

DURATOCIN[®]

QUALITATIVE AND QUANTITATIVE COMPOSITION

Carbetocin 100 micrograms/ml.

For a full list of excipients, see section LIST OF EXCIPIENTS.

PHARMACEUTICAL DOSAGE FORM

Solution for injection.

A clear colourless solution.

CLINICAL PARTICULARS

Therapeutic indications

Prevention of postpartum haemorrhage due to uterine atony.

Posology and method of administration

Posology

Caesarean section under epidural or spinal anaesthesia:

Withdraw 1 ml of DURATOCIN[®] containing 100 micrograms carbetocin and administer only by intravenous injection, under adequate medical supervision in a hospital.

Vaginal delivery:

Withdraw 1 ml of DURATOCIN[®] containing 100 micrograms carbetocin and administer by intravenous injection or intramuscular injection, under adequate medical supervision in a hospital.

Paediatric population

There is no relevant use of carbetocin in children below 12 years of age.

The safety and efficacy of carbetocin in adolescents has not yet been established.

Currently available data are described in section 5.1 but no recommendation on a posology can be made.

Method of administration

Carbetocin must only be administered after delivery of the infant, and as soon as possible after delivery, preferably before the delivery of the placenta.

For intravenous administration carbetocin must be administered slowly, over 1 minute.

DURATOCIN[®] is intended for single use only. No further doses of carbetocin should be administered.

Contraindications

- Pregnancy and labour before delivery of the infant.
- Induction of labour.
- Serious cardiovascular disorders.
- Hypersensitivity to carbetocin, oxytocin or to any of the excipients listed in "LIST OF EXCIPIENTS".
- Hepatic or renal disease.
- Epilepsy

Special warnings and precautions for use

Carbetocin is intended for use only at well equipped specialist obstetrics units with experienced and qualified staff available at all times.

The use of carbetocin at any stage before delivery of the infant is not appropriate because its uterotonic activity persists for several hours. This is in marked contrast to the rapid reduction of effect observed after discontinuation of an oxytocin infusion.

In case of persistent vaginal or uterine bleeding after administration of carbetocin the cause must be determined. Consideration should be given to causes such as retained placental fragments, perineal, vaginal and cervix lacerations, inadequate repair of the uterus, or disorders of blood coagulation.

Carbetocin is intended for single administration only, intramuscular or intravenous. In case of intravenous administration, it must be administered slowly over 1 minute. In case of persisting uterine hypotonia or atonia and the consequent excessive bleeding, additional therapy with another uterotonic should be considered. There are no data on additional doses of carbetocin or on the use of carbetocin following persisting uterine atony after oxytocin.

Animal studies have shown carbetocin to possess some antidiuretic activity (vasopressin activity: <0.025 IU/vial) and therefore the possibility of hyponatraemia cannot be excluded, particularly in patients also receiving large volumes of intravenous fluids. The early signs of drowsiness, listlessness and headache should be recognised to prevent convulsions and coma.

In general, carbetocin should be used cautiously in the presence of migraine, asthma and cardiovascular disease or any state in which a rapid addition to extracellular water may produce hazard for an already overburdened system. The decision of administering carbetocin can be made by the physician after carefully weighing the potential benefit carbetocin may provide in these particular cases.

No data is available on the use of carbetocin in patients with eclampsia. Patients with eclampsia and pre-eclampsia should be carefully monitored.

Specific studies have not been undertaken in gestational diabetes mellitus.

INTERACTION WITH OTHER MEDICAMENTS AND OTHER FORMS OF INTERACTION

During clinical trials, carbetocin has been administered in association with a number of analgesics, spasmolytics and agents used for epidural or spinal anaesthesia, and no drug interactions have been observed. Specific interaction studies have not been undertaken.

Since carbetocin is closely related in structure to oxytocin, the occurrence of interactions known to be associated with oxytocin cannot be excluded: severe hypertension has been reported when oxytocin was given 3 to 4 hours following prophylactic administration of a vasoconstrictor in conjunction with caudal-block anaesthesia.

During combination with ergot-alkaloids, such as methylergometrine, oxytocin and carbetocin may enhance the blood pressure enhancing effect of these agents. If oxytocin or methylergometrine are administered after carbetocin there may be a risk of cumulative effect.

