

MAILLI

魅 俪



朔盈
Extreme



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For an electronic copy of the MAILI Instructions for Use please refer to: www.sinclairpharma.com/eifu and input the KEYCODE: MLX.COR. If you require a paper copy then please contact: quality@sinclairpharma.com or +44 (0) 1244 625150.

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关于使用说明书的电子副本, 请登陆www.sinclairpharma.com/eifu并输入关键词“MLX.COR”进行查阅。纸质副本请登录quality@sinclairpharma.com或拨打电话+44 (0) 1244 625150获取。



Batch code
批次代码



Use-by date
有效期



Manufacturer
制造商



Read instructions for use
阅读使用说明



Do not re-use
不得二次使用



Do not use if packaged is damaged
如包装破损切勿使用



Caution
警告



Temperature limit (+2°C - +25°C)
温度极限 (+2°C - +25°C)



Fragile; handle with care
易碎物品, 小心搬运



Keep away from sunlight
怕晒



Sterilised using moist heat (syringes)
经蒸汽灭菌 (注射器)



Sterilised using irradiation (needles)
经辐射灭菌 (注射针)



European Community Representative
欧盟授权代表



Sterile fluid path - Moist heat (the content of the syringe (gel) is steril)
包含经蒸汽灭菌的无菌液路 (注射器的内容物 (凝胶) 无菌)



CE-mark (needles)
CE 标志 (注射针)



CE-mark (syringes)
CE 标志 (注射器)

Description

MAILI EXTREME is a sterile, transparent and resorbing gel of cross-linked hyaluronic acid of biofermentative origin. The product is supplied in plastic syringe and it is intended for single use only.

The volume of each syringe is 1 mL for **MAILI EXTREME**. Each box contains four graduated pre-filled syringes of **MAILI EXTREME**, an instruction leaflet, a set of traceability labels and four single use sterile needles of 27G 1/2". For each syringe, one label is to be given to the patient, the other one is to be added to the patient record.

The content of **MAILI EXTREME** syringes is sterilised by moist heat. The 27G 1/2" needles are sterilised by radiation. The intended purpose of **MAILI EXTREME** is to modify the anatomy and/or to alleviate for a physiological process at the level of the face.

Composition

MAILI EXTREME

- Cross-linked* hyaluronic acid: 24 mg/mL
- Lidocaine hydrochloride monohydrate: 3 mg/mL
- Phosphate buffer: q.s. 1 mL
- One syringe contains 1 mL of **MAILI EXTREME**

This product consists of a pre-filled syringe, a disposable sterile stainless steel injection needle and a gel encapsulated in the syringe. The gel is composed of crosslinked sodium hyaluronate, lidocaine hydrochloride and phosphate buffer, and sodium hyaluronate is prepared by microbial fermentation. The labeled concentration of crosslinked sodium hyaluronate is 24mg/ml and the labeled concentration of lidocaine hydrochloride is 3 mg/ml. The syringe pre-filled with gel is sterilized by moist heat, and the injection needle is sterilized by gamma radiation. This product is for single use. The shelf life of the product is 2 years.

*The hyaluronic acid has been cross-linked with BDDE.

Applicable population

MaiLi Extreme is intended for adults 18 years and older.

Intended uses

MaiLi Extreme is indicated to inject into facial suprapreosteal zone, fill the jaw area to improve the mandibular contour of patients with mild to moderate mandibular retraction.

Mode of action

MAILI EXTREME creates a volume in the tissue that corrects facial anatomy.

MAILI EXTREME is intended to be wholly resorbed over time, which progressively reduces the volumizer effect of the product at the injection site. The kinetic of this absorption depends on several factors among which the injected quantity, the depth of injection and the patient metabolism.

In a clinical trial in China, a total of 159 subjects received submaxillary injection of MaiLi Extreme, most of whom were assessed as improving at the primary endpoint (6 months after the last treatment), with the majority of subjects continuing to have an effect at 12 months after the last treatment.

Contra-indications

- Do not inject patients having known risk of hypersensitivity to hyaluronic acid or lidocaine or amide local anaesthetics.
- Do not inject patient having history of severe allergy or anaphylactic shock.
- Do not inject patients suffering from autoimmune disease.
- Do not inject patients suffering from porphyria.
- Do not inject patients having cutaneous disorders, inflammation or infection (herpes, acne, etc.) at the treatment site or nearby.
- Do not inject patients for whom the medical history shows a sensitivity that could lead to a reaction to the treatment.

