precautions for use"), if applicable in combination with a neuroleptic (preferably Droperidol).</p>