Since it has been found that prostaglandins potentiate the effect of oxytocin, it is expected that this can also occur with carbetocin. Therefore, it is not recommended that prostaglandins and carbetocin be used together. If they are concomitantly administered, the patient should be carefully monitored.

Some inhalation-anesthetics, such as halothane and cyclopropane may enhance the hypotensive effect and weaken the effect of carbetocin on the uterus. Arrhythmias have been reported for oxytocin during concomitant use.

Fertility, pregnancy and lactation

Pregnancy

Carbetocin is contraindicated during pregnancy and must not be used for the induction of labour (see section Contraindications).

Breastfeeding

No significant effects on milk let-down have been reported during clinical trials. Small amounts of carbetocin have been shown to pass from plasma into breast milk of nursing women (see section Pharmacokinetics). The small amounts transferred into colostrum or breast milk after a single injection of carbetocin, and subsequently ingested by the infant are assumed to be degraded by enzymes in the gut.

Breast-feeding does not need to be restricted after the use of carbetocin.

Effects on ability to drive and use machines

Not relevant.

Undesirable effects

The adverse events observed with carbetocin during the clinical trials were of the same type and frequency as the adverse events observed with oxytocin

Intravenous administration* - Tabulated summary of adverse reactions

System Organ Class	Very common ≥ 1/10	Common ≥ 1/100 and < 1/10	Not known (cannot be estimated from the available data)
Blood and the lymphatic system disorders		Anaemia	
Nervous system disorders	Headache, tremor	Dizziness	
Cardiac disorders			Tachycardia, bradycardia***, arrhythmia***, myocardial ischaemia***, and QT prolongation***
Vascular disorders	Hypotension, flushing		
Respiratory, thoracic and mediastinal disorders		Chest pain, dyspnoea	
Gastrointestinal disorders	Nausea, abdominal pain	Metallic taste, vomiting	
Skin and subcutaneous tissue disorders	Pruritus		
Musculoskeletal and connective tissue disorders		Back pain	
General disorders and administration site conditions	Feeling of warmth	Chills, pain	

* Based on studies in caesarean section

*** Reported with oxytocin (closely related in structure to carbetocin)

In the clinical trials sweating and tachycardia were reported as sporadic cases.

Intramuscular administration** – Tabulated summary of adverse reactions

System Organ Class	Uncommon ≥ 1/1,000 and <1/100	Rare ≥ 1/10,000 and <1/1,000	Not known (cannot be estimated from the available data)
Blood and the lymphatic system disorders	Anaemia		
Nervous system disorders	Headache, dizziness	Tremor	
Cardiac disorders	Tachycardia		Bradycardia***, arrhythmia***, myocardial ischaemia***, and QT prolongation***
Vascular disorders	Hypotension	Flushing	
Respiratory, thoracic and mediastinal disorders	Chest pain	Dyspnoea	
Gastrointestinal disorders	Nausea, abdominal pain, vomiting		
Skin and subcutaneous tissue disorders		Pruritus	
Musculoskeletal and connective tissue disorders	Back pain, muscular weakness		
Renal and urinary disorders		Urinary retention	
General disorders and administration site conditions	Chills, pyrexia, pain		

** Based on studies in vaginal delivery

*** Reported with oxytocin (closely related in structure to carbetocin)

OVERDOSE

Overdosage of carbetocin may produce uterine hyperactivity whether or not due to hypersensitivity to this agent. Hyperstimulation with strong (hypertonic) or prolonged (tetanic) contractions resulting from oxytocin overdose can lead to uterine rupture or postpartum haemorrhage.

Overdosage of oxytocin may lead to hyponatraemia and water intoxication in severe cases, especially when associated with excessive concomitant fluid intake. As carbetocin is an analogue of oxytocin, the possibility of a similar event cannot be excluded.

Treatment of overdosage of carbetocin consists of symptomatic and supportive therapy. When signs or symptoms of overdosage occur oxygen should be given to the mother. In cases of water intoxication it is essential to restrict fluid intake, promote diuresis, correct electrolyte imbalance, and control convulsions that may eventually occur.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

Pharmacotherapeutic group: Oxytocin and analogues

ATC code: H01BB03

The pharmacological and clinical properties of carbetocin are those of a long acting oxytocin agonist.

