Enbrel® (etanercept) 50 mg Solution for Injection in Pre-Filled Pen (MYCLIC®)

A step-by-step guide to preparing and injecting Enbrel MYCLIC® pre-filled pen

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Enbrel Patient Support

Step 1: Preparing for your Enbrel injection

The first step is ***Preparing for your Enbrel injection***.

- Keep the area where you inject and your injection supplies as clean and germ-free as possible
- Select a clean, well-lit, flat work surface
- Gather the items that you will need for your injection, and place them on your work surface:
  - One MYCLIC pen from the carton of pens you keep in the refrigerator (remember not to shake the pen)
  - One alcohol swab
  - One cotton-wool ball or gauze
  - Sharps bin

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Step 1: Preparing for your Enbrel injection

Items you will need

One cotton-wool ball or gauze

One sharps bin

One MYCLIC pen

One alcohol swab

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Step 1: Preparing for your Enbrel injection

Demonstration tip

Use the demonstration device to point out:

- **White needle cap**
- **Green activation button**
- **Inspection window (should be clear before injection)**
- **Expiry date**

- Select a clean, well lit, flat work surface
- Gather the items you will need for your injection (remember – do not shake the MYCLIC pen)
- Check the expiry date on the MYCLIC pen
- Inspect the solution in the MYCLIC pen by looking through the inspection window
- Remember to keep your box of Enbrel stored in a refrigerator (between 2ºC and 8ºC). Do not freeze them

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Step 1: Preparing for your Enbrel injection

MYCLIC *Pen features*

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Step 1: Preparing for your Enbrel injection

- Leave the white needle cap in place and wait 15 to 30 minutes to allow the Enbrel solution in the MYCLIC pen to reach room temperature
  - Allowing the MYCLIC pen to reach room temperature may help reduce potential discomfort when you inject
- Do not warm Enbrel in any other way. For example, do not warm it in a microwave or in hot water
- Remember: Always keep MYCLIC pens out of sight and reach of children

Key to successful injecting

- ***Wait 15 to 30 minutes for the Enbrel solution in the MYCLIC pen to reach room temperature***

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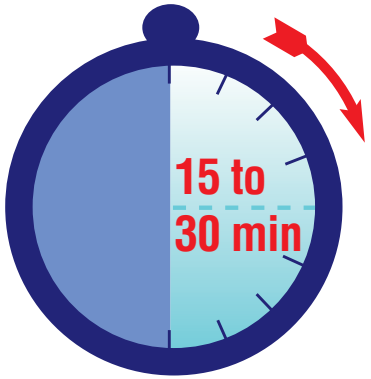
Step 1: Preparing for your Enbrel injection

Allow your MYCLIC *pen to reach room temperature before using*



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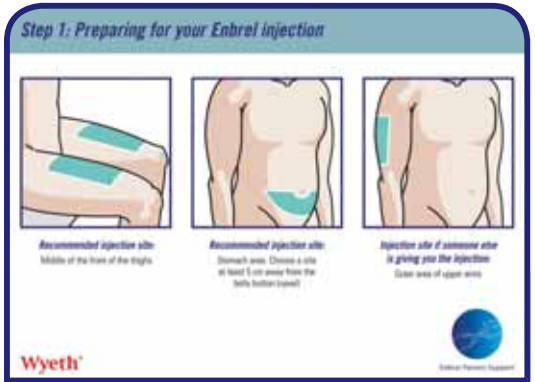
Step 2: Choosing an injection site



Demonstration tip

- **Ask patients to trace appropriate areas with their fingertip to ensure they understand the correct area(s) within which they should inject**

The next step is ***Choosing an injection site***.

