Idacio®
adalimumab

Idacio®

單次使用預充式注射筆使用說明

Single use pre-filled pen for subcutaneous injection

使用Idacio®預充式注射筆前請詳細閱讀使用說明
Read carefully these entire instructions before using your Idacio® pre-filled pen

只可在接受完醫護人員訓練如何正確使用預充式注射筆後，才可使用
Only use Idacio pre-filled pen if your healthcare professional has trained you how to use it correctly

請勿將手指插入護針器的開口
Do not insert your fingers into the opening of the safety guard

如Idacio®預充式注射筆曾被冰凍或置於正射陽光下，請勿使用
Do not use an Idacio® pre-filled pen that has been frozen or left in direct sunlight

將預充式注射筆存放在 2˚C至8˚C的冰箱內
Store the pre-filled pen in a refrigerator between 2°C to 8°C

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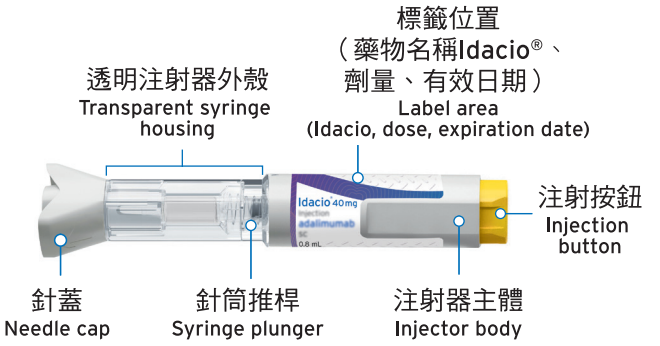
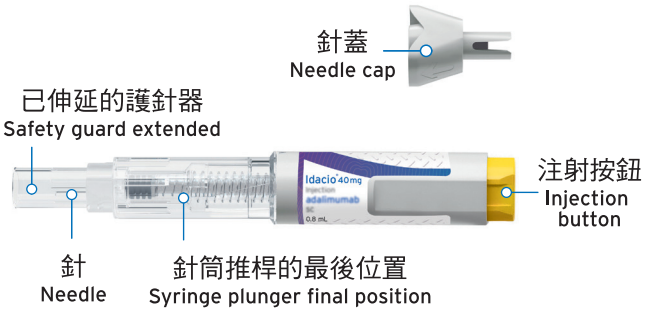
Idacio® 單次使用預充式注射筆皮下注射使用說明
Single use pre-filled pen for subcutaneous injection

了解您的預充式注射筆
Get Familiar with your Idacio® Pre-filled pen

使用前 Before Use



使用後After Use

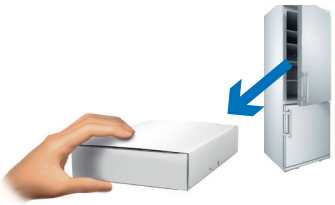


1 準備你的注射 Prepare for your Injection

在光線充足的地方準備一個乾淨的平面，例如桌子或枱面
Prepare a clean flat surface, such as a table or countertop, in a well-lit area

你還需要 You will also need:

- 酒精墊（包含在包裝盒中）alcohol pad (included in the box)
- 棉花球或紗布 cotton ball or gauze, and
- 棄針桶 sharps disposal container



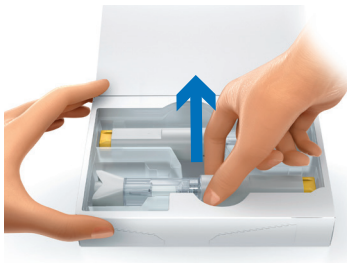
從冰箱中取出注射筆盒
Remove the box from the refrigerator

檢查包裝盒側面的有效日期
Check the expiration date on the side of the box

- 如有效期已過，請勿使用 Do not use if expiration date has passed

從原包裝盒中取出注射筆
Take a pre-filled pen out of the original box:

- 將兩隻手指放在印有標籤的位置 Place two fingers on the label area
- 將注射筆向上從包裝拉出，放置在一個潔淨的平面上
  Pull the pre-filled pen straight up and out of the packaging
  Put it on a clean flat surface



將餘下未使用之注射筆連盒放回2°C 至 8°C的冰箱內
Place the remaining pre-filled pen(s) in original box back in the refrigerator

將注射筆在室溫下放置至少30分鐘讓藥物升溫
Leave the pre-filled pen at room temperature for at least 30 minutes to allow the medicine to warm up

警告: 請勿以任何其他方式加熱注射筆，如微波爐、熱水或陽光直射
未準備好注射前，請勿取下針蓋

Warning: Do not warm the pre-filled pen any other way, such as in a microwave, hot water, or direct sunlight.
Do not remove the needle cap until you are ready to inject.