Like oxytocin, carbetocin selectively binds to oxytocin receptors in the smooth muscle of the uterus, stimulates rhythmic contractions of the uterus, increases the frequency of existing contractions, and raises the tone of the uterus musculature.

On the postpartum uterus, carbetocin is capable of increasing the rate and force of spontaneous uterine contractions. The onset of uterine contraction following carbetocin is rapid after intravenous or intramuscular administration, with a firm contraction being obtained within 2 minutes.

A single 100 micrograms intravenous or intramuscular dose of carbetocin administered after the delivery of the infant is sufficient to maintain adequate uterine contraction that prevents uterine atony and excessive bleeding comparable with an oxytocin infusion lasting for several hours.

Clinical efficacy and safety

The efficacy of carbetocin in the prevention of postpartum haemorrhage due to uterine atony following Caesarean section was established in a randomised, active controlled, double-blind, double dummy, parallel-group trial designed to establish the efficacy and safety of carbetocin compared to oxytocin 25 IU. Six-hundred fifty nine healthy pregnant women undergoing elective Caesarean section under epidural anaesthesia received either carbetocin 100 µg/ml as an IV bolus dose or oxytocin 25 IU as an 8 h IV infusion.

The results of analysis of the primary endpoint, the need for additional oxytocic intervention, showed that additional oxytocic intervention was required in 15 (5%) of the subjects receiving carbetocin 100 µg IV compared with 32 (10%) of the subjects in the oxytocin 25 IU group (p=0.031).

The efficacy of carbetocin in the prevention of postpartum haemorrhage following vaginal delivery was established in one randomised, active controlled, double-blind trial. In total 29645 subjects were randomised to receive a single intramuscular dose of either carbetocin 100 µg or oxytocin 10 IU. For the primary endpoint of blood loss of ≥500 mL or use of additional uterotonics, similar rates were obtained in both treatment groups (carbetocin: 2135 subjects, 14.47%; oxytocin: 2122 subjects, 14.38%; relative risk [RR] 1.01; 95% CI: 0.95 to 1.06), demonstrating non-inferiority of carbetocin compared with oxytocin with regard to the primary endpoint.

Paediatric population

In the clinical development of carbetocin for prevention of postpartum haemorrhage following vaginal delivery 151 women between 12 and 18 years of age received carbetocin at the recommended dosage of 100 µg and 162 received oxytocin 10 IU. Efficacy and safety was similar for the two treatment arms in these patients.

Pharmacokinetics properties

The pharmacokinetics of carbetocin have been investigated in healthy female subjects. Carbetocin shows a biphasic elimination after intravenous administration with linear pharmacokinetics in the dose range of 400 to 800 micrograms. The median terminal elimination half-life is 33 minutes after intravenous administration and 55 minutes after intramuscular administration. After intramuscular administration, peak concentrations are reached after 30 minutes and the bioavailability is 77%. The mean volume of distribution at pseudo-equilibrium (Vz) is 22 L. Renal clearance of the unchanged form is low, with <1% of the injected dose excreted unchanged by the kidney.

After intramuscular administration of 70 µg carbetocin in 5 healthy nursing mothers, carbetocin concentrations were detectable in milk samples. Mean peak concentrations in milk were below 20 µg/mL, which was approximately 56 times lower than in plasma at 120 min.

Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicology and genotoxicity and local tolerance. A reproductive toxicity study in rats, with daily drug administration from parturition to day 21 of lactation, showed a reduction in offspring body weight gain. No other toxic effects were observed. The indication did not warrant studies on fertility or embryotoxicity or carcinogenicity.

Carcinogenicity studies have not been performed with carbetocin due to the single dose nature of the indication.

PHARMACEUTICAL PARTICULARS

List of excipients

L-methionine
Succinic acid
Mannitol
Sodium hydroxide for pH adjustment
Water for injections

Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

Special precautions for storage

Keep vials in the outer carton, in order to protect from light.

Store below 30°C. Do not freeze.

Nature and contents of container

Type 1 glass vials (2R) with type 1 bromobutyle stoppers with aluminium crimp cap containing 1 ml of solution for injection.

Packs of 5 vials.

Special precautions for disposal and other handling

DURATOCIN[®] is for intravenous and intramuscular use only.

Only clear solutions practically free from particles should be used.

Any unused product or waste material should be disposed of in accordance with local requirements.