- The recommended injection sites are the **middle of the front of the thighs** or the **stomach area**, but make sure you choose a site at least 5 cm away from the belly button (navel)
- If someone else is giving you the injection, the **outer area of the upper arms** also may be used

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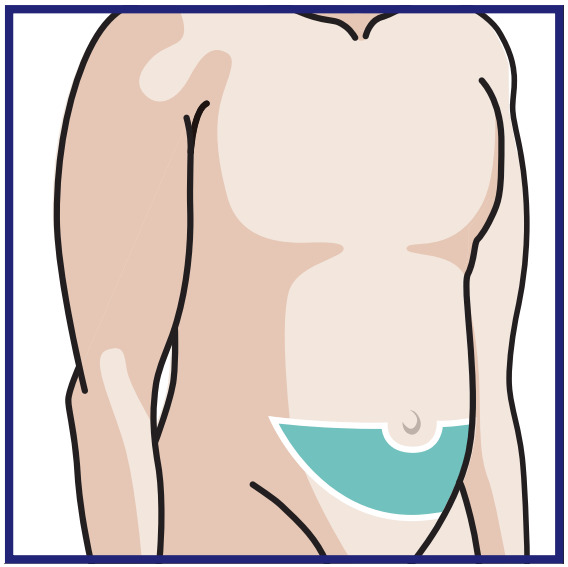
Step 2: Choosing an injection site

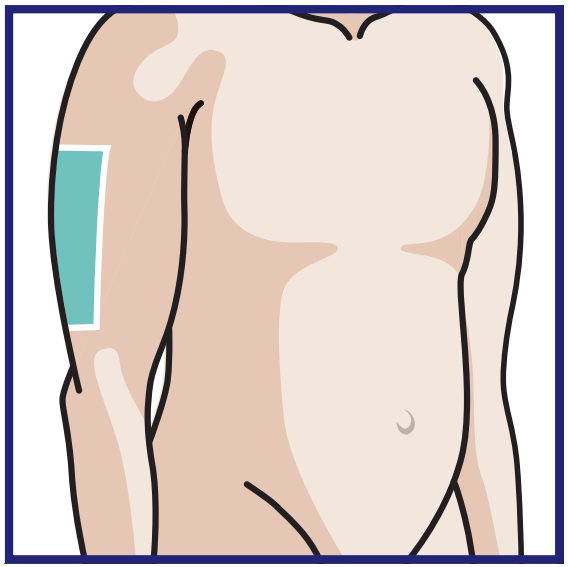
Recommended injection site:

Middle of the front of the thighs



Recommended injection site:

Stomach area. Choose a site at least 5 cm away from the belly button (navel)



Injection site if someone else is giving you the injection:

Outer area of upper arms

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Step 2: Choosing an injection site

Demonstration tips

- **Show patients what 3 cm looks like**
- **Point out any problem areas into which patients should not inject**

- Each new injection should be given at least 3 cm (or the width of 3 fingers) from where you last injected
  - Keeping notes may help you remember where you have recently injected
- Do not inject into tender, bruised, broken or hard skin
- Avoid scars or stretch marks
- If you have psoriasis, do not inject directly into any raised, thick, red, or scaly skin

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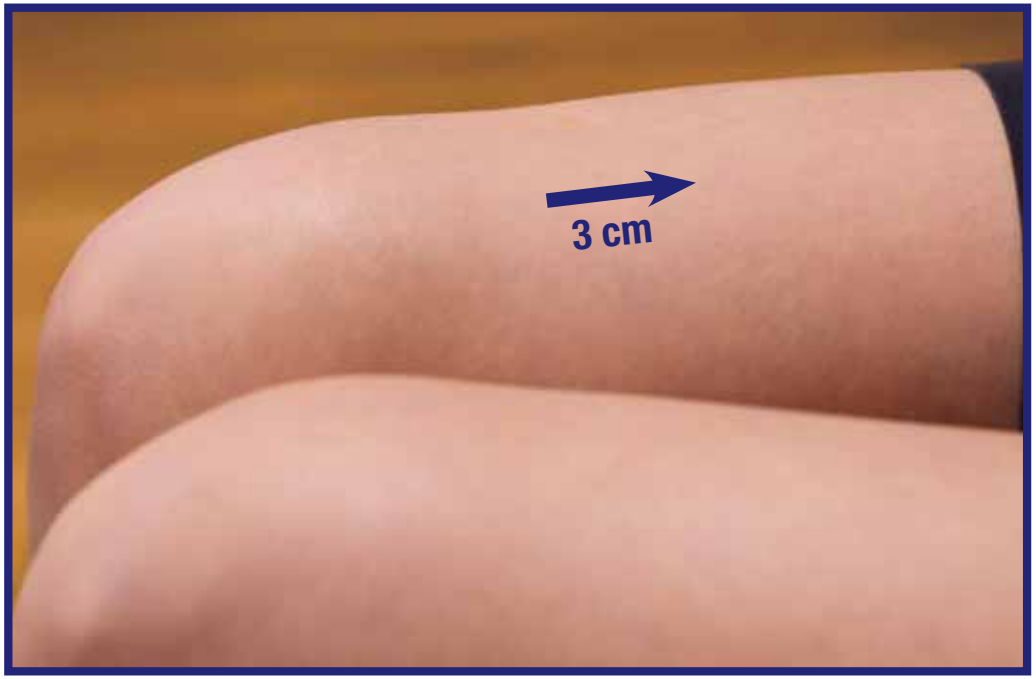
Step 2: Choosing an injection site

