

裕利股份有限公司 函

M111059-2/3

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發文日期：中華民國111年01月27日

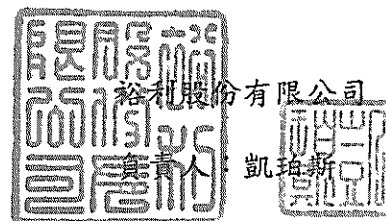
發文字號：111 裕字-第000183號

主旨：本公司銷售台灣默克股份有限公司之產品「Mavenclad Tablets 10mg，瑪威克錠10毫克(衛部罕藥輸字第000058號)」仿單變更通知，詳如說明段。

說明：

- 一、本公司銷售台灣默克股份有限公司之產品「Mavenclad Tablets 10mg，瑪威克錠10毫克(衛部罕藥輸字第000058號)」，承蒙貴院採用，特此致謝。
- 二、接獲原廠通知，上述產品自即日起，仿單變更，原核准資訊不變(藥品許可證字號、成份、含量等)。
- 三、仿單內容變更說明請見附件。新包裝批號自00029543起變更。
- 四、特此說明，敬請轉知 貴院相關單位，並請繼續支持本公司為禱。

附件：原廠公文、仿單變更對照表、中英文仿單、許可證





台灣默克股份有限公司 函

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受文者：裕利股份有限公司、吉程股份有限公司

發文日期：中華民國 111 年 01 月 26 日

發文字號：台灣默克藥字第 111010 號

速別：

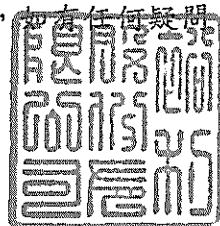
密等及解密條件：普通

附件：藥品許可證、仿單、變更說明

主旨：「瑪威克錠 10 毫克 Mavenclad Tablets 10 mg」仿單變更通知。

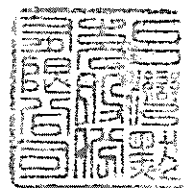
說明：

- 一、自即日起台灣默克股份有限公司產品瑪威克錠 10 毫克 Mavenclad Tablets 10 mg，仿單內容變更，原核准資訊不變（藥品許可證字號、成份、含量等）。
- 二、仿單內容變更說明請見附件
- 三、新包裝批號自 00029543 將陸續出貨至各醫療院所
- 四、特以此函通知 貴公司轉發至相關醫療院所，如有任何疑問，請電洽：
台灣默克股份有限公司



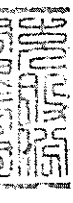
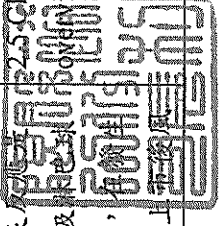
台灣默克股份有限公司

代表 負責人 李俊隆



瑪威克錠 10 毫克中文仿單

	原核准版本	變更版本	備註及參考資料
特殊警語及使用注意事項	轉換成 cladribine 或換其他藥物治療 先前使用免疫調節或免疫抑制藥物治療的病人，在開始使用 cladribine 治療前應考量相關的作用機轉及效期期間(參見第 4.2 節)。在 MAVENCLAD 治療後，接著使用這些藥物，可能對免疫系統產生加成效果，因此需要小心留意(參見第 4.5 節)。 果糖不耐症 MAVENCLAD 含有 sorbitol，因此，不建議使用於患有果糖不耐症的病人。	轉換成 cladribine 或換其他藥物治療 先前使用免疫調節或免疫抑制藥物治療的病人，在開始使用 cladribine 治療前應考量相關的作用機轉及效期期間。在 MAVENCLAD 治療後，接著使用這些藥物，可能對免疫系統產生加成效果，因此需要小心留意(參見第 4.5 節)。	修正與現行核准 EU SmPC 一致。
與其他藥物的交互作用，及其他形式交互作用	MAVENCLAD 含有 hydroxypropylbetadex，可能與其他藥物形成複合物，進而增加藥物的生體可用率(尤其是低溶解度的藥物，參見第 5.2 節)。因此，建議在服用 cladribine 的治療天數裡，所有其他口服藥物皆與 MAVENCLAD 給藥間隔至少 3 小時。	MAVENCLAD 含有 hydroxypropylbetadex，可能與其他藥物形成複合物，進而增加藥物的生體可用率(尤其是低溶解度的藥物)。因此，建議在服用 cladribine 的治療天數裡，所有其他口服藥物皆與 MAVENCLAD 給藥間隔至少 3 小時。	修正與現行核准 EU SmPC 一致。
不良反應	安全性摘要 臨床研究顯示，MS 病人於兩年間接受建議累積劑量為 3.5 毫克/公斤的 cladribine，發生最具臨床相關性的不良反應是淋巴球減少症及帶狀皰疹。相較於未發生第 3 或 4 級淋巴球減少症期間(<500 至 200 cells/mm³ 或 <200 cells/mm³)，在發生期間，帶狀皰疹的發生率較高(參見第 4.4 節)。	安全性摘要 臨床研究顯示，MS 病人於兩年間接受建議累積劑量為 3.5 毫克/公斤的 cladribine，發生最具臨床相關性的不良反應是淋巴球減少症及帶狀皰疹。相較於未發生第 3 或 4 級淋巴球減少症期間(<500 至 200 cells/mm³ 或 <200 cells/mm³)，在發生期間，帶狀皰疹的發生率較高(參見第 4.4 節)。經由上述研究顯示，帶狀皰疹的發生率較高(參見第 4.4 節)。	本次新增段落，不良反應請詳見 2.5 Clinical Review。