使用肥皂和水清洗您的手並擦乾
Wash your hands with soap and water and dry them well

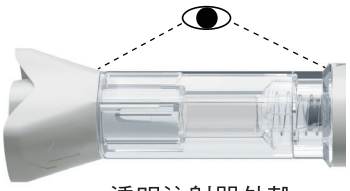
2 檢查預充式注射筆 Check the Pre-filled Pen

檢查透明注射器外殼以確保：
Check the transparent syringe housing to make sure that:

- 液體是清澈、無色、無顆粒 The liquid is clear, colorless, and free of particles
- 玻璃注射器沒有破裂或破損 The glass syringe is not cracked or broken.

警告: 如果液體含有顆粒，或變得混濁或變色、有薄片、有任何損壞跡象，請勿使用注射筆

Warning: Do not use the pre-filled pen if the liquid contains particles, or is cloudy or if it is colored, or has flakes in it or shows any sign of damage.



透明注射器外殼
Transparent syringe housing

檢查標籤以確保 Check the label to make sure that:

- 注射筆上的名稱是 Idacio® The name on the pre-filled pen says Idacio®
- 注射筆未超過有效日期
  The expiration date on the pre-filled pen has not passed

警告: 如標籤上的名稱不是Idacio®及/或有效日期已過，請勿使用注射筆

Warning: Do not use the pre-filled pen if the name on the label is not Idacio and/or the expiration date on the label has passed.

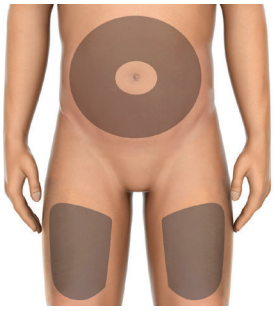
3 選擇注射位置 Choose the Injection Site

在以下選擇一個注射位置:
Choose an injection site on:

- 大腿頂部 Top of the thighs
- 腹部（在距離肚臍至少5厘米位置注射）
  Abdomen (inject at least 5 centimeters away from the belly button).

  每次選擇不同的位置注射(與上次注射位置的距離少2.5厘米），以減少發紅、刺激或其他皮膚問題

  Choose a different site (at least 2.5 centimeters away from the previous injection site) each time to reduce redness, irritation or other skin problems.



警告: 請勿在酸痛(易痛)、瘀青、發紅、變硬、有疤痕或有妊娠紋的皮膚注射
如果您患有銀屑病，請勿在任何病變或發紅、變厚、凸起或鱗片屑的位置注射

Warning: Do not inject into an area that is sore (tender), bruised, red, hard, scarred or where you have stretch marks.
If you have psoriasis, do not inject into any lesions or red, thick, raised or scaly patches

使用酒精墊清潔注射位置的皮膚
Wipe the skin of your injection site with an alcohol pad to clean it

4 注射 Give your Injection

移去針蓋 Remove the needle cap

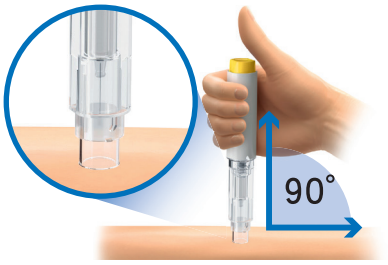
- 握住注射筆並向上將針蓋拉出
  Hold the pre-filled pen upwards and pull the needle cap straight off

警告: 請勿擰轉針蓋。請勿重新蓋上注射筆
Warning: Do not twist the cap. Do not recap the pre-filled pen

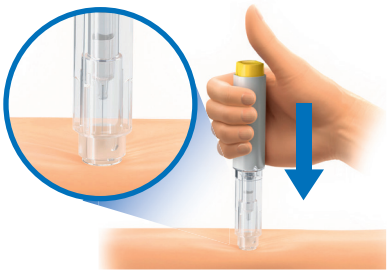
注射筆位置 Position the pre-filled pen

- 握住注射筆以便看到透明的注射器外殼
  Hold the pre-filled pen so that you can see the transparent syringe housing

將注射筆以90°角放在皮膚上
Place the pre-filled pen against your skin at a 90° angle

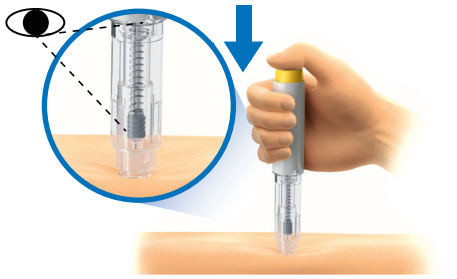


將注射筆緊緊按住皮膚上，直到完全按下護針器這代表注射按鈕已被解鎖
Push and hold the pre-filled pen firmly against your skin until the safety guard is fully depressed. This will unlock the injection button



