REJURAN®

| 멸균의료기기 | 재사용금지 | 일회용 | 허가번호 : 제허 14-825호 |

·제품명: 리쥬란(Rejuran), 리쥬란 아이(Rejuran i), 리쥬란 에스(Rejuran s)
·모델명 : 리쥬란(Rejuran), 리쥬란 아이(Rejuran i), 리쥬란 에스(Rejuran s), M2-001, M2-002, M2-003
·품목명 : 조직수복용생체재료
·사용목적 : 성인의 안면부 주름을 일시적으로 개선하기 위해 사용
·사용방법
가. 사용 전 준비사항
1) 사용 전에 포장의 손상 여부를 확인하고, 손상이 있는 경우 사용하지 않습니다.
2) 라벨의 사용기한을 확인하고, 사용기간이 지난 것은 사용하지 않습니다.
3) 의사가 아닌 사람이 사용해서는 안 됩니다.
4) 주입 전에 본 품을 실온에 두십시오.
5) 시술 테크닉이 치료 성공에 필수적이므로, 본 시술에 대해 능숙한 의사가 사용 하도록 합니다.
6) 치료 전에 환자에게 제품의 적응증, 금기, 부적합성 및 부작용에 대해 숙지 시킵니다.
나. 조작방법
1) 주사기가 들어 있는 포장을 개봉합니다.
2) 주사기 마개를 천천히 제거합니다.
3) 주사기에 제공된 주사침을 결합한 후, 주사침 보호용 뚜껑을 수평으로 잡아 뺍니다.
4) 주입 전에 적용 부위를 철저히 소독을 합니다.
5) 주입액을 서서히 피부에 주입하십시오, 주입하는 양은 적용하는 범위에 따라 다릅니다.
6) 주사침이 잘 들어가지 않으면 강제로 밀어 넣지 말고, 빼서 다른 부위에 적용하십시오.
7) 내용물을 주입한 후 고르게 분포되도록 시술 부위를 마사지 합니다.
다. 사용 후의 보관 및 관리 방법
1) 1회 사용에 한하며, 재사용해서는 안 됩니다.
2) 재멸균하여 사용하지 않습니다.
3) 사용이 끝난 주사기와 주사침은 의료용폐기물로서 관련규정에 따라 폐기처분 합니다.
·사용시 주의사항
1. 금기
1) 재흡수가 되지 않는 필러로 치료를 받거나, 최근에 필러로 치료를 받은 부위에는 사용하지 않는다.
2) NSAIDs, 응집억제제, 항응고제, 면역억제제등을 투여 받고 있는 환자
3) 알러지성 질환, 자가면역질환, 사르코이드성 육아종성 병리, Oslers내막염 환자
4) 혈관 내에 주사하지 않는다.
5) 과다사용하지 않는다.
6) 제품의 구성성분(폴리뉴클레오티드나트륨)에 대하여 과민증이 있는 자
7) 임신부, 수유부
8) 본 제품은 성인의 안면부 주름을 일시적으로 개선하기 위해 사용하는 제품으로, 미성년자에게 사용을 금지한다.
9) 염증이나 감염 등 손상된 피부에 사용하지 않는다
2. 경고
1) 사용 전에 포장의 손상 여부를 확인하고, 손상이 있는 경우 사용하지 않는다.
2) 라벨의 사용기한을 확인하고, 사용기간이 지난 것은 사용하지 않는다.
3) 재사용하지 않는다.
4) 재멸균하여 사용하지 않는다.
5) 사용한 제품은 관련규정에 따라 폐기처분한다.
3. 부작용
의사는 이 의료기기의 사용과 관련하여 환자에게 나타날 수 있는 중장기 부작용에 대해 환자에게 숙지시켜야 한다.
1) 주입 부위에 압력을 가하면 염증(발적, 부종, 홍반)이 가려움이나 통증과 함께 나타날 수 있다. 이러한 반응은 1주일 정도 지속 될 수 있다.
2) 주입 부위 결절 또는 경화, 주입 부위의 변색, 치료 효과 결핍이 나타날 수 있다.
3) 1주일 이상 염증이 지속되거나 알려진 종류 이외의 다른 부작용이 발생하면 가능한 신속히 의사의 진찰을 받도록 환자에게 숙지시킨다. 의사는 적절한 치료를 실시해야 한다.
4) 알려진 종류 이외의 다른 부작용은 제조업체나 판매업체에 보고해야 한다.
4. 일반적 주의사항
1) 주사 후 12시간 동안 화장을 피하고, 2주 동안 태양, UV광선, 추위 또는 열 (사우나, 증기룸 등)에 장기 노출을 피해야 한다.
2) 본 제품의 시술에 대해 충분한 훈련을 받은 의사가 시술하여야 한다.
3) 시술 전 의사는 환자에게 본 제품의 적응증, 금기사항, 잠재적 부작용에 대해 충분히 설명해야 한다.
4) 사용 전 멸균 상태가 손상되지 않았는지 확인한다.
5) 제품 라벨상의 유효기간을 확인한다.
6) 혈관폐쇄(이로인한 조직괴사)가 발생할 가능성이 있는 혈관에서 사용을 피한다.
7) 감염 및 염증이 제어되거나 해결될 때 까지 사용하지 말아야 한다.
8) 입술확대술에 대한 안전성, 유효성은 확립되어 있지 않다.
9) 포진성 발진이 있었던 환자에 대한 주사는 포진성이 재발할 수 있다.
10) 켈로이드형성, 과색소침착, 비후성반흔에 감수성이 있는 환자에 대한 안전성은 확립되어 있지 않다.