Each new injection should be at least 3 cm from the previous injection site



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Step 3: Injecting the Enbrel solution

Demonstration tip

- **Illustrate proper cleaning method – rotating outward in a circular motion**

Your next step is ***Injecting the Enbrel solution***.

- After waiting 15 to 30 minutes for the solution in the MYCLIC pen to warm to room temperature, wash your hands with soap and water
- Ensure the injection site is clean. You may wish to use the alcohol swab provided to achieve this
- Do not touch this area again before injecting

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Step 3: Injecting the Enbrel solution

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Step 3: Injecting the Enbrel solution

Demonstration tips

- **Use the demonstration device to show proper removal of white needle safety cap**
- **Point out the purple needle safety shield**

- Remove the white needle cap by pulling it straight off
- To avoid damaging the needle inside the MYCLIC pen, do not bend or twist the white needle cap while you are removing it, and do not re-attach it once it has been removed
  - After you remove the white needle cap, you will see the purple needle safety shield at the end of the MYCLIC pen

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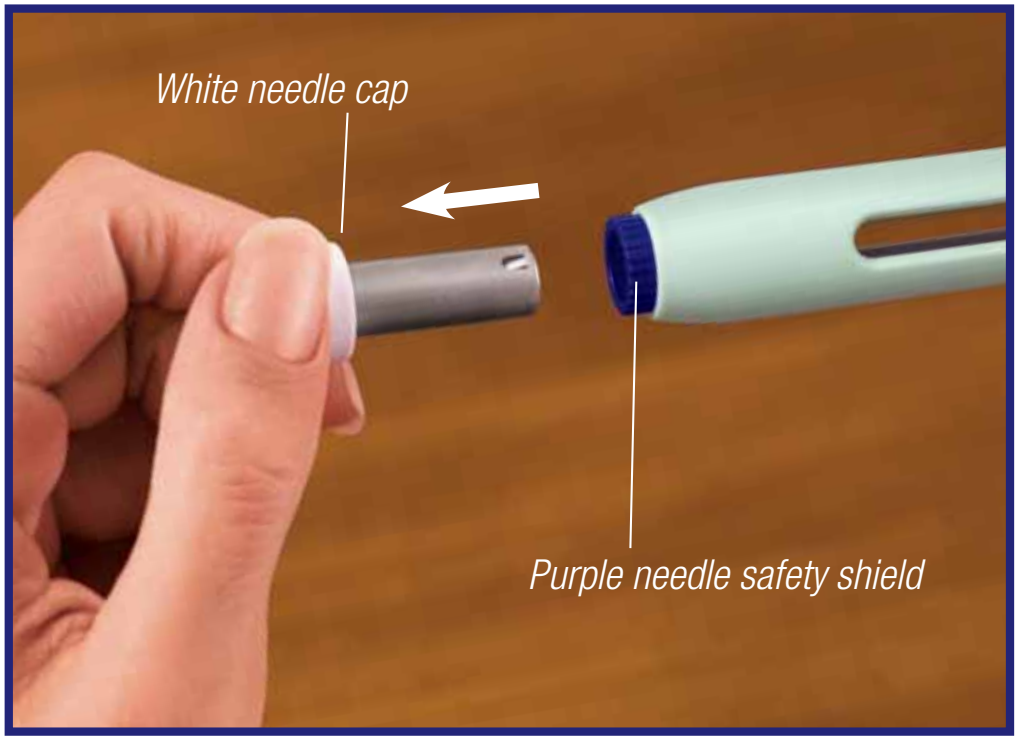
Step 3: Injecting the Enbrel solution