進行注射 Administer the Injection

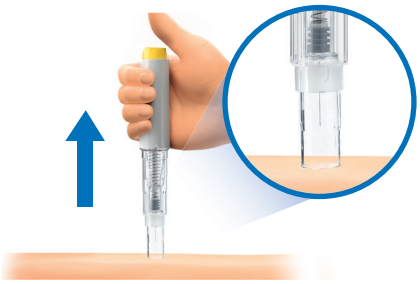
- 按下注射按鈕，您會聽到一下點擊聲響，這表示注射已經開始
  Push the injection button. You will hear a loud click, which means the injection has started.
- 觀察針筒推桿以確保它完全推至底部
  WATCH the syringe plunger to make sure it moves all the way down to the bottom



警告: 待針筒推桿完全推至底部及所有藥物注射後，才可將注射筆從皮膚抽出。

Warning: Do not lift the pre-filled pen from the skin until the plunger has moved all the way down and all the liquid has been injected.

- 當針筒推桿完全推至底部及停止移動後，繼續保持5秒
  When the syringe plunger has moved to the bottom and has stopped moving, continue holding it for 5 seconds.
- 將注射筆從皮膚上抽出
  Lift the pre-filled pen from your skin.



如果皮膚上有血或液體，用棉球或紗布輕輕按壓注射部位
If there is blood or liquid on the skin, treat the injection site by gently pressing a cotton ball or gauze on the site

使用後立即將用過的注射筆扔到棄針桶
Throw away your used pre-filled pen in a sharps disposal container right away after use

警告: 將您的棄針桶放在兒童接觸不到的地方。
請勿將注射筆丟棄在家庭垃圾中。

Warning: Keep your sharps disposal container out of the reach of children.
Do not throw away the pre-filled pen in your household trash.