임상연구를 통하여 밝혀진 기간 이외의 장기간 사용에 대한 안전성, 유효성은 확인 되지 않았다.

·사용기한 : 제조일로부터 24개월
·보관 또는 저장방법 : 실온 (1~30 °C), 차광 보관
· 중량 또는 포장단위 : 리쥬란(Rejuran, M2-001) : 2 syringe/box
리쥬란 아이(Rejuran i, M2-002), 리쥬란 에스(Rejuran s, M2-003) : 1 syringe/box
·제조업자 : ㈜파마리서치, 강원특별자치도 강릉시 과학단지로 77-19(대전동)
·고객상담실 : 031-8039-1500
·부작용 보고 관련 문의처 : 한국의료기기안전정보원, 080-080-4183
·첨부문서의 작성연월 : 2024년 12월

PharmaResearch

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REJURAN®

滅菌医療機器 | 再利用禁止 | 使い捨て | 許可番号：第14-825号

■**製品名：**リジュラン(Rejuran)、リジュラン・アイ(Rejuran i)、リジュラン・エス(Rejuran s)
■**モデル名：**リジュラン(Rejuran)、リジュラン・アイ(Rejuran i)、リジュラン・エス(Rejuran s)、M2-001、M2-002、M2-003、M2-005
■**品目名：**組織修復用生体材料
■**使用目的：**大人の顔にできたシワの一時的な改善
■**使い方**
ア　使用前の注意事項
1) 使用する前にパッケージの破損有無を確認し、破損された場合は使用しないでください。
2) ラベルに記載されている使用期限を確認し、使用期限が切れた場合は使用しないでください。
3) この製品を患者(対象者)に使用できるのは医者だけです。
4) 本製品は対象者に注射する前は室温で保管してください。
5) 施術には高度の技術が必要なため、必ず専門の医者から施術を受けるようにしてください。
6) 施術前に患者に施術を受けた後の適応症、禁止事項、不適合性及び副作用について説明し、患者が熟知するようにしてください。
イ　使い方
1) 注射器が入っているパッケージを開封してください。
2) 注射器の蓋を外してください。
3) 注射器と一緒に提供された注射針を注射器につけます。その後、注射針を保護するために付けられている蓋を水平に引いて外してください。
4) 注射する前に注射する部位をしっかり消毒してください。
5) 肌に注射してください。この際、ゆっくり注入されるようにしてください。注入量は適用範囲によって異なります。
6) 注射針を刺しにくい場合、強引に注射しないでください。別の部位に注射してください。
7) 注射し、注入が終わったら効果が広がるように施術した部位をマッサージしてください。
ウ　使用後の廃棄方法
1) この製品は使い捨てです。再使用しないでください。
2) 再滅菌して使用しないでください。
3) 使用した注射器と注射針は医療廃棄物です。関連規定に従って廃棄してください