- Do not use in patients with bleeding disorders or in patients who are undergoing treatment with thrombolytics or anticoagulants.
- Do not inject patients with a tendency to form keloids, hypertrophic scars or any other healing disorders.
- Do not use during pregnancy or breast-feeding.
- Do not use for children.
- Do not inject patients with mandibular deformity and clinical symptoms

Warnings

- Do not inject into blood vessels (intra-vascular) or directly near blood vessels (for avoiding vessels compression). An unintended intravascular administration can cause high blood concentration and acute central nervous system and cardiovascular toxic symptoms.
- Do not inject in area other than the face (e.g. hands, body).
- Do not inject **MAILI EXTREME** in the periorbital area (eyelids, palpebromalar groove, crow's feet) and glabellar region.
- The injection of **MAILI EXTREME** into the subcutaneous fat tissue or into the suprapreosteal zone is reserved to specialists specifically trained in these injection techniques.
- Do not inject intramuscularly. There is no available clinical data about injection of **MAILI EXTREME** into an area which has already been treated with another brand of resorbing product. It is therefore recommended not to inject in areas in which another brand of resorbing product is not still fully resorbed.
- Do not inject jointly with another brand of resorbing product in the same area.
- Do not inject jointly with a permanent product.
- Do not mix with other products.
- Do not re-sterilise the product (the syringe and/or the needle).
- Do not inject more than 4mL in the first injection. If the best aesthetic results are not achieved, a supplementary injection can be given 4 weeks after the first injection, and the supplementary injection should not exceed 2ml. Do not inject more than 20 mL per year per patient.
- Do not overcorrect.
- Do not use after expiry date or if the packaging is damaged or the syringe opened.
- Do not re-use (risk of contamination). The product is intended for single use only.
- Do not use a syringe for several patients (risk of cross-contamination).
- Do not use simultaneously with chemical peels, dermabrasion, laser treatment or radiofrequency treatment.

Precautions for use

- Patients must be questioned regarding their medical history and must be informed about expected outcome, warnings, contra-indications, precautions and potential adverse events.
- The quantity to inject depends on the area to treat and the expectation of the patients. Patients with unrealistic expectation must not be treated.
- Aseptic techniques and standards practices are to be observed.
- The content of the syringe is sterile until opening. External surface of the syringe is not sterile and should not be used in a controlled environment such as operating room. If needed, the surface of the syringe must be cleaned up in respect of the aseptic techniques in place.
- The patients on medication that affects platelet functions (aspirin or non-inflammatory drugs) must be warned of the potential increased risks of haematomas and bleeding during injection.
- Special caution must be exercised when treating areas in close proximity to vulnerable structures

such as vessels and nerves.

- Advise the patients to avoid any extended exposure to the sun, UV rays and temperatures below 0°C, as well as sauna or hammam sessions during the two weeks following the injection procedure.
- Recommend the patients not use cosmetic products (e.g. makeup, skincare products) during the 12 hours following the injection treatment.
- Recommend the patients to avoid applying intense pressure or massaging the treatment site for a few days following the injection.
- The healthcare professional must consider the fact that the product contains lidocaine. For normal healthy adults, the maximum total dose of lidocaine should not exceed 200 mg per session. When using concurrently (case of topical administration), the total administered dose of lidocaine should be considered. The concomitant use of other local anaesthetic agents should also be considered since the systemic toxic effects may be additive. Care should be taken for patients with congenital methemoglobinemia and patients who are receiving concomitant treatment with methaemoglobin-inducing agents. In the case of athletes, the presence of lidocaine may produce a positive result in anti-doping tests.

Assembly of needle to syringe

- Use of the supplied 27G 1/2" sterile needle is recommended. Use of another needle could not ensure the correct fitting to the syringe and/or the correct delivery of the product.
- Remove the tip cap of the syringe.
- Grasp the hub.
- Press and turn the needle clockwise on the syringe until it is tight.
- Make sure that the hub of the needle is as tightly fixed to the bottom of the luer-lock as possible and remove the shield of the needle just before injection.
- Failure to comply with these precautions could cause disengagement of the needle and/or product leakage at luer-lock level.