Abbreviated Prescribing Information: 40mg/0.8mL adalimumab in pre-filled syringe/pre-filled pen. **Indications and Dosage:** Subcutaneous injection, refer to package insert for details. Rheumatoid arthritis (RA): Adults: Combination with methotrexate (MTX) for moderate to severe, active RA with inadequate response to disease-modifying anti-rheumatic drugs (DMARDs) including MTX, for severe, active and progressive RA not previously treated with MTX. Dosage: 40mg every other week (EOW). Concomitant MTX should be continued. Consider interruption e.g. before surgery/serious infection occurs. Polyarticular juvenile idiopathic arthritis (pJIA): Adolescents 13-17 years: Combination with MTX for active pJIA with inadequate response to one/more DMARDs. Dosage: ≥30kg: 40mg EOW. Ankylosing spondylitis (AS): Adults: For severe active AS with inadequate response to conventional therapy. Psoriatic arthritis (PsA): Adults: For active and progressive PsA with inadequate response to DMARDs. Dosage (AS, PsA): 40mg EOW. Psoriasis: Adults: For moderate to severe chronic plaque psoriasis in patients who are failed to respond to/contraindicated to/intolerant to other systemic therapy including cyclosporine, methotrexate/PUVA. Dosage: Week 0: 80mg, from Week 1: 40mg EOW. Crohn's disease (CD): Adults: For severe active CD with no response despite full and adequate course of, intolerance to/contraindication for corticosteroid and/or immunosuppressant therapy. Dosage: Induction: Week 0: 80mg, Week 2: 40mg, Maintenance: 40mg EOW. Corticosteroids may be tapered according to clinical guidelines. **Contraindications:** Hypersensitivity to any ingredients; Active tuberculosis (TB)/other severe infections e.g. sepsis and opportunistic infections; Moderate to severe heart failure (NYHA class III/IV). **Warnings and Precautions:** Record the name and batch number of administered product for traceability. Patients taking TNF-antagonists are more susceptible to serious infections. Impaired lung function increases that risk. Monitoring for infections, including TB, before, during and for 4 months after treatment. Do not initiate treatment during active infection, until infection is controlled. Consider risk/benefit before treatment in patients exposed to TB/travelled in high TB/endemic mycoses risk areas. Evaluate new infections during treatment and monitor closely. Stop treatment if new serious infection/sepsis, treat appropriately until controlled. Caution in patients with history of recurring infections/predisposed to infections, including concomitant immunosuppressives. Serious infections, including associated with hospitalization/death, were reported. Reactivation and new onset of TB, both pulmonary and extra-pulmonary, were reported. Screen patients before therapy initiation for active/inactive TB. Detailed medical assessment and appropriate screening tests for TB in patients. Do not initiate treatment if diagnosed active TB. Consult physician if suspected latent TB and follow local treatment recommendations for prophylaxis before treatment initiation. Consider anti-tuberculosis prophylaxis treatment in patients with several/significant TB risk factors. Despite prophylaxis, TB reactivation has occurred on adalimumab. Opportunistic infections including invasive fungal infections were observed. Stop treatment if signs and symptoms of infections occurs. Consult physician for diagnosis and administration of empiric antifungal therapy. Hepatitis B reactivation occurred in chronic carriers (surface antigen positive); some cases had fatal outcome. Evaluate HBV infection before initiating treatment. HBV carriers should consult specialist physician and closely monitored for HBV reactivation throughout therapy and for several months following treatment termination. If reactivation occurs, stop treatment and initiate appropriate antiviral and supportive treatment. Caution in patients with pre-existing or recent-onset central or peripheral nervous system demyelinating disorders. Consider discontinuation if any of these disorders develop. Serious allergic reactions including anaphylaxis were reported. For serious allergic or anaphylactic reaction, stop Idacio immediately and initiate appropriate therapy. Possible risk of malignancy, some fatal, including lymphomas and leukaemia, in patients treated with TNF-antagonists. Examine patients, especially with medical history of extensive immuno-suppressant therapy/psoriasis patients with history of PUVA treatment, for non-melanoma skin cancer before and during treatment. Melanoma and Merkel cell carcinoma reported in patients treated with TNF-antagonists including adalimumab; caution in COPD patients, and patients with increased risk for malignancy due to heavy smoking. Adverse events of haematologic system, including medically significant cytopenia, were reported. Patients to seek immediate medical attention if signs and symptoms of blood dyscrasias develop during treatment. Patients may receive concurrent vaccinations, except live vaccines. Bring paediatric patients up to date with all immunisations before initiating Idacio treatment. Caution with mild heart failure (NYHA class I/II). Discontinue treatment if new/worsening symptoms of congestive heart failure. Autoimmune antibodies may form with Idacio. Stop treatment if lupus-like syndrome develops with positive antibodies against dsDNA. Consider long half-life of Idacio for planned surgical procedures. Monitor closely for infections. Limited safety experience in patients undergoing arthroplasty. Failed treatment response for CD may indicate presence of fixed fibrotic stricture that may require surgical treatment. Serious infections were higher in patients >65 years, some had fatal outcome. Consider infection risk in these patients. **Pregnancy and lactation:** Not recommended during pregnancy. Women of childbearing age to use adequate contraception, continue use for at least 5 months after last treatment. Do not administer live vaccines to infants exposed to adalimumab in utero for 5 months following mother's last adalimumab treatment during pregnancy. Idacio can be used during breastfeeding. **Adverse Reactions:** Very common: Respiratory tract infections (including lower and upper respiratory tract infection, pneumonia, sinusitis, pharyngitis, nasopharyngitis and pneumonia herpes viral), leucopenia (including neutropenia and agranulocytosis), anaemia, lipids increased, headache, abdominal pain, nausea and vomiting, elevated liver enzymes, rash (including exfoliative rash), musculoskeletal pain, injection site reaction (including injection site erythema); Common: Systemic infections (including sepsis, candidiasis and influenza), intestinal infections (including gastroenteritis viral), skin and soft tissue infections (including paronychia, cellulitis, impetigo, necrotising fasciitis and herpes zoster), ear infections, oral infections (including herpes simplex, oral herpes and tooth infections), reproductive tract infections (including vulvovaginal mycotic infection), urinary tract infections (including pyelonephritis), fungal infections, joint infections, skin cancer excluding melanoma (including basal cell carcinoma and squamous cell carcinoma), benign neoplasm, leucocytosis, thrombocytopenia, hypersensitivity, allergies (including seasonal allergy), hypokalaemia, uric acid increased, blood sodium abnormal, hypocalcaemia, hyperglycaemia, hypophosphatemia, dehydration, mood alterations (including depression), anxiety, insomnia, paraesthesias (including hypoesthesia), migraine, nerve root compression, visual impairment, conjunctivitis, blepharitis, eye swelling, vertigo, tachycardia, hypertension, flushing, haematoma, asthma, dyspnoea, cough, GI haemorrhage, dyspepsia, gastroesophageal reflux disease. Sicca syndrome, worsening/new onset of psoriasis (including palmoplantar pustular psoriasis), urticaria, bruising (including purpura), dermatitis (including eczema), onychodasis, hyperhidrosis, alopecia, pruritus, muscle spasms (including blood creatine phosphokinase increased), renal impairment, haematuria, chest pain, oedema, pyrexia, coagulation and bleeding disorders (including activated partial thromboplastin time prolonged), autoantibody test positive (including dsDNA antibody), blood lactate dehydrogenase increased, impaired healing. **Revision Date:** July 2021

Refer to package insert for complete product details.

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