■**使用時の注意事項**
1. 禁止事項
1) 再吸収されないフィラーで治療を受けた部位や最近フィラーで治療を受けた部位には使用しないでください。
2) NSAIDs、凝集抑制剤、抗凝固剤、免疫抑制剤を投与されている患者には使用しないでください。
3) アレルギー性疾患、自己免疫疾患、サルコイドーシスのような肉芽腫性病変、オスラー結節(感染性心内膜炎)を患っている患者には使用しないでください。
4) 血管に注射しないでください。
5) 乱用しないでください。
6) 製品の成分(ポリヌクレオチドナトリウム)に対し、過敏症の症状が起こる者
7) 妊婦、授乳婦
8) 本製品は大人の顔にできたシワを一時的に改善するために使う製品です。未成年者には使用しないでください。
9) 炎症や感染などが発生、また傷がある部位(肌)には使用しないでください。
2. 警告事項
1) 使用する前にパッケージの破損有無を確認し、破損された場合は使用しないでください。
2) ラベルに記載されている使用期限を確認し、使用期限が切れた場合は使用しないでください。
3) 再使用しないでください。
4) 再滅菌して使用しないでください。
5) 使用した製品は関連規定に従って廃棄してください。
3. 副作用に関する注意事項
医者はこの医療機器(本製品)の使用に関し、使用した後に患者に発生する可能性がある中長期的な副作用について患者が熟知するようにしなければなりません。
1) 注入した部位に圧力がかかると、痒みや痛症が炎症(発赤、浮腫(むくみ)、紅斑)と同時に発生する可能性があります。この症状は一週間ほど続く場合があります。
2) 注入した部位に結節や硬化、変色が発生する可能性があります。また治療効果が肉眼で確認できるぐらいには表れない可能性があります。
3) 一週間以上炎症が続く、また上記1)、2)の症状以外の副作用が発生した場合、できる限り速やかに医者の診察を受けるように患者に熟知させてください。(医者は適切に治療を行わなければなりません。)
4) 上記1)、2)の症状以外の副作用が発生した場合、その症状について医療機器(本製品)のメーカーまた販売業者に報告してください
4. 一般的な注意事項
1) 注入した後12時間は化粧しないでください。また二週間直射日光、UV光線(紫外線)、寒い環境や暑い環境に長時間さらされないようにしてください。
2) 本製品は施術の訓練を十分に受けた医者が施術しなければなりません。
3) 施術する前、医者は患者に本製品の使用に関する禁止事項、本製品を使用した後に発生する可能性がある適応症や潜在的に発生する可能性がある副作用について十分に説明しなければなりません。
4) 使用する前に滅菌状態に異常がないか確認してください。
5) 製品に付けられているラベルの有効期限を確認してください。
6) 血管閉塞(血管閉塞による組織壊死)が発生する可能性がある血管に注射しないでください。
7) 感染や炎症をコントロール可能、または完全に治療できるまでは本製品を使用しないでください。
8) 口唇拡大術の安全性、有効性は確立されていません。
9) 疱疹状皮膚炎が発生した病歴がある患者に注射した場合、疱疹状皮膚炎が再発する可能性があります。
10) ケロイド、過色素沈着、肥厚性瘢痕に対する感受性がある患者の安全性は確立されていません。

臨床研究によって把握した期間以外の長期間使用の安全性、有効性は確立されていません。

■**使用期限：**製造日から24カ月
■**保管方法：**室温 (1～30℃)、遮光保管
■**重量、パッケージング単位**
リジュラン(Rejuran、M2-001、M2-005)：2 syringe/box
リジュラン・アイ(Rejuran i、M2-002)、リジュラン・エス(Rejuran s、M2-003)：1 syringe/box
■**メーカー(製造業者)、住所：**(株)ファマリサーチ(PharmaResearch)、江原特別自治道江陵市科学団地路77-19(大田洞)
■**カスタマーセンター：**+82-031-8039-1500
■**副作用報告関連問い合わせ先：**韓国医療機器安全情報院、+82-080-080-4183
■**添付文書作成日：**2025年 4月