MANUFACTURER

Ferring GmbH
Wittland 11, D-24109 Kiel Germany

PACKAGER

Zuellig Pharma Specialty Solutions Group Pte. Ltd.
15 Changi North Way, #01-02, #02-02, #02-10, Singapore 498770

衛署藥輸字第025800號
本藥限由醫師使用

巧特欣注射劑

DURATOCIN[®] Injection 100mcg/ml

成分

每一毫升含主成分carbetocin 100微克
本品賦形劑成分詳見〔賦形劑〕。

藥物劑型

注射液劑
無色透明溶液

臨床特性

〔適應症〕
預防子宮收縮乏力造成的產後出血。

〔用法用量〕

用量

硬膜外或脊髓麻醉下剖腹產時

抽出1毫升內含100微克carbetocin的DURATOCIN[®]，只能靜脈注射，並需在醫院內有適當醫療監督下施打。

陰道生產時

抽出1毫升內含100微克carbetocin的DURATOCIN[®]，在醫院內有適當醫療監督下靜脈注射或肌肉注射。

兒童族群

無12歲以下兒童使用carbetocin的相關資料。青少年使用carbetocin之療效及安全性尚未確立。現有資料敘述在藥效學特性一節中，但無法建議使用劑量。

用法

Carbetocin僅能在嬰兒出生後施打。生產後要儘快施打，最好能在移除胎盤前。

靜脈注射carbetocin應以不低於1分鐘的速度緩慢施打。

DURATOCIN[®]只能施打一劑，不應再施打更多劑的carbetocin。

〔禁忌症〕

- 嬰兒出生前之懷孕和生產陣痛
- 引產(induction of labor)
- 嚴重心血管疾病
- 對carbetocin、oxytocin或對任一所列賦形劑過敏
- 肝臟疾病或腎臟疾病
- 癱瘓。

〔警語及使用上注意事項〕

只有在設備良好的產科專科醫院，而且隨時都有經驗豐富且合格的專業人員情況下，才能施打carbetocin。

在嬰兒出生前任何一產程都不適宜使用carbetocin，因其子宮收縮作用會持續數小時。這和oxytocin停止輸注後，藥物作用會快速降低的現象成明顯對比。

如果施打carbetocin後陰道或子宮還是持續出血，必須要找出出血的原因。要考慮的原因有：胎盤組織殘留、會陰、陰道及子宮頸撕裂、子宮修復不完全或凝血異常等

Carbetocin僅供單次靜脈或肌肉注射使用。靜脈注射使用必須緩慢施打不低於1分鐘。如果子宮持續張力不足或收縮乏力，造成大量出血，應考慮使用其他子宮收縮劑治療。對於使用額外劑量的carbetocin或施打oxytocin後子宮持續收縮乏力時，再施打carbetocin的情況，目前並沒有研究資料。

一些動物研究顯示，carbetocin有一些抗利尿作用(血管加壓素活性<0.025 IU/vial)，因此無法排除低血鈉症的可能性，尤其是當病人也接受大量靜脈輸注液體時。要能辨識出倦怠、昏昏欲睡和頭痛等初期表徵，以預防抽搐和昏迷。

一般而言，下列情況下要小心使用carbetocin：偏頭痛、氣喘和心血管疾病、或對已經過度負荷的生理系統因任何快速添加細胞外水分可能會造成危險的狀態。醫師要仔細衡量過carbetocin所可能提供給這些特殊病人的潛在效益後，才能決定施打carbetocin。

未有子癩病人使用carbetocin之研究資料。罹患子癩和子癩前症的病人需要小心監測。

目前尚未針對妊娠糖尿病的病人執行臨床研究。

〔與其他藥物的交互作用〕

在臨床試驗中carbetocin曾經和一些止痛劑、解痙藥、硬膜外或脊髓麻醉藥劑一起給予，並未觀察到有藥物的交互作用。目前還未進行過個別藥物交互作用研究。

因為carbetocin的結構相當接近oxytocin，所以並不能排除會發生已知與oxytocin相關的交互作用；當進行尾椎阻斷麻醉並同時給予預防性的血管收縮劑之後，注射oxytocin 3到4小時時曾有過嚴重高血壓的通報。