	險監測發現到的不良反應以星號[*]標註。		本次新增段落， 不良反應請詳見 2.5 Clinical overview。																									
	免疫系統疾病 常見：過敏反應*，包含搔癢、蕁麻疹、皮疹和罕見的血管性 水腫。																											
藥效學特 性	表 3、CLARITY 研究的臨床結果(96 週) <table><tr><th rowspan="2">參數</th><th rowspan="2">安慰劑 (n = 437)</th><th colspan="2">Cladribine 累積劑量</th></tr><tr><th>3.5 毫克/公 斤 (n=433)</th><th>5.25 毫克/公 斤 (n = 456)</th></tr><tr><td>年度復發率 (95% CI)</td><td>0.33 (0.29, 0.38)</td><td>0.14* (0.12, 0.17)</td><td>0.15* (0.12, 0.17)</td></tr><tr><td>相對減少 (cladribine 相對於安慰劑)</td><td></td><td>57.6%</td><td>54.5%</td></tr><tr><td>96 週無復發的 病人比例</td><td>60.9%</td><td>79.7%</td><td>78.9%</td></tr><tr><td>發生 EDSS 惡化 3 個月的時間危 險比，第 10 百 分位(月)</td><td>10.8</td><td>13.6</td><td>13.6</td></tr><tr><td>風險比(95% CI)</td><td></td><td>0.67* (0.48, 0.93) p = 0.018</td><td>0.69* (0.49, 0.96) p = 0.026</td></tr></table> * p < 0.001，相較於安慰劑	參數	安慰劑 (n = 437)	Cladribine 累積劑量		3.5 毫克/公 斤 (n=433)	5.25 毫克/公 斤 (n = 456)	年度復發率 (95% CI)	0.33 (0.29, 0.38)	0.14* (0.12, 0.17)	0.15* (0.12, 0.17)	相對減少 (cladribine 相對於安慰劑)		57.6%	54.5%	96 週無復發的 病人比例	60.9%	79.7%	78.9%	發生 EDSS 惡化 3 個月的時間危 險比，第 10 百 分位(月)	10.8	13.6	13.6	風險比(95% CI)		0.67* (0.48, 0.93) p = 0.018	0.69* (0.49, 0.96) p = 0.026	修正與現行核准 EU SmPC 一致， 新增 p 值 (CLARITY CSR, table 25643-15)。
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資料日期	資料修訂日期：2019 年 6 月	資料修訂日期：2021 年 1 月 (CCDSv10)	修正為安全性更 新日期																									

MAVENCLAD[®] tablets 10 mg

Version No. 00058

1. NAME OF THE MEDICINAL PRODUCT

MAVENCLAD tablets 10 mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 10 mg of mavenciclovir.

3. PHARMACEUTICAL FORM

Tablet, white, round, marked with 'M' on one side and '10' on the other side.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

MAVENCLAD is indicated for the treatment of adult patients with relapsing multiple sclerosis (RMS) who have had at least one relapse in the previous 12 months.