无菌医疗器械 | 禁止重复使用 | 一次性 | 许可编号：制造许可 第14-825号

■**产品名称：**丽珠兰 (Rejuran)、丽珠兰 i (Rejuran i)、丽珠兰 s (Rejuran s)
■**型号名称：**丽珠兰 (Rejuran)、丽珠兰 i (Rejuran i)、丽珠兰 s (Rejuran s)、M2-001、M2-002、M2-003、M2-005
■**产品类别名称：**组织修复用生物材料
■**预期用途：**用于成人面部皱纹的暂时性改善
■**使用方法**
一、使用前准备事项
1) 使用前请检查包装是否完好，如发现包装破损，请勿使用。
2) 请确认产品标签所示的有效期，请勿使用过期产品。
3) 本产品仅限专业医疗人员操作，非医生不得使用。
4) 注射前请将本产品置于室温环境中。
5) 施术技术对治疗效果至关重要，应由熟练掌握本施术的专业医生进行操作。
6) 治疗前应向患者充分说明本产品的适应症、禁忌事项、不适合性及不良反应。
二、操作方法
1) 打开包含注射器的包装。
2) 缓缓取下注射器保护盖。
3) 连接注射器与配套注射针头，水平取下针头保护套。
4) 注射前，对注射部位进行彻底消毒。
5) 将注射液缓慢注入皮肤，注射剂量依据适用范围而异。
6) 如针头无法顺利插入，请勿强行推进，应更换注射部位后重新注射。
7) 注射后可轻柔按摩施术部位，以促使药液均匀分布。
三、使用后的保管与处理方法
1) 本产品为一次性使用产品，严禁重复使用。
2) 禁止再次灭菌后重复使用。
3) 使用完毕的注射器与针头应作为医疗废弃物，依据相关规定进行废弃处置。
■**使用注意事项**
1. 禁忌事项
1) 禁止用于曾接受不可吸收性填充剂治疗，或近期接受过其他填充治疗的部位。
2) 禁止用于正在接受非甾体抗炎药 (NSAIDs)、凝集抑制剂、抗凝药或免疫抑制剂治疗的患者。
3) 禁止用于具有过敏性疾病、自身免疫性疾病、类肉瘤性肉芽肿性病变或Oslers内膜炎的患者。
4) 禁止注射入血管内。
5) 禁止过量使用。
6) 禁止用于对本产品成分 (多核苷酸钠) 过敏者。
7) 禁止用于孕妇及哺乳期妇女。
8) 本产品仅用于成人面部皱纹的暂时性改善，禁止用于未成年人。
9) 禁止用于存在炎症、感染等症状的受损皮肤。
2. 警告事项
1) 使用前请检查包装是否完好，如发现包装破损，请勿使用。
2) 请确认产品标签所示的有效期，请勿使用过期产品。
3) 禁止重复使用。
4) 禁止再次灭菌后重复使用。
5) 使用后的产品应依据相关规定妥善废弃处置。
3. 不良反应
医生在使用本医疗器械前，应向患者充分说明可能出现的中长期不良反应，以便其知情同意。
1) 在注射部位施加压力后，可能出现炎症反应 (红肿、肿胀、红斑)，并伴随瘙痒或疼痛等症状。此类反应可能持续约1周时间。
2) 注射部位可能出现结节、硬化、变色，或治疗效果不佳等现象。
3) 如炎症反应持续超过1周，或出现已知类型以外的其他不良反应，应及时就医，由医生进行评估并采取适当治疗。
4) 对于已知类型以外的其他不良反应，应及时向制造商或销售商报告。
4. 一般注意事项
1) 注射后12小时内应避免化妆，并在2周内避免长时间暴露于阳光、紫外线、寒冷或高温环境 (如桑拿、蒸汽房等)。
2) 本产品应由接受过本产品施术相关充分培训的医生进行操作。
3) 施术前，医生应向患者充分说明本产品的适应症、禁忌事项以及潜在不良反应。
4) 使用前应确认产品的无菌状态是否破损。
5) 请检查产品标签上所标注的有效期。
6) 避免在可能导致血管闭塞 (从而引发组织坏死) 的血管区域使用。
7) 在感染或炎症被控制或消退前，不得使用本产品。
8) 本产品用于丰唇术的安全性与有效性尚未确立。
9) 对曾有疱疹性皮疹病史的患者，注射后可能引发疱疹复发。
10) 对具有瘢痕疙瘩形成倾向、色素沉着倾向或肥厚性瘢痕倾向者的安全性尚未确立。