與ergot-alkaloid類藥物(例如：methylergometrine)合併使用時，oxytocin和carbetocin可能增強這些藥物的血壓增強作用。如果施打carbetocin後再給予oxytocin或methylergometrine，可能有累積作用的風險。

由於prostaglandins可能影響oxytocin的效能，預期也可能對carbetocin有相同的影響。因此不建議同時服用prostaglandins與carbetocin。如需同時服用此兩種藥物，須對病人小心監測。

一些吸入型麻醉藥物(例如：halothane和cyclopropane)可能會增強低血壓作用，和降低carbetocin對子宮的作用。曾有與oxytocin同時使用時發生心律不整的通報。

〔生殖、懷孕和哺乳〕

懷孕

Carbetocin在懷孕期間禁止使用且不可用於引產(請參閱禁忌症一節)。

哺乳

臨床試驗報告指出，對乳汁分泌沒有明顯的影響。目前已經顯示會有少量的carbetocin從血漿進入到哺乳婦女的乳汁中(請參閱藥物動力學一節)。Carbetocin單一劑注射後，少量carbetocin跑到初乳和乳汁中，嬰兒攝食後一般認為會被腸道中的酵素降解。

使用carbetocin後不需禁止哺乳。

〔對開車和使用機器的影響〕

不相關。

〔不良反應〕

臨床試驗中，使用carbetocin所觀察到的不良反應，與使用oxytocin觀察到的不良事件的類型和頻率相同。

靜脈注射*-不良反應列表

系統器官	非常常見 ≥1/10	常見 ≥1/100和<1/10	未知(從現有資料無法評估)
血液和淋巴系統疾病		貧血	
神經系統疾病	頭痛，顫抖	頭暈	
心臟方面異常			心搏過速， 心搏過慢***， 心率不整***， 心肌缺氧***及 QT波延長***
血管疾病	低血壓，潮紅		
呼吸、胸腔和縱膈疾病		胸痛，呼吸困難	
胃腸疾病	噁心，腹痛	金屬味，嘔吐	
皮膚和皮下組織疾病	搔癢		
肌肉骨骼和結締組織疾病		背痛	
全身異常和施打部位疾病	感覺發熱	寒顫，疼痛	

*根據剖腹產之試驗

***根據oxytocin(與carbetocin結構相似)之報告

臨床試驗中偶而有出汗和心跳加速的報告。

肌肉注射**-不良反應列表

系統器官	不常見 ≥1/1000和<1/100	罕見 ≥1/10,000和<1/1,000	未知(從現有資料無法評估)
血液和淋巴系統疾病	貧血		
神經系統疾病	頭痛，頭暈	顫抖	
心臟方面異常	心搏過速		心搏過慢***， 心率不整***， 心肌缺氧***及 QT波延長***
血管疾病	低血壓	潮紅	
呼吸、胸腔和縱膈疾病	胸痛	呼吸困難	
胃腸疾病	噁心，腹痛，嘔吐		
皮膚和皮下組織疾病		搔癢	

肌肉骨骼和結締組織疾病	背痛，肌肉無力		
腎臟和泌尿系統的異常		尿液滯留	
全身異常和施打部位疾病	寒顫，發熱，疼痛		

**根據自然產之試驗

***根據oxytocin(與carbetocin結構相似)之報告

〔藥物過量〕

無論是不是因為對carbetocin過敏，carbetocin藥物過量可能會造成子宮過度收縮。

Oxytocin藥物過量引起子宮過度刺激伴隨強力(高張性)或長時間(強直性)的子宮收縮，可能造成子宮破裂或產後出血。

Oxytocin藥物過量在嚴重情況下可能會造成低血鈉症和水中毒，尤其是同時攝取過量液體時。因為carbetocin是oxytocin的類似物，所以不能排除發生類似事件的可能性。

Carbetocin藥物過量的治療包括症狀治療和支持性療法。當出現藥物過量的表徵及症狀時需供給母體氧氣。當水中毒時須限制液體的攝取，應增加利尿以修正電解質不平衡，並且控制抽搐的發生。

藥理學

〔藥效學特性〕

藥物治療組別：Oxytocin和類似物。

ATC碼：H01BB03。

在藥理和臨床性質，carbetocin屬長效型的oxytocin作用劑。

與oxytocin一樣，carbetocin會選擇性地結合到子宮平滑肌上的oxytocin受體，刺激子宮規律收縮、增加本來已經有的收縮頻率和提高子宮肌肉的張力等。

