

IXEKIZUMAB

Information leaflet

1. What is ixekizumab and how does it work?

Ixekizumab (Taltz®) is a biologic medicine which targets a chemical messenger known as a cytokine called interleukin-17A (IL-17A). IL-17A is one of the main causes of inflammation in psoriasis and psoriatic arthritis.

- 2. What skin conditions are treated with ixekizumab?
- ·Psoriasis
- ·Psoriatic arthritis
- 3. How long will I need to take ixekizumab before it has an effect?

Some improvement may be seen in the first few weeks of treatment, but it can take 3 months to see the full benefit.

4. How do I take ixekizumab?

Ixekizumab 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.

For the first dose you will need to inject 160 mg (two injections) of ixekizumab. After this you need to inject 80 mg (one injection) every two weeks for 6 doses (i.e. week 2, 4, 6, 8, 10, 12). After the first 12 weeks of treatment, you need to inject 80 mg (one injection) every 4 weeks.

Ixekizumab must be stored in a refrigerator between 2 to 8°C. Ixekizumab may be stored unrefrigerated for up to 5 days at a temperature not above 30°C.

- 5. What are the possible side effects of ixekizumab?
- a. Mild
- ·Reaction at the injection site: redness, rash, swelling, itching, bruising
- ·Cold and flu symptoms, sore throat, stuffy nose
- ·Gastroenteritis, diarrhoea, nausea
- ·Cold sores (herpes simplex)
- ·Bacterial skin infections (cellulitis)
- ·Mild fungal infections, e.g. athlete's foot, oral thrush
- ·Headaches, rash, hives (urticaria)
- ·Eye infections (conjunctivitis)
- ·Aching joints
- b. Potentially severe
- ·Serious infections
- ·Blood problems: inadequate blood cells that fight infections or stop bleeding
- ·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 history e.g. prone to cold sores or urinary tract infections
- ·Vaccination history and plans
- ·Crohn's disease or ulcerative colitis
- ·Cancer
- 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 ixekizumab?

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



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- ·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 ixekizumab 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 ixekizumab.
- c. If you develop symptoms of tuberculosis (e.g. a persistent dry cough, weight loss, fever, night sweats), inform your doctor.
- d. Discuss with your doctor prior to surgery as you may be advised to stop ixekizumab prior to the surgery due to the increased risk of infection afterwards.
- e. Avoid pregnancy and breastfeeding. Discuss with your doctor if you are pregnant or planning to become pregnant.
- f. Discuss with your doctor if you are planning to travel abroad. Depending on where you are travelling, precautions may be needed against infections.
- g. While on ixekizumab, you should not be given any 'live' vaciones (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, ixekizumab should be stopped at least 6 months before (12 months in the case of shingles vaccine) and until 4 weeks after the vaccination.



IXEKIZUMAB (伊克苏单抗)

Information leaflet

·1. 什么是伊克苏单抗,它是如何起作用的?

伊克苏单抗(Taltz®)是一种生物制剂药物,靶向一种名为白细胞介素-17A(IL-17A)的细胞因子。IL-17A是银屑病和银屑病关节炎的主要因素之一。

- 2. 伊克苏单抗用于治疗哪些皮肤病?
- •银屑病
- •银屑病关节炎
- 3. 看到伊克苏单抗的效果需要多长时间?

在治疗最初的几周可能会有些改善,但通常需要3个月后才能看到完整的效果。

4. 我该如何使用伊克苏单抗?

伊克苏单抗以皮下注射的方式使用预充式注射笔进行注射。注射可以在腹部、大腿或上臂外侧进行。

首次剂量需要注射160毫克(两次注射)。此后,每隔两周注射80毫克(一次注射),共6次(即第2、4、6、8、10、12周)。 在开始治疗的头12周后,需要每4周注射80毫克(一次注射)。

伊克苏单抗必须存放在2至8°C的冰箱中。伊克苏单抗可以在不超过30°C的温度下不冷藏保存最多5天。

- 5. 伊克苏单抗可能带来的副作用有哪些?
- a. 轻度
- ·注射部位反应: 红肿、皮疹、肿胀、瘙痒、淤青
- 感冒和流感症状、喉咙痛、鼻塞
- •肠胃炎、腹泻、恶心
- •唇疱疹(单纯疱疹)
- •细菌性皮肤感染(蜂窝织炎)
- •轻度真菌感染,例如足癣、口腔念珠菌感染/鹅口疮
- •头痛、皮疹、荨麻疹
- ·眼部感染(结膜炎)
- 关节疼痛

b. 可能严重

- •严重的感染
- ·血液问题:白细胞数量不足以对抗感染或停止出血
- ·过敏反应(罕见)

6. 在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、血液检查和胸部X光检查。您将被询问以下问题:

- •结核病,或者与患有结核病的人的密切接触
- ·肝炎或艾滋病毒感染,或者您是否认为自己处于风险之中
- · 感染史,例如容易出现唇疱疹或尿路感染
- •疫苗接种史和计划
- 克罗恩病或溃疡性结肠炎
- •癌症
- •是否计划进行重大手术
- •如果您正在怀孕、计划怀孕或正在哺乳

7. 在使用伊克苏单抗期间,我会接受怎样的监测?

在诊所预约时,您将定期被问及副作用,并进行定期血液检查(例如每6个月一次)。请告知您的医生:

- 药物变化情况
- 计划的医疗程序和手术
- · 感染或不消退的感染症状/体征:发烧、乏力、咳嗽、类似流感症状、排尿灼痛、牙科问题、夜间盗汗。您的医生可能建议 暂停使用伊克替单抗。



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- •淤青、易出血、面色苍白
- 严重过敏反应迹象:面部/舌头肿胀、喉咙紧绷、呼吸困难。请立即拨打999呼叫救护车,并前往最近的医院急诊科。事后请通知您的皮肤科医生。
- 8. 我应该采取哪些预防措施?
- a. 避免与重感冒、流感或胸腔感染患者密切接触。
- b. 在使用伊克替单抗期间频繁洗手。
- c. 如果出现结核病症状(如持续干咳、体重减轻、发烧、夜间盗汗),请告知您的医生。
- d. 在进行手术前请与您的医生讨论,因为您可能会被建议在手术前停止使用伊克替单抗,以减少术后感染风险。
- e. 避免怀孕和哺乳。如果您已怀孕或计划怀孕,请与您的医生讨论。
- f. 如果您计划出国旅行,请与您的医生讨论。根据您的旅行地点,可能需要采取预防措施以防止感染。
- g. 在使用伊克替单抗期间,您不应该接种任何"活"疫苗(例如鼻喷流感疫苗、麻疹、腮腺炎和风疹(MMR)、黄热病、卡介苗、轮状病毒、口服伤寒、水痘和带状疱疹疫苗)。如果您需要接种活疫苗,应在接种前至少6个月停止使用伊克替单抗(带状疱疹疫苗为12个月),并在接种后至少4周停止使用。