超出临床研究所确立使用周期的长期使用，其安全性和有效性尚未验证。

■**有效期：**自生产日期起24个月
■**保管或贮存方法：**常温保存 (1~30°C)，遮光存放
■**重量或包装单位：**丽珠兰 (Rejuran，M2-001，M2-005)：2支/盒
丽珠兰 i (Rejuran i，M2-002)、丽珠兰 s (Rejuran s，M2-003)：1支/盒
■**生产企业：**(株) PharmaResearch，江原特别自治道江陵市科学园区路77-19 (大田洞)
■**客户咨询室：**031-8039-1500
■**不良反应报告及咨询机构：**韩国医疗器械安全信息院，080-080-4183
■**附件编制日期：**2025年 4月

Sterile Medical Device | Do Not Reuse | Single Use Only | Approval Number: KFDA No. 14-825

■**Name of product :** Rejuran, Rejuran i, and Rejuran s
■**Model name :** Rejuran, Rejuran i, Rejuran s, M2-001, M2-002, M2-003, M2-005
■**Product Category :** Graft/prosthesis, biomaterial
■**Intended Use :** For the temporary improvement of facial wrinkles in adults
■**Instruction for Use**
A. Preparation of Before Use
1) Check the package for any damage before use, and do not use the product if the package is found to be damaged.
2) Check the expiry date on the label and do not use if expired.
3) This product must only be used by licensed physicians or medical professionals trained in injection procedures.
4) Bring the product to room temperature before use.
5) Proper injection technique is essential for successful results. The procedure must be performed by a skilled physician.
6) Before treatment, the patient must be fully informed about the indications, contraindications, precautions, and potential side effects.
B. Instruction for Use
1) Open the pouch and take out the syringe.
2) Remove the cap slowly from the syringe
3) Attach the needle to the syringe and remove the needle cap by pulling it straight off.
4) Thoroughly disinfect the injection site prior to injection.
5) Slowly inject the solution into the skin. The injection volume may vary depending on the treatment area.
6) If the needle does not penetrate easily, do not force it. Instead, withdraw the needle and inject into another site.
7) After the injection, gently massage the treated area to help evenly distribute the product.
C. Post-Treatment Handling
1) For single use only. Do not reuse.
2) Do not re-sterilize.
3) Dispose of the used syringe and needle in accordance with applicable regulations for medical waste.
■**Precautions for Use**
1. Contraindication
1) Do not use in patients with a history of non-absorbable filler use or recent treatment with other dermal fillers.
2) Patients currently taking NSAIDs, antiplatelet agents, anticoagulants, or immunosuppressants.
3) Patients with allergic or autoimmune diseases, sarcoid-type granulomatous conditions, or Osler's endocarditis.
4) Do not inject into blood vessels.
5) Do not overuse.
6) Patients with known hypersensitivity to any of the ingredients, including Sodium Polynucleotide.
7) Pregnant and lactating women.
8) This product is intended for the temporary improvement of facial wrinkles in adults and must not be used in children or adolescents.
9) Do not use on areas of skin damaged by inflammation or infection.
2. Warnings
1) Check the package for any damage before use, and do not use the product if the package is found to be damaged.
2) Check the expiry date on the label and do not use if expired.
3) Do not reuse.
4) Do not re-sterilize.
5) Dispose of the used product in accordance with the relevant regulations.
3. Adverse events
The physician must inform the patient in advance about potential mid- to long-term adverse events that may arise in relation to the use of this medical device.
1) Applying pressure to the injection site may cause inflammation—such as erythema, swelling, or redness—accompanied by itching or pain. These symptoms may persist for approximately one week.
2) Nodules or induration at the injection site, skin discoloration, or lack of therapeutic effect may occur.
3) If inflammation continues for more than one week, or if adverse events other than those already known occur, the patient should be instructed to seek prompt medical consultation. The physician must provide appropriate treatment based on the patient's condition.
4) Any adverse events not previously identified must be reported to the manufacturer or distributor.
4. General precaution
1) The patient should avoid wearing makeup for 12 hours after injection and should avoid prolonged exposure to sunlight, UV rays, cold, or heat (e.g., saunas, steam rooms, etc.) for two weeks.
2) The procedure must be performed by a physician who has received sufficient training in the use of this product.
3) Prior to treatment, the physician must fully explain the product's indications, contraindications, and potential adverse effects to the patient.
4) Before use, check that the sterile condition of the product has not been compromised.
5) Check the expiration date on the product label prior to use.
6) Do not use this product in blood vessels where there is a risk of vascular occlusion, which may lead to tissue necrosis.
7) Do not use the product until any infection or inflammation in the intended treatment area has been controlled or resolved.
8) The safety and efficacy of this product for lip augmentation have not been established.
9) Injection in patients with a history of herpetic rash may trigger a recurrence of herpetic dermatitis.
10) The safety and efficacy of this product have not been established for patients who are prone to keloid formation, hyperpigmentation, or hypertrophic scarring.