4.2 Posology and method of administration

Treatment with MAVENCLAD must be initiated and supervised by a physician experienced in the treatment of RMS.

4.3 Contraindications

The recommended cumulative dose of MAVENCLAD is 1.5 mg/kg body weight over 2 years. MAVENCLAD is contraindicated in patients with severe renal impairment (creatinine clearance < 30 mL/min).

4.4 Special warnings and precautions for use

At least 100 mg of MAVENCLAD should be taken daily for the first 10 days of treatment. The treatment should be continued for 2 years.

4.5 Interactions

MAVENCLAD should not be taken with other drugs that may increase the risk of renal impairment, such as NSAIDs, ACE inhibitors, and diuretics.

4.6 Pregnancy and lactation

The safety of MAVENCLAD in pregnancy and lactation has not been established. MAVENCLAD should not be taken during pregnancy or lactation.

4.7 Effects on ability to drive and operate machines

MAVENCLAD may cause dizziness or blurred vision. Patients should be cautious when driving or operating machines until they know how MAVENCLAD affects them.

4.8 Undesirable effects

The most common side effects of MAVENCLAD are headache, dizziness, and blurred vision. These side effects are usually mild and resolve on their own.

4.9 Overdose

There is no specific antidote for MAVENCLAD overdose. Patients should be monitored for signs and symptoms of toxicity.

4.10 Laboratory tests

MAVENCLAD may affect the results of certain laboratory tests, including uric acid and creatinine. Patients should inform their physician of any laboratory tests they are having.

4.11 Medication errors

Patients should be careful not to take more MAVENCLAD than prescribed. They should also be careful not to take MAVENCLAD if they are allergic to it.

4.12 Storage

MAVENCLAD tablets should be stored in their original packaging, protected from light and moisture. The storage temperature should be below 30°C.

4.13 Disposal

Patients should dispose of their MAVENCLAD tablets properly. They should not throw them away in the trash or flush them down the toilet.

4.14 Patient information

Patients should read the patient information leaflet (PIL) that comes with their MAVENCLAD tablets. They should also talk to their physician if they have any questions.

4.15 Summary of benefits versus risks

The benefits of MAVENCLAD outweigh the risks for patients with relapsing multiple sclerosis. MAVENCLAD is a safe and effective treatment for RMS.

4.16 Conclusion

MAVENCLAD is a new and effective treatment for relapsing multiple sclerosis. It is well tolerated and has a low risk of side effects.

4.17 References

1. European Medicines Agency. MAVENCLAD (mavenciclovir) tablets. EMA/123456/2019.

4.18 Other information

MAVENCLAD is a registered trademark of Merck & Co., Inc. All rights reserved.

4.19 Date of approval

MAVENCLAD was approved by the European Medicines Agency on 15 June 2019.

4.20 Date of revision

This document was last revised on 15 June 2019.

4.21 Author

Merck & Co., Inc., Kenilworth, NJ, USA.

4.22 Contact information

For more information, please contact your local Merck representative.

4.23 Disclaimer

This document is for informational purposes only and does not constitute an offer of MAVENCLAD.

4.24 Final statement

MAVENCLAD is a promising new treatment for relapsing multiple sclerosis. It offers a new hope for patients with this condition.

4.25 Acknowledgements

The authors would like to thank the patients and clinicians who participated in the MAVENCLAD clinical trials.

4.26 Bibliography

1. European Medicines Agency. MAVENCLAD (mavenciclovir) tablets. EMA/123456/2019.

4.27 Other references

2. National Multiple Sclerosis Society. Multiple Sclerosis Fact Sheet. 2018.

4.28 Glossary

Abbreviations: RMS = relapsing multiple sclerosis; EMA = European Medicines Agency.

4.29 Index

MAVENCLAD, 10 mg tablets, 15.

4.30 Appendix

Appendix 1: Summary of clinical trial results.

4.31 Appendix 2

Appendix 2: Detailed description of the clinical trials.

4.32 Appendix 3

Appendix 3: List of adverse events and their frequencies.

4.33 Appendix 4

Appendix 4: Laboratory test results and interpretation.

4.34 Appendix 5

Appendix 5: Patient satisfaction and quality of life data.