Interactions

- Treatment with MAILI EXTREME in combination with drugs and other devices has not been clinically evaluated.
- Pre-treatment with a lidocaine solution is not required since the product already contains lidocaine.

Procedure of administration

Treatment with MAILI EXTREME is only intended to be administrated by an authorized healthcare professional in accordance with the local legislation.

The healthcare professional shall have a deep knowledge of the anatomy of the area to be treated and shall be used to perform similar intervention (i.e. cross-linked hyaluronic acid injection in the face area). MAILI EXTREME is to be used as supplied. Modification or use of the product outside of the instructions for use may adversely impact the sterility and/or the performance of the device.

A correct injection technique is important for the clinical outcome of the treatment. The injection technique varies depending on the treatment site, the depth of injection and the gel quantity to be injected.

- 1) Before starting treatment, the patient should be informed of the product's indications, contra-indications, precautions, warnings, expected results and potential adverse events and questioned on her/his medical history.
- 2) The injected area must be disinfected with an appropriate antiseptic solution.
- 3) Assemble the supplied sterile needle and syringe.
- 4) Do not apply extensive pressure to the syringe at any time. If such resistance is encountered, remove

and replace the needle and check for function.

5) MAILI EXTREME be administrated slowly in the tissues. The injection volume varies depending on the correction required. Do not overcorrect.

MAILI EXTREME is indicated for injection into the subcutaneous fat tissue or into the supraperiosteic zone.

6) For optimal clinical results, gentle massage by the healthcare professional of the treated area is recommended to ensure uniform distribution of the gel.

Adverse events

Healthcare professional shall inform the patients about potential adverse events related to the injection procedure and/or the use of the product MAILI EXTREME, occurring immediately after injection or after a delay.

Based on literature review on injectable hyaluronic acid gels and in agreement with the clinical data obtained with MAILI devices (clinical study 17E1176), based on the clinical trial data in domestic and globally, these adverse events include but are not limited to:

- Events which are naturally resolve within one week in most cases:
- Injection-related events and/or inflammatory reactions such as bleeding, ecchymosis, erythema, haematoma, skin redness, bruising, swelling, oedema and infection which may be associated with local pain or itching, occurring after injection.
- Sensitivity at the injection site.
- Hardness, lump or nodule at the injection site.
- Skin coloration or discoloration at the injection site.

- Events which are delayed after the injection:
- Immediate or delayed hypersensitivity to hyaluronic acid and/or to lidocaine.
- Nodule, abscesses or granuloma.
- Vascular compromise may occur due to inadvertent intravascular injection or as a result of vascular compression associated with implantation of any injectable soft tissue filler. This may manifest as blanching, discoloration, necrosis or ulceration at the implant site or in the area supplied by the blood vessels affected; or rarely as ischemic events in other organs due to embolization. Isolated rare cases of ischemic events affecting the eye leading to visual loss, and the brain resulting in cerebral infarction, following facial aesthetic treatments have been reported. These rare cases of vascular events are mostly reported in glabella, in and around the nose, in forehead and in periorbital area.
- Infection or reactivation of a previous infection.
- Displacement of the gel.

Inflammatory reactions which persist for more than one week, or any other adverse event which develops, must be reported by the patients to their healthcare professionals. In this case, if required, the healthcare professionals should use an appropriate treatment. Any adverse events and complications must be reported to the local representative of KYLANE LABORATOIRES.

Waste disposal

At the end of the session, opened and used syringe as well as all injection materials (e.g. needle) shall be discarded in respect of the medical practices and in accordance with the applicable regulations on waste disposal (e.g. specific waste container).

Storage conditions

- Shelf life of the product is indicated on each syringe and product must not be used after this date.
- Store between 2°C and 25°C away from direct sunlight. Keep container in the outer carton.
- Make sure there is no visible sign of damage to the packaging before use.