The safety and efficacy of long-term use beyond the period demonstrated in clinical studies have not been established.

■**Shelf life :** 24 months from the date of manufacture
■**Storage or Preservation Method :** Store at room temperature (1-30°C); protect from light.
■**Weight or Packing Unit :** Rejuran (M2-001, M2-005): 2 syringes/box
Rejuran i (M2-002), Rejuran s (M2-003): 1 syringe/box
■**Manufacturer :** PharmaResearch Co., Ltd. 77-19, Gwahakdanji-ro, Gangneung-si, Gangwon State, Korea
■**Customer Service :** +82-31-8039-1500
■**Adverse Event Reporting Contact :** National Institute of Medical Device Safety Information, 080-080-4183
■**Date of Document Preparation :** April, 2025

PharmaResearch

REJURAN®

ENG_General

1. Product name
REJURAN, REJURAN i, REJURAN s
Injectable Dermal Filler

2. Category
Graft/prosthesis, biomaterial

3. Intended purpose
REJURAN, REJURAN i and REJURAN s are the injectable gel which are intended for injection into the mid to deep dermis to promote tissue restoration and reconstruction, and improvement of physical appearance. It is highly versatile and easy to handle and can be used on areas of the skin: face (especially around the eyes, perioral area), neck, Décolleté, hands, and other areas. Only physician is allowed to use these medical device.

REJURAN, REJURAN i and REJURAN s are prohibited to child, adolescent, and pregnant and lactating women.

4. Instruction for Use
1) Preparation before use
(1) Do not use if package is opened or damaged.
(2) Check the expiration date printed on the package prior to use and do not use the expired product.
(3) Only physicians are allowed to use this medical device.
(4) Keep at room temperature before use
(5) Since administration technique is essential for the good result, skilled physicians must perform this treatment.
(6) Prior to treatment, the patients should be fully informed of indications, contraindications, precautions, and adverse reactions.
2) Instruction for use
(1) Open the pouch and take out the syringe.
(2) Remove the cap slowly from the syringe
(3) The syringe can then be twisted onto the Luer-lock fitting of the needle. The needle must be tightened securely to the syringe and primed with the product.
(4) Pull the needle cap to opposite direction to be removed.
(5) Prior to injection, ensure the disinfection of the application area.
(6) Inject slowly the injectable solution into dermis, the injection volume can be varied depending on the application area.
(7) If needling is difficult, do not increase the pressure on the plunger rod, instead, apply into another site.
(8) After treatment, massage skin to spread evenly.
3) Post treatment guideline
(1) Single use only. Do not reuse.
(2) The product is for single use, do not re-sterilize.
(3) Dispose the syringe and needle according to relative regulation for medical waste.