Pull the white needle cap straight off the MYCLIC pen



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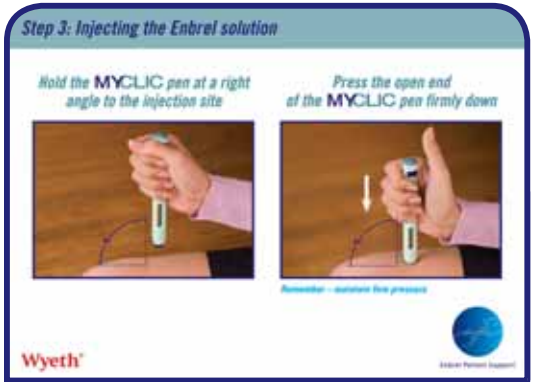
Step 3: Injecting the Enbrel solution



Demonstration tip

- **At a recommended site, use the demonstration device to show the MYCLIC pen going down over the safety shield**

- Without pressing the green button on top of the MYCLIC pen, hold the MYCLIC pen at a right angle (90º) to the injection site
- Press the open end of the MYCLIC pen firmly down on the skin until the safety shield can no longer be seen
  - – You will probably see a slight depression in the skin
- The MYCLIC pen must be pressed firmly against the skin throughout the injection, or the MYCLIC PEN MAY NOT WORK

Key to successful injecting

- ***Do not press the green button until the MYCLIC pen has been pressed firmly against your skin and the safety shield can no longer be seen***

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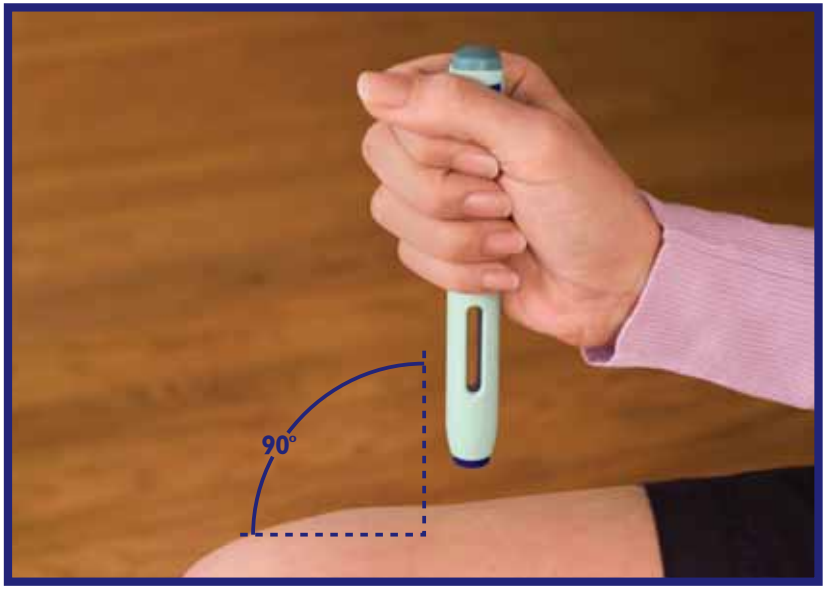
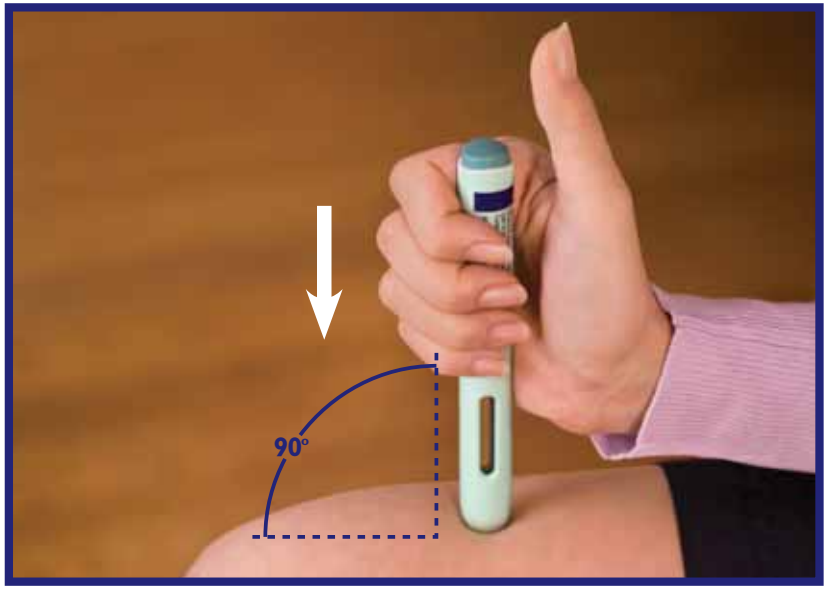
Step 3: Injecting the Enbrel solution