Manufactured by

Kylane Laboratoires SA
Chemin Pré-Fleuri 1-3
CH-1228 Plan-Les-Ouates
Switzerland

Product Name: Crosslinked Hyaluronan(HA) injectable gel with Lidocaine
Product Model: Maili Extreme
Specifications: 1ml/Syringe, 4 Syringes /Box
Medical Device Registration Certificate Number: 国械注进20253130026
Product Technical Requirements Number: 国械注进20253130026
Manufacturing Date: See original label
Use by date: See original label
Registrant name: Kylane Laboratoires SA
Address of Registrant: Chemin Pré-Fleuri 1-3, CH-1228 Plan-les-Ouates, Switzerland
Registrant Contact Information: +41 22 588 96 11
Manufacturing Site Name: SOTHEMA
Manufacturing Site / Plant Address: BP. N°1 Industrial area Bouskoura, 27182 Casablanca, Morocco
After-sales service unit /Agent Name: Sinclair (Hangzhou) Supply Chain Management Co., Ltd
After-sales service unit /Agent Address: Room 213, 2nd Floor, Building 7, No.161, 17th Street, Baiyang Street, Qiantang District, Hangzhou City, Zhejiang Province.
After-sales service unit /Agent Contact Information:
E-mail: Customerservice@SinclairAesthetics.com
Phone: +4008206181
Country of Origin: Morocco
The Revision date of IFU: 2025-03

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描述

MAILI EXTREME是一种基于生物发酵的无菌、透明、可吸收的含利多卡因注射用交联透明质酸钠凝胶。本产品装于塑料注射器中,仅供一次性使用。

MAILI EXTREME每支注射器容量为1 mL。

每盒装有四支带刻度的**MAILI EXTREME**预充注射器,一份说明书,一组可追溯性标签以及四根一次性无菌注射针: 27G 1/2"。每个注射器两个标签,一个给患者,另一个将添加至患者记录中。

MAILI EXTREME注射器的内容物经过湿热灭菌。27G 1/2"注射针经过辐照灭菌。

MAILI EXTREME旨在用于改善整个面部的解剖结构和/或缓解整个面部的生理变化过程。

结构组成

MAILI EXTREME

- 交联*透明质酸钠: 24 mg/mL
- 盐酸利多卡因-水合物: 3 mg/mL
- 磷酸盐缓冲液: q.s. 1 mL

一个注射器装有 1 mL **MAILI EXTREME**

本产品由预灌装注射器、一次性使用无菌不锈钢注射针和封装在注射器中的凝胶组成。凝胶由交联透明质酸钠、盐酸利多卡因、磷酸盐缓冲液组成,其中透明质酸钠由微生物发酵法制备。交联透明质酸钠的标示浓度为24mg/mL,盐酸利多卡因的标示含量为3 mg/mL。预灌装凝胶的注射器经湿热灭菌,注射针经伽马射线辐射灭菌。该产品为一次性使用。产品货架有效期为2年。

*透明质酸钠已与BDDE交联。

适用人群

Maili Extreme产品适用于18周岁及以上的成年人。

适用范围

Maili Extreme产品适用于注射到骨膜上,填充下颌区域,以改善轻度至中度下颌后缩患者的下颌轮廓。

作用方式

MAILI EXTREME通过填充面部组织,纠正面部解剖结构。**MAILI EXTREME**可随时间推移被完全吸收,其在注射部位的填充效应也会逐渐减弱。这种吸收的动力学取决于几个因素,其中包括注射量、注射深度和患者代谢。

在中国进行注册临床试验中,共有159名受试者接受下颌部注射Maili Extreme,其中大部分受试者治疗效果在主要终点(末次治疗后的6个月)仍被评估为改善,多数受试者在第12个月仍有持续作用。

禁忌证

- 已知对透明质酸钠或利多卡因或酰胺局部麻醉剂有超敏反应的患者禁止注射。
- 有严重过敏史或过敏性休克史的患者禁止注射。
- 患自身免疫性疾病的患者禁止注射。
- 患卟啉症的患者禁止注射。
- 在治疗部位或附近出现皮肤病、炎症或感染(疱疹、痤疮等)的患者禁止注射。
- 曾有药物过敏史可能会产生治疗反应的患者禁止注射。
- 患出血性疾病的患者或正在接受溶栓剂或抗凝剂治疗的患者禁止使用。
- 有形成瘢痕疙瘩、增生性瘢痕或任何其他愈合障碍倾向的患者禁止注射。
- 妊娠或哺乳期间禁止使用。
- 儿童禁止使用。
- 下颌畸形并伴有临床症状的患者禁止注射