5. Precaution
1) Contraindication
(1) As with all transcutaneous procedures, the injectable product carries a risk of infection. Standard precautions to minimize infections associated with intradermal injectable materials should be followed.
(2) In order to minimize the risks of potential complications, this product should only be used by health care practitioners who have appropriate training, experience, and who are knowledgeable about the anatomy at and around the site of injection.
(3) Do not apply to the sites injected with un-absorbable filler or recently treated with other fillers.
(4) Patients taking NSAIDs, platelet aggregation inhibitors, anticoagulants and immunosuppressant.
(5) Patients with allergic disease, autoimmune disease, sarcoidosic granulomatous pathology and Osler's endocarditis.
(6) Must not be implanted into blood vessels.
(7) Do not overuse.
(8) Patients with hypersensitivity to product ingredient (Sodium Polynucleotide).
(9) Pregnant and lactating women.
(10) Child and adolescent.
(11) Do not use on specific sites of skin, which is damaged by inflammation or infection.
2) Warning
(1) Do not use if package is opened or damaged. Once the product has been opened, the sterility is not guaranteed which could cause infection.
(2) Check the expiration date printed on the package prior to use and do not use the expired products.
(3) Do not reuse. Reuse of such a device would present a risk to the public health.
(4) The product is for single use, do not re-sterilize.
(5) It is prohibited for half use and another injection at separate set. The sterility is not guaranteed which could cause infection.
(6) Dispose according to relative regulation.
3) Adverse events
(1) Patients should be fully informed by a physician about mid-long term adverse events could be occurred.
(2) When the pressure is applied to the injection site, inflammation (erythema, edema) with itching or pain can be appeared. And this reaction may continue for a week.
(3) Nodules or sclerosis and discoloration of injection site and deficiency of treatment effect may occur.
(4) Patients should take immediate checkup with physicians if inflammation is prolonged more than one week and unknown adverse events appears. In this case, the physicians should give optimized treatment to patients.
(5) In case of unknown adverse events, must be reported to the manufacturer or supplier.
4) General Precaution
(1) Patients should avoid make-up for 12 hours after injection and sun, UV ray, coldness and heat exposure (sauna, evaporation room etc.) for 2 weeks.
(2) This product should be performed by fully trained physicians.
(3) Prior to treatment, patients should be fully informed of indications, contraindications, precautions, and adverse events by physician.
(4) Before use, the sterilization condition must be checked.
(5) Before use, the expiration date labeled on the product must be checked.
(6) Should avoid implanting into the blood vessel which could cause infarction(tissue necrosis).
(7) The product must not be used until the infection and infarction(tissue necrosis) is controlled or settled.
(8) The safety and efficacy for lip augmentation have not been established.
(9) Injection on patient with a history of herpetic rash can cause recurrent herpetic dermatitis.
(10) The safety and efficacy for patient who are sensitive in keloid formation, hyperpigmentation, hypertrophic scar have not been established.
(11) After use, syringes and needles should be handled as potential biohazards. Disposal should be in accordance with accepted medical practice and applicable local, state and federal requirements.

The safety and efficacy of long term use are not ensured beside the period, which is proofed through clinical studies.

6. Storage Condition
Store at room temperature (1~30°C), protect from sunlight

7. Shelf Life
24 months

8. Packing unit
REJURAN: 2mL syringe + 2 needles (33G), 2 blisters/box
REJURAN i: 1mL syringe + 1 needle (34G), 1 blister/box (white color)
REJURAN s: 1mL syringe + 1 needle (30G), 1 blister/box (blue color)
CE certified needles are used (CE0068)

PharmaResearch Co., Ltd.
77-19, Gwahakdanji-ro, Gangneung-si, Gangwon-do, 25452, Korea
Product Inquiry +82-31-8039-1500

PharmaResearch

REJURAN®

Thailand

1. Product name
REJURAN, REJURAN i, REJURAN s
Injectable Dermal Filler

2. Model name
REJURAN-001, REJURAN i-002, REJURAN s-003

3. Intended purpose
REJURAN-001, REJURAN i-002 and REJURAN s-003 are the injectable gel which are intended for injection into the mid to deep dermis to promote tissue restoration and reconstruction, and improvement of physical appearance. It is highly versatile and easy to handle and can be used on areas of the skin: face (especially around the eyes, perioral area), neck, Décolleté, hands, and other areas. Only physician is allowed to use these medical device.