Hold the MYCLIC pen at a right angle to the injection site



Press the open end of the MYCLIC pen firmly down



Remember – maintain firm pressure

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Step 3: Injecting the Enbrel solution

Demonstration tip

- **Use the demonstration device to show proper injection technique**

- Start the injection by pressing and immediately releasing the green button on the top of the MYCLIC pen with your thumb. Alternatively if you find it more comfortable, you may wish to press the green button using the heel of your other hand
- On pressing the button, you will hear a click. This indicates that the injection is starting
- Remove your thumb from the button, **or there will be no second click when the injection is complete**
- Do not lift the MYCLIC pen until you hear a second click. On hearing the second click (or, if you do not hear a second click, after 10 seconds have passed) your injection will be complete
  - Holding the MYCLIC pen in place for the appropriate amount of time will help ensure that you receive your full dose of Enbrel

Keys to successful injecting

- *Immediately release your thumb after the first click and move your thumb to the side of the MYCLIC pen and keep firm pressure on the skin during the injection*

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Step 3: Injecting the Enbrel solution

Press and immediately release the green button

Hold the MYCLIC pen in place until you hear a second click (or for 10 seconds if no second click is heard)

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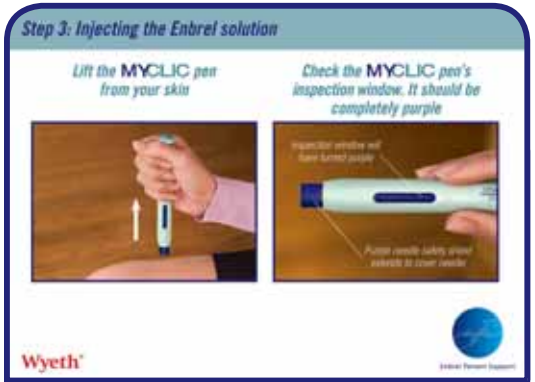
Step 3: Injecting the Enbrel solution



Demonstration tip

- **Use the demonstration device to point out the needle shield and purple inspection window**

- When the injection has been completed, lift the MYCLIC pen from your skin
- The purple needle safety shield will automatically extend to cover the needle
- The MYCLIC pen's inspection window should now be completely purple, confirming that the dose has been injected correctly
  - If the window is not completely purple, contact your doctor, nurse, or homecare provider for assistance, since the MYCLIC pen may not have injected the Enbrel solution completely
- If you notice a spot of blood at the injection site, you should press the cotton-wool ball or gauze over the injection site for at least 10 seconds. Do not rub the injection site