對於產後的子宮，carbetocin能增加子宮自然收縮的速率和力量。靜脈或肌肉注射carbetocin後會迅速開始子宮收縮作用，並能在2分鐘內到達強力收縮。

嬰兒出生後，與需要輸注幾小時的oxytocin相比，靜脈或肌肉注射單次100微克carbetocin就足以維持適度的子宮收縮，以防止子宮乏力和大量出血的情形。

臨床療效及安全性

一項隨機分配、有效療法對照、雙盲、雙虛擬、平行對照組之試驗，以carbetocin對照oxytocin 25 IU評估其療效及安全性，carbetocin預防剖腹產產後子宮收縮乏力造成的產後出血之療效已確立。硬膜外麻醉下剖腹產之659位健康懷孕婦女接收carbetocin 100微克/毫升靜脈注射或oxytocin 25 IU靜脈輸注8小時。

主要療效指標為需要額外給予oxytocin，其分析結果顯示靜脈注射carbetocin 100微克後有15位(5%)受試者需要額外給予oxytocin，相對於oxytocin 25 IU組有32位(10%)受試者(p=0.031)。

一項隨機分配、有效療法對照、雙盲之試驗，carbetocin預防陰道生產產後出血之療效已確立。共29645位受試者隨機分配至單劑肌肉注射carbetocin 100微克或oxytocin 10 IU。主要療效指標為出血量≥500毫升或額外使用子宮收縮劑，兩個治療組比例相似(carbetocin: 2135位受試者，14.47%; oxytocin: 2122位受試者，14.38%; 相對風險(relative risk [RR]) 1.01; 95% 信賴區間(CI): 0.95到1.06)，顯示carbetocin之主要療效指標不劣於oxytocin。

兒童族群

臨床開發試驗中，151位12歲至18歲女性在陰道生產後使用carbetocin建議劑量100微克及162位使用oxytocin 10 IU以預防產後出血。兩治療組病人的療效及安全性相似。

〔藥物動力學特性〕

Carbetocin藥物動力學已由健康女性為受試者進行研究。Carbetocin顯示出在靜脈注射後，會呈現二相的排除，在400到800微克劑量範圍內呈現線性的藥物動力學。靜脈注射後之最終排除半衰期中位數為33分鐘，而肌肉注射後為55分鐘。肌肉注射30分鐘後達最高血中濃度，且生體可用率為77%。假性平衡下之平均分佈體積(Vz)為22公升。原型藥物的腎臟清除率很低，低於1%的注射藥物以原型經由腎臟排除。

5位健康哺乳婦女肌肉注射70微克carbetocin後，於乳汁中可以偵測到carbetocin濃度。乳汁中的平均最高血中濃度低於20 pg/mL，比第120分鐘時的血漿濃度低約56倍。

〔臨床前安全性數據〕

經由安全性試驗、重複藥物毒性試驗以及基因毒性試驗和局部耐受性之臨床前試驗數據顯示，carbetocin對於人類沒有特別的風險。

大鼠的生殖毒性研究顯示，從生產到哺乳第21天每日給藥，下一代的體重增加較少。尚未觀察到其他的毒性作用。此適應症並未要求提供生殖、胚胎毒性和致癌性研究。

並無執行致癌性試驗，因為carbetocin只能施打一劑。

藥劑學特性

〔賦形劑〕

L-methionine、succinic acid、mannitol、調整pH使用之sodium hydroxide及注射用水

〔不相容性〕

因為沒有相容性研究，所以本藥劑不能和其他藥劑混合。

〔儲存〕

將小瓶放在外盒中以避免光照。

存放在30°C以下，避免冷凍。

〔包裝數量〕

每一瓶帶有鋁蓋及橡膠塞(type I)之玻璃小瓶(type I glass vials (2R))含有1毫升注射液。

每盒內有5小瓶。

〔丟棄的特別預防措施〕

DURATOCIN[®]只能用於靜脈或肌肉注射。

只有無顆粒、透明溶液才能使用。

所有未使用過的藥品或廢棄物都要按照當地法規丟棄。

製造廠

Ferring GmbH

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D-24109 Kiel

Germany

包裝廠

Zuellig Pharma Specialty Solutions

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