REJURAN-001, REJURAN i-002 and REJURAN s-003 are prohibited to child, adolescent, pregnant and lactating women.

4. Instruction for Use
1) Preparation before use
(1) Do not use if package is opened or damaged.
(2) Check the expiration date printed on the package prior to use and do not use the expired product.
(3) Only physicians are allowed to use this medical device.
(4) Keep at room temperature before use
(5) Since administration technique is essential for the good result, skilled physicians must perform this treatment.
(6) Prior to treatment, the patients should be fully informed of indications, contraindications, precautions, and adverse reactions.
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(2) Remove the cap slowly from the syringe
(3) The syringe can then be twisted onto the Luer-lock fitting of the needle. The needle must be tightened securely to the syringe and primed with the product.
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(8) After treatment, massage skin to spread evenly.
3) Post treatment guideline
(1) Single use only. Do not reuse.
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(3) Dispose the syringe and needle according to relative regulation for medical waste.

5. Precaution
1) Contraindication
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(2) In order to minimize the risks of potential complications, this product should only be used by health care practitioners who have appropriate training, experience, and who are knowledgeable about the anatomy at and around the site of injection.
(3) Do not apply to the sites injected with un-absorbable filler or recently treated with other fillers.
(4) Patients taking NSAIDs, platelet aggregation inhibitors, anticoagulants and immunosuppressant.
(5) Patients with allergic disease, autoimmune disease, sarcoidosic granulomatous pathology and Osler's endocarditis.
(6) Must not be implanted into blood vessels.
(7) Do not overuse.
(8) Patients with hypersensitivity to product ingredient (Sodium Polynucleotide).
(9) Pregnant and lactating women.
(10) Child and adolescent.
(11) Do not use on specific sites of skin, which is damaged by inflammation or infection.
2) Warning
(1) Do not use if package is opened or damaged. Once the product has been opened, the sterility is not guaranteed which could cause infection.
(2) Check the expiration date printed on the package prior to use and do not use the expired products.
(3) Do not reuse. Reuse of such a device would present a risk to the public health.
(4) The product is for single use, do not re-sterilize.
(5) It is prohibited for half use and another injection at separate set. The sterility is not guaranteed which could cause infection.
(6) Dispose according to relative regulation.
3) Adverse events
(1) Patients should be fully informed by a physician about mid-long term adverse events could be occurred.
(2) When the pressure is applied to the injection site, inflammation (erythema, edema) with itching or pain can be appeared. And this reaction may continue for a week.
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(4) Before use, the sterilization condition must be checked.
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(7) The product must not be used until the infection and infarction(tissue necrosis) is controlled or settled.
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The safety and efficacy of long term use are not ensured beside the period, which is proofed through clinical studies.

6. Storage Condition
Store at room temperature (1~30°C), protect from sunlight

7. Shelf Life
24 months

8. Packing unit
REJURAN-001: 2 ml 1 syringe + 2 needles (33G)/1 blister, 2 blisters/box
REJURAN i-002: 1 ml 1 syringe + 1 needle (34G)/1 blister, 1 blister/box
REJURAN s-003: 1 ml 1 syringe + 1 needle (30G)/1 blister, 1 blister/box
CE certified needles are used (CE0068)

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SYMBOL

No.	Symbol	Title
1	LOT	Batch code
2		Use by
3		Manufacturer
4		Do not re-use
5		Keep away from sunlight
6		Do not use if package is damaged
7	30°C 1°C	Temperature limitation
8	STERILE	Sterile using steam or dry heat
9		Consult instructions for use
10	STERILIZE	Do not resterilize
11		Caution, consult accompanying documents
12		Fragile
13	STERILE EO	Sterilized using ethylene oxide (Only needle)

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