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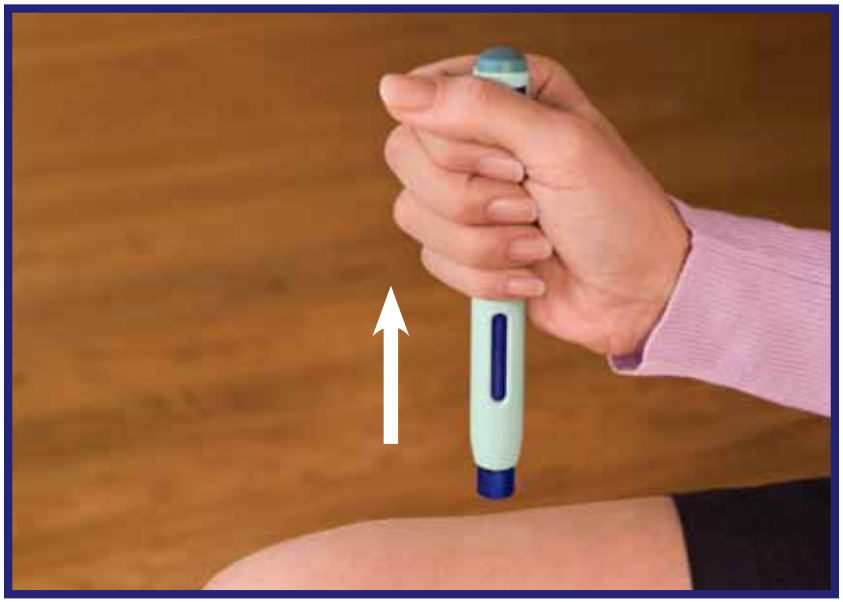
Step 3: Injecting the Enbrel solution

Lift the MYCLIC pen from your skin



Check the MYCLIC pen's inspection window. It should be completely purple

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Step 4: Disposing of the used MYCLIC pen

Demonstration tip

- **Demonstrate the proper disposal of used materials**

The MYCLIC pen must only be used once – it should NEVER be reused. NEVER recap a needle. Throw away the alcohol swab and cotton-wool ball.

- The MYCLIC pen must be disposed of correctly (as instructed by your doctor, nurse or homecare provider). DO NOT throw away the MYCLIC pen in your regular rubbish
- If you have any questions regarding Enbrel, please speak to a doctor, nurse or homecare provider who is familiar with Enbrel

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Step 4: Disposing of the used MYCLIC pen

Used MYCLIC Pen

Proper Disposal

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Key points for successful injecting with MYCLIC

- Wait 15 to 30 minutes for the Enbrel solution in the MYCLIC pen to reach room temperature
- Do not press the green button until the MYCLIC pen has been pressed firmly against your skin and the safety shield can no longer be seen
- Maintain firm pressure throughout the injection
- Immediately release your thumb after the first click and move it to the side of the MYCLIC pen
- Do not lift the MYCLIC pen until you hear a second click (or until 10 seconds have passed if no second click is heard)

Properly trained patients may be more likely to become successful self-injectors.