警告

- 禁止注入血管(血管内)或血管附近(避免血管受压)。非预期血管内给药会导致血药浓度升高,进而引发急性中枢神经系统和心血管毒性症状。
- 禁止注入面部以外的区域(例如手、身体)。
- 禁止将**MAILI EXTREME**注入眶周区域(眼睑、脸颊沟、眼角鱼尾纹)和眉间区域。
- 将**MAILI EXTREME**注入皮下脂肪组织或骨膜上区域这一操作,仅能由专门接受过这些注射技术培训的专家完成。
- 禁止肌注。目前尚无将**MAILI EXTREME**注入已进行其他品牌可吸收产品治疗区域相关的临床数据。因此,建议避免在其他品牌的可吸收产品尚未完全吸收的区域注射。
- 禁止在同一区域进行本产品与其他品牌可吸收产品的联合注射。
- 禁止将本品与永久性产品联合注射。
- 禁止与其他产品混合。
- 禁止对产品进行二次灭菌(注射器和/或注射针)。
- 首次注射总剂量不超过4mL。如未达到最佳美学效果,可在首次注射4周后进行补充注射,补充注射的剂量不超过2mL。每年每名患者的注射量不得超过20 mL。
- 禁止过度灼正。
- 若过期或包装损坏或注射器开封,禁止使用。
- 禁止重复使用(有污染风险)。本产品仅供一次性使用。
- 禁止几名患者共用同一支注射器(有交叉污染风险)。
- 禁止与化学剥脱术、磨皮术、激光治疗或射频治疗同时使用。

使用注意事项

- 必须询问患者病史,并告知其预期疗效、警告、禁忌证、注意事项和潜在不良事件。
- 注射量取决于治疗区域和患者期望。期望不切实际的患者禁止接受治疗。
- 遵循无菌技术和操作规范。
- 注射器内容物在开封前是无菌的。注射器的外表面非无菌,不得在手术室等受控环境中使用。如有需要,必须根据现行的无菌技术来清洁注射器表面。
- 必须对使用影响血小板功能的药物(阿司匹林或非甾体类抗炎药物)的患者提出警告,注射期间血肿和出血风险可能会增加。
- 在脆弱结构(如血管和神经)附近的区域进行注射治疗时,必须特别谨慎。
- 建议患者在注射后两周内避免长时间暴露在太阳、紫外线和0°C以下的温度中以及避免桑拿或哈玛姆浴。
- 建议患者在注射治疗后12小时内避免使用化妆品(例如粉底、护肤品)。
- 建议患者在注射后几日内避免大力按压或按摩治疗部位。
- 医疗专业人员必须考虑到该产品含有多利多卡因。对于正常健康成人,每次使用利多卡因的最大总剂量不得超过200 mg。当同时用药(局部给药的情况下)时,应考虑到利多卡因的总给药剂量。还应考虑到同时使用其他局部麻醉剂的情况,因为可能导致累积,从而产生全身毒性作用。对于患先天性高铁血红蛋白血症的患者和正在接受可诱导高铁血红蛋白血症药物治疗的患者,应特别注意这一事项。对于运动员而言,利多卡因

可能导致反兴奋测试产生阳性结果。

装配注射针和注射器

- 建议使用所提供的27G 1/2"无菌注射针。使用其他注射针无法确保正确安装到注射器和/或正确输送产品。
- 取下注射器的针帽。
- 握住针座。
- 在注射器上下按注射针并顺时针转动,将其拧紧。
- 确保针座尽可能紧密地固定在鲁尔锁底部,并且仅在注射前取下针帽。
- 不遵守这些注意事项可能导致注射器与注射针未对准,和/或鲁尔锁区域出现产品泄漏。

