仿單標籤粘貼表

產品中文名稱	“麥林可” 歐得麥造影劑	申請廠商	集德醫材管理顧問有限公司
衛生福利部給證號碼	衛署藥輸字第 024175 號		



103. 1. 08

“麥林可” 歐得麥造影劑

“Mallinckrodt” Optimark 0.5mmol/ml Injection
衛署藥輸字第 024175 號
製造廠名稱： Mallinckrodt Inc.
製造廠地址： 8800 Durant Road, Raleigh, North Carolina 27616, USA
藥商名稱： 集德醫材管理顧問有限公司
藥商地址： 新竹縣竹北市和平街 8 號 10 樓
製造日期及批號： 詳如英文標示
保存期限： 詳如英文標示
本藥限由醫師使用

※ 裝訂原廠之仿單、使用說明書及其中文仿單稿、最小包裝、標籤

※ 中文仿單稿包括適應症、禁忌症、型號（規格）、產品說明及注意事項等敘述，最後段須加刊製造廠名稱、地址及藥商名稱、地址，如有附件、配件請一併列明

※ 仿單標籤等實物過大或印於玻璃金屬容器等不便於黏貼時可將照相影本代替黏貼報核

衛生福利部 食品藥物管理署 核准 103. 1. 08

7711CT
R07/11

Please Recycle Carton

Rx Only

This container contains 1 syringe

MALLINCKRODT

tyco / Healthcare

(gadoversetamide injection)

OptiMARK™ 0.5mmol/mL 10 mL 1177-11

OptiMARK™ 0.5mmol/mL 10 mL 1177-11

(gadoversetamide injection)

Lot
Exp Date

7711CT
R07/11

OptiMARK™ 0.5mmol/mL 10 mL 1177-11

(gadoversetamide injection)

Sterile Solution

This container contains 1 syringe

Each mL of OptiMARK™ contains 330.9 mg of gadoversetamide (0.5 millimole), 28.4 mg of calcium versetamide sodium (0.05 millimole), 0.7 mg of calcium chloride dihydrate (0.005 millimole), and water for injection. Sodium hydroxide and hydrochloric acid may have been added for pH adjustment.

MEDICATION AND FLUID PATHWAY ARE STERILE
OUTSIDE OF SYRINGE IS NOT STERILE
SINGLE DOSE UNIT, DISCARD UNUSED PORTION

For Intravenous Injection Only
Dosage: See package insert.

PROTECT FROM LIGHT • PROTECT FROM FREEZING
Store at Controlled Room Temperature 20-25°C (68-77°F) [see USP].

Mallinckrodt Inc.
8800 Durant Road, Raleigh, NC 27616, USA
www.Mallinckrodt.com

tyco Healthcare

MALLINCKRODT

OptiMARK™ 0.5mmol/mL 10 mL 1177-11

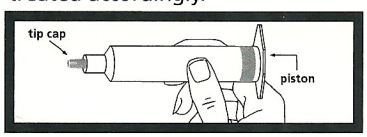
7711CT
R07/11

Push Here Then Lift To Open

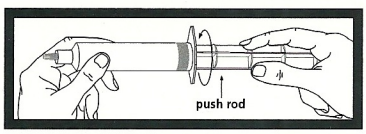
Assembly and Inspection

NOTE: Exterior of syringe is **not sterile.**

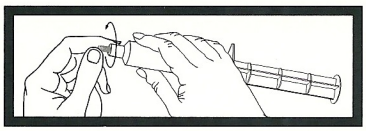
Contents of syringe and area **under gray tip cap and piston ribs are sterile** and should be treated accordingly.



Remove syringe from carton and inspect the area around the **tip cap** and outside of **piston** for signs of leakage. Do not use if leakage is observed.



After screwing the push rod into the syringe piston, it is important to **turn the push rod an additional 1/2 turn** so that the gray piston rotates freely.



Prior to using the syringe, twist off gray tip cap and discard. The area under the tip cap is sterile, caution should now be used when handling. **Syringe is now ready for needle or infusion tubing attachment.**

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衛生福利部食品藥物管理署給證號碼	衛署藥輸字第 024175 號		

※ 外文仿單應檢附中文譯文

市售藥品得僅放置經審查核定之中文仿單。但如市售藥品同時放置中、外文仿單者，外文仿單內容須與核定本之中文仿單內容相符，廠商得依核定之中文仿單自行修正其外文仿單內容。