



GUSELKUMAB

Information leaflet

1. What is guselkumab and how does it work?

Guselkumab (Tremfya®) is a biologic medicine which targets a chemical messenger known as a cytokine called interleukin-23 (IL-23). IL-23 is one of the main causes of inflammation in psoriasis.

2. What skin conditions are treated with guselkumab?

- Psoriasis

3. How long will I need to take guselkumab before it has an effect?

Some improvement may be seen in the first few weeks of treatment, but it can take 4 months to see the full benefit.

4. How do I take guselkumab?

Guselkumab is given as an injection under your skin (subcutaneous) using a pre-filled pen device. Injections can be performed on the stomach, thighs or upper outer arms. One injection is used for the first dose and then the second dose is injected 4 weeks later. After this, injections should be performed once every 8 weeks. Guselkumab must be stored in a refrigerator between 2 to 8°C. When travelling, guselkumab must be kept in a cool box/bag with icepacks. Once guselkumab has been removed from the refrigerator and has reached room temperature (up to 25°C), it must either be used or discarded.

5. What are the possible side effects of guselkumab?

a. Mild

- Reaction at the injection site: redness, rash, swelling, itching, bruising
- Cold and flu symptoms, sore throat
- Gastroenteritis, diarrhoea
- Mild fungal infections, e.g. athlete's foot
- Cold sores (herpes simplex)
- Headache, rash, hives (urticaria)
- Aching joints

b. Potentially severe

- Serious infections
- Allergic reaction (rare)

6. What happens before starting treatment?

You will have a consultation with your dermatologist, including a clinical examination, blood tests and a chest X-ray. You will be asked about:

- Tuberculosis, or close contact with someone who has it
- Hepatitis or HIV infection, or if you think you are at risk
- Infection (e.g. cold sores, urinary tract infections)
- Cancer
- Vaccination history
- If you are scheduled to have major surgery
- If you are pregnant, planning to become pregnant or breastfeeding

7. How will I be monitored while I am taking guselkumab?

You will be asked about side effects and have blood tests from time to time (e.g. every 6 months) at your clinic appointments. Inform your doctor about:

- Changes to medications
- Planned procedures and surgery
- Infection or symptom/sign of infection that does not go away: fever, lethargy, cough, influenza-like symptoms, burning on passing urine, dental problems, night sweats. Your doctor may suggest stopping guselkumab temporarily.
- Bruising, easy bleeding, look pale
- Signs of severe allergic reaction (anaphylaxis): swollen face/tongue, throat tightness, difficulty breathing. Please dial 999 for an ambulance immediately and go to the nearest hospital Accident and Emergency department. You should inform your dermatologist afterwards.

8. What precautions should I take?

- a. Avoid close contact with anyone who has a bad cold, influenza or chest infection.
- b. Wash hands frequently while on guselkumab.
- c. Discuss with your doctor prior to surgery as you may be advised to stop guselkumab prior to the surgery due to the increased risk of infection afterwards.
- d. Avoid pregnancy and breastfeeding. Discuss with your doctor if you are pregnant or planning to become pregnant.
- e. Discuss with your doctor if you are planning to travel abroad. Depending on where you are travelling, precautions may be needed against infections.
- f. While on guselkumab, you should not be given any 'live' vaccines (e.g. flu vaccine administered through the nose, measles, mumps and rubella (MMR), yellow fever, BCG, rotavirus, oral typhoid, chickenpox and shingles). If you require a live vaccine, guselkumab should be stopped at least 12 weeks before (12 months in the case of shingles vaccine) and until 2 weeks after the vaccination.



GUSELKUMAB (古塞库单抗)

Information leaflet

1. 什么是古塞库单抗及其作用原理？

古塞库单抗（Tremfya®）是一种生物制剂，靶向一种名为白细胞介素-23（IL-23）的细胞因子。IL-23是银屑病炎症的主要原因之一。

2. 古塞库单抗治疗哪些皮肤病？

- 银屑病

3. 需要服用古塞库单抗多久才会见效？

治疗的前几周可能会有些许改善，但需要4个月才能看到完整的效果。

4. 如何服用古塞库单抗？

古塞库单抗以预填充注射笔注射于皮下（腹部、大腿或上臂外侧）。第一次注射4周后将进行第二次注射，此后每8周进行一次注射。

古塞库单抗必须存放在2至8°C的冰箱中。外出时，古塞库单抗必须被收在装有冰袋的冷藏箱/袋中。一旦从冰箱中取出并达到室温（最高25°C），就必须使用或丢弃它。

5. 古塞库单抗可能造成的副作用有哪些？

a. 轻微

- 注射部位反应：发红、皮疹、肿胀、瘙痒、淤青
- 感冒和流感症状，喉咙痛
- 胃肠炎、腹泻
- 轻度真菌感染，如脚癣
- 唇疱疹（单纯疱疹）
- 头痛、皮疹、荨麻疹
- 关节疼痛

b. 潜在的严重副作用

- 严重感染
- 过敏反应（罕见）

6. 开始治疗前会发生什么？

您将与您的皮肤科医生进行面诊，包括临床检查、血液测试和胸部X光检查。您会被询问有关以下问题：

- 结核病或与结核病患者的密切接触
- 肝炎或艾滋病毒感染，或如果您认为自己有风险
- 感染（如唇疱疹、尿路感染）
- 癌症
- 疫苗接种史
- 是否计划进行重大手术
- 是否怀孕、计划怀孕或正在哺乳

7. 在服用古塞库单抗期间我会如何被监测？

在诊所预约时，您将被询问相关副作用并定期进行血液检查（例如每6个月一次）。请告知您的医生关于：

- 药物的变化
- 计划的医疗程序和手术
- 感染或难以消失的感染症状/体征：发烧、乏力、咳嗽、类似流感症状、排尿时有灼烧感、牙科问题、夜间出汗。您的医生可能建议暂停使用古塞库单抗。
- 淤青、易出血、面色苍白
- 严重过敏反应的体征：面部/舌头肿胀、喉咙紧绷、呼吸困难。请立即拨打999急救电话并前往最近的医院急诊室。随后通知您的皮肤科医生。



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8. 我应该采取哪些预防措施？

- a. 避免与患有重感冒、流感或胸腔感染的人密切接触。
- b. 服用古塞库单抗期间经常洗手。
- c. 在手术前与医生讨论，因手术后感染风险增加，您可能会被建议在手术前停止使用古塞库单抗。
- d. 避免怀孕和哺乳。如果您已怀孕或计划怀孕，请与医生讨论。
- e. 如果您计划出国旅行，请与您的医生讨论。根据旅行地点，可能需要采取预防感染的措施。
- f. 服用古塞库单抗期间，您不应接种任何“活”疫苗（如鼻喷流感疫苗、麻疹、腮腺炎和风疹（MMR）、黄热病、卡介苗、轮状病毒、口服伤寒、水痘和带状疱疹）。如果您需要接种活疫苗，古塞库单抗应在接种前至少12周停止使用（带状疱疹疫苗应为12个月），并在接种后2周内停止服用。