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ABBREVIATED PRESCRIBING INFORMATION. Enbrel®▼ etanercept. Before prescribing Enbrel please refer to full Summary of Product Characteristics. **Presentation: *Enbrel Pre-filled Syringe:*** Enbrel 25 mg or 50 mg solution for injection in a pre-filled syringe. Each pre-filled syringe contains either 25 mg or 50 mg etanercept. ***Enbrel Powder:*** Enbrel 25 mg powder and solvent for solution for injection. Each vial contains 25 mg etanercept and each pre-filled syringe contains 1 ml water for injections. ***Enbrel Paediatric:*** Enbrel 25 mg/ml powder and solvent for solution for injection for paediatric use. Each vial contains 25 mg etanercept and each pre-filled syringe contains 1 ml bacteriostatic water for injections. **Uses: *Adults:*** Moderate to severe active rheumatoid arthritis (RA), in combination with methotrexate, when response to DMARDs, including methotrexate (unless contraindicated), has been inadequate. Enbrel can be given as monotherapy in the case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate. Severe, active and progressive RA without prior methotrexate treatment. Enbrel alone or with methotrexate has been shown to reduce the rate of progression of joint damage measured by X-ray and to improve physical function. Patients with moderate to severe plaque psoriasis (PP) who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapy including cyclosporine, methotrexate or PUVA. Active and progressive psoriatic arthritis (PsA) when response to DMARDs has been inadequate. Enbrel has been shown to improve physical function in PsA patients, and to reduce the progression rate of peripheral joint damage as measured by X-ray in patients with polyarticular symmetrical subtypes of PsA. Severe active ankylosing spondylitis (AS) when response to conventional therapy has been inadequate. ***Children aged 4-17 years (25 mg only):*** Active polyarticular juvenile idiopathic arthritis (JIA) when inadequate response to, or intolerant of methotrexate. ***Children aged 8-17 years:*** Chronic severe psoriasis when inadequately controlled by, or intolerant to, other systemic therapies or phototherapies. **Dosage:** By subcutaneous injection. ***Adults:*** RA – 25 mg twice weekly or 50 mg once weekly. PP 25 mg twice weekly or 50 mg once weekly for up to 24 weeks, or 50 mg twice weekly for up to 12 weeks followed by 25 mg twice weekly or 50 mg once weekly for a further 12 weeks if needed. Discontinue if no response after 12 weeks. For re-treatment: 25 mg twice weekly or 50 mg once weekly for up to 24 weeks. AS and PsA – 25 mg twice weekly or 50 mg once weekly. ***Children aged 4-17 years:*** JIA in children aged 4-17 years – 0.4 mg/kg (maximum per dose 25 mg) twice weekly with an interval of 3 – 4 days. ***Children aged 8-17 years:*** Plaque psoriasis in children aged 8-17 years – 0.8 mg/kg (maximum per dose 50 mg) once weekly for up to 24 weeks. Discontinue if no response after 12 weeks. For re-treatment: 0.8 mg/kg (maximum per dose 50 mg) once weekly for up to 24 weeks. **Contra-indications:** Hypersensitivity to any of the ingredients, sepsis or risk of sepsis, active infections. ***Enbrel Paediatric:*** Must not be given to premature babies or neonates as the bacteriostatic water for injections contains benzyl alcohol. **Warnings and Precautions:** Enbrel should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of RA, JIA, PsA, AS or PP. Use carefully in patients predisposed to, or with history of, infection due to underlying diseases other than RA (e.g. advanced or poorly controlled diabetes) or with history of blood dyscrasias, pre-existing or predisposition to CNS demyelinating disease or congestive heart failure. Cases of active tuberculosis have been reported, therefore all patients should be evaluated for both active and inactive TB prior to being treated with Enbrel. If active TB is diagnosed, Enbrel should not be initiated. Caution should be used when administering Enbrel to patients identified as carriers of hepatitis B virus and there have been reports of worsening hepatitis C in patients receiving Enbrel. Whether treatment with Enbrel might influence the development and course of active and/or chronic infections is unknown. Concurrent administration of Enbrel and anakinra has been associated with increased risk of serious infections and neutropenia, and is therefore not recommended. In clinical studies, concurrent administration of abatacept and Enbrel resulted in increased incidences of serious adverse events, and is therefore not recommended. Reports of various malignancies have been received in the post-marketing period, therefore with current knowledge, a possible risk for the development of lymphomas or other malignancies in patients treated with a TNF-antagonist cannot be excluded. Non-melanoma skin cancer has been reported in patients treated with TNF-antagonists, including Enbrel, and periodic skin examination is recommended for all