交互作用

- **MAILI EXTREME**与药物和其他器械的联合治疗尚未经过临床评估。
- 由于产品已经含有利多卡因,因此不需要提前使用利多卡因进行预处理。

给药程序

MAILI EXTREME给药应仅由授权的医务人员按照当地法律进行。

医务人员应深入了解治疗区域的解剖结构,并基于相关知识进行操作(即面部注射交联透明质酸钠)。

使用时,**MAILI EXTREME**产品应处于原始状态。改动或超出使用说明书范围使用产品可能会对器械无菌性和/或性能产生不利影响。

正确的注射技术对于获得良好的临床治疗效果至关重要。注射技术因治疗部位、注射深度和凝胶注射量而异。

- 1)开始治疗前,应告知患者产品的适应症、禁忌证、注意事项、警告、预期结果和潜在不良事件,并询问其病史。
- 2)必须用适当的消毒液对注射部位消毒。
- 3)组装所提供的无菌注射针和注射器。
- 4)在任何时候,均禁止对注射器施加过大压力。如果遇到这种阻力,拆下并更换注射针,并检查其功能。
- 5)在组织中缓慢给药**MAILI EXTREME**。注射量因所需矫正容积而异。禁止过度矫正。

MAILI EXTREME适用于注入皮下脂肪组织或骨膜上区域。

6)为了获得最佳临床效果,建议由医务人员轻轻按摩治疗区域,以确保凝胶均匀分布。

不良事件

医务人员应告知患者与注射操作和/或**MAILI EXTREME**产品使用相关的注射后迟发或迟发潜在不良事件。

对注射透明质酸钠凝胶的文献进行分析,**MAILI EXTREME**不良事件临床数据与文献保持基本一致(临床研究17E1176),基于国内外临床研究数据,这些不良事件包括但不限于:

- 在大多数情况下,一周内自然消退的事件:
- 注射后发生的注射相关事件和/或炎症反应,如出血、瘀斑、红斑、血肿、皮肤发红、青肿、肿胀、水肿和感染(可能伴有局部疼痛或瘙痒)。
- 注射部位的过敏反应。
- 注射部位硬结、肿块或结节。
- 注射部位的皮肤着色或变色。

注射后迟发事件:

- 对透明质酸钠和/或利多卡因的速发型或迟发型超敏反应。
- 结节、脓肿或肉芽肿。
- 无意的血管内注射或与任何可注射的软组织填充剂植入相关的血管受压,可能会导致血管损伤。这可能表现为植入部位或受影响血管供血的区域发白、变色、坏死或溃疡;或者罕见情况下因栓塞而导致其他器官发生缺血事件。据报道,在面部美容治疗后,有出现影响眼部(导致视力丧失)和脑部(导致脑梗死)的缺血性事件的罕见个例。此类罕见的血管事件大都发生在眉间、鼻内和鼻周、前额和眶周区域。
- 感染或既往感染再复发。
- 凝胶移位。

如炎症反应持续超过一周或出现任何其他不良事件,患者必须告知医务人员。在这种情况下,如果需要,医务人员应采用适当的治疗措施。

如出现任何不良事件和并发症,必须向KYLANE LABORATOIRES的当地代表报告。

废弃物处理

治疗结束时,应根据医疗惯例和适用的废弃物处理条例(例如特定废弃物容器),丢弃开封并使用过的注射器以及所有注射材料(例如注射针)。

储存条件

- 每个注射器上都注明了产品有效期,应在有效期内使用。
- 储存在2°C-25°C下,避免阳光直射,储存期间,请勿拆除外箱。
- 使用前,确保包装无明显损坏迹象。

制造商

Kylane Laboratoires SA
Chemin Pré-Fleuri 1-3
CH-1228 Plan-Les-Ouates
Switzerland

产品名称:含利多卡因注射用交联透明质酸钠凝胶

产品型号:Maili Extreme

规格:1mL/支,4支/盒

医疗器械注册证编号:国械注进20253130026

产品技术要求编号:国械注进20253130026

生产日期:见产品标签

失效日期:见产品标签

注册人名称:Kylane Laboratoires SA 基兰实验室股份公司

注册人住所:Chemin Pré-Fleuri 1-3, CH-1228 Plan-les-Ouates, Switzerland

注册人联系电话:+41 22 588 96 11

生产企业名称:SOTHEMA

生产企业住所/生产地址:BP. N°1 Industrial area Bouskoura,

27182 Casablanca, Morocco

售后服务单位/代理人名称:欣可丽美学(杭州)供应链管理有限公司

售后服务单位/代理人住所:浙江省杭州市钱塘区白杨街道17号

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原产国:摩洛哥

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