4.35 Appendix 6

Appendix 6: Summary of regulatory submissions.

4.36 Appendix 7

Appendix 7: List of patents and intellectual property.

4.37 Appendix 8

Appendix 8: Other relevant information.

Merck

Patients with symptomatic relapses should be actively monitored for signs and symptoms of relapse. Patients should be advised to avoid alcohol and other substances that may increase the risk of relapse. Patients should also be advised to avoid driving or operating machines if they experience dizziness or blurred vision.

MAVENCLAD is a new and effective treatment for relapsing multiple sclerosis. It is well tolerated and has a low risk of side effects. Patients should be advised to take MAVENCLAD exactly as directed by their physician.

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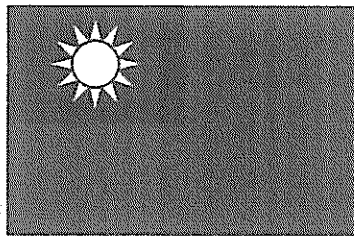
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衛生福利部藥品許可證

衛部罕藥輸字第 000058 號

簽審文件號碼：DHA07000005806

中文名稱：瑪威克錠 10 毫克

英文名稱：Mavenclad Tablets 10mg

類別：須由醫師處方使用 藥商名稱：台灣默克股份有限公司

劑型：錠劑 製造廠名稱：NERPHARMA S.R.L.

包裝種類：1-1000 錠 Alu/Alu 鋁箔盒裝 製造廠地址：VIALE PASTEUR, 10, 20014 NERVIANO (MI), ITALY (續如後)

處方：

Each tablet contains:

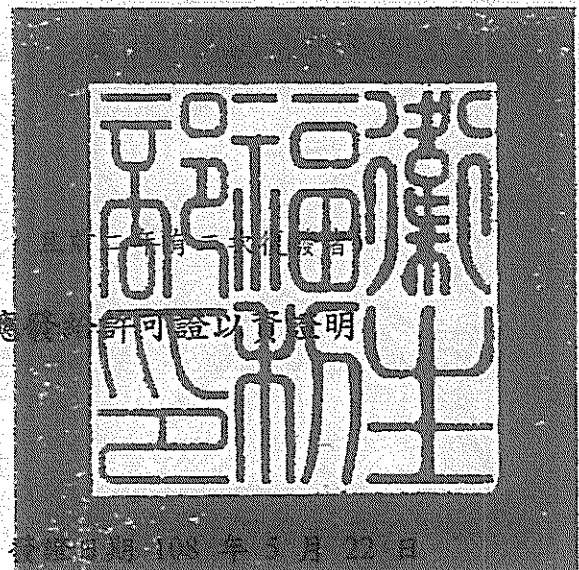
CLADRIBINE.....10.00 MG

適應症：復發型多發性硬化症(臨床上有發作) (註：本藥係仿製自德國之「瑪威克」)

前項藥品經本部審核與藥事法之規定相符應發給許可證以資證明

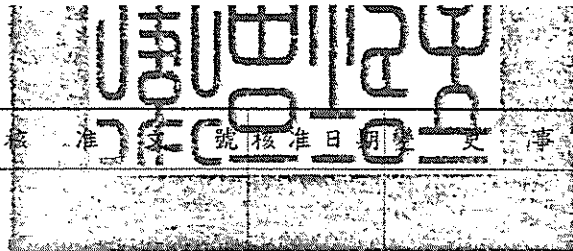
衛生福利部部長

陳時中



有效日期 118 年 5 月 22 日

核准 展 延 至	年 月 日	年 月 日		
文號				



其 他	變 更 事 項	核 准 文 號	核 准 日 期	變 更 事 項	核 准 文 號	核 准 日 期

二級包裝廠：R-PHARM GERMANY GMBH

HEINRICH-MACK-STRASSE 35, 89257 ILLERTISSEN, GERMANY

DMF Number : DMF(43)2960

成分名 : CLADRIBINE

廠名 : CILAG AG

廠址 : HOCHSTRASSE 201, 8200 SCHAFFHAUSEN, SWITZERLAND

本品係依 102 年 2 月 21 日署授食字第 1021401257 號公告檢
送原料藥主檔案技術資料，核准編號為 DMF(43)2960，並依
FDA 藥字第 1050041363 號合併於許可證管理。

1081405252