patients who are at increased risk of NMSC, particularly patients with psoriasis or a history of PUVA therapy. Enbrel has not been studied in combination with other systemic therapies or phototherapy for the treatment of psoriasis. Monitor closely if patient develops new infection during treatment. Discontinue treatment if serious infection or allergic reaction develops or if blood dyscrasias are confirmed. Caution should be used in patients who have moderate to severe alcoholic hepatitis and Enbrel should not be used in patients for the treatment of alcoholic hepatitis. Discontinue temporarily if significantly exposed to varicella virus. Live vaccines should not be given concurrently with Enbrel. Paediatric patients should have received all vaccines recommended in current immunisation guidelines prior to starting Enbrel. Treatment with Enbrel may result in the formation of autoantibodies. Enbrel is not recommended for the treatment of Wegener's granulomatosis. ***Enbrel Paediatric:*** Contains benzyl alcohol as an excipient, which may cause toxic and/or anaphylactic reactions in infants and children up to 3 years old. **Pregnancy & Lactation:** Enbrel is not recommended in pregnant or breast-feeding women. **Undesirable Effects: *Adults:*** Very common side effects reported with clinical trial and post marketing experience include infections and injection site reactions. Common adverse events were allergic reactions, pruritus, autoantibody formation and fever. Uncommon side effects have included serious infections, thrombocytopenia, interstitial lung disease (including pneumonitis and pulmonary fibrosis), non-melanoma skin cancers, angioedema, urticaria, rash, psoriasiform rash and psoriasis. Rare reports of lupus-like syndrome, CNS demyelinating events, seizures, serious allergic reactions, elevated liver enzymes, cutaneous vasculitis, Stevens-Johnson syndrome, erythema multiforme, anaemia, leucopenia, neutropenia, pancytopenia, tuberculosis and opportunistic infections (including invasive fungal, protozoal, bacterial and atypical mycobacterial infections). Aplastic anaemia and toxic epidermal necrolysis have been reported very rarely. The frequency of macrophage activation syndrome and anti-neutrophilic cytoplasmic positive vasculitis has not been accurately estimated through clinical studies. In clinical trials serious adverse events occurred with a frequency similar to placebo and methotrexate. These included: serious infections, malignancies, asthma, heart failure, MI and ischaemia, chest pain, syncope, cerebral ischaemia, hyper- and hypotension, cholecystitis, pancreatitis, GI haemorrhage, bursitis, confusion, depression, dyspnoea, abnormal healing, renal insufficiency, kidney calculus, deep vein thrombosis, pulmonary embolism (PE), membranous glomerulonephropathy, polymyositis, thrombophlebitis, liver damage, leucopenia, paresis, paresthesia, vertigo, allergic alveolitis, angioedema, scleritis, bone fracture, lymphadenopathy, ulcerative colitis, intestinal obstruction, eosinophilia, haematuria and sarcoidosis. Rate of new malignancies was similar to that expected for the population studied. Fatalities associated with serious infections, pancytopenia, and aplastic anaemia have also been reported. ***Paediatrics:*** Generally as for adults, except the following were more common: headaches, nausea, vomiting and abdominal pain. In addition the following were reported as severe events: varicella, appendicitis, gastroenteritis, depression/personality disorder, cutaneous ulcer, oesophagitis/gastritis, group A streptococcal septic shock, type I diabetes mellitus and soft tissue and post operative wound infection. **Legal Category:** POM. **Package Quantities: *Enbrel Pre-filled Syringe:*** Each carton contains 4 pre-filled syringes containing either 25 mg or 50 mg of Enbrel and 8 alcohol swabs. ***Enbrel Powder:*** Each carton contains 4 vials of Enbrel 25mg powder, 4 pre-filled syringes of water for injections, 4 needles, 4 vial adaptors and 8 alcohol swabs. ***Enbrel Paediatric:*** Each carton contains 4 vials of Enbrel 25 mg powder, 4 pre-filled syringes of bacteriostatic water for injections, 8 empty plastic syringes, 20 needles and 24 alcohol swabs. **Basic NHS Cost:** 25mg (all presentations): £357.50 per carton 50mg (all presentations): £715 per carton. **European Marketing Authorisation Number: *Enbrel Pre-filled Syringe 25 mg:*** EU/1/00/126/013 Enbrel Pre-filled Syringe 50 mg: EU/1/99/126/017 ***Enbrel Powder 25 mg:*** EU/1/99/126/003 Enbrel Paediatric 25 mg: EU/1/99/126/012. For full prescribing information and details of other side effects see Summary of Product Characteristics. Full prescribing information is available on request from: Wyeth Pharmaceuticals, Huntercombe Lane South, Taplow, Maidenhead, Berkshire SL6 0PH. Telephone: 0845 367 0098. **Date of Prescribing Information:** 29 May 2009.

Code no. ZAPI109. Doc ID 52176.

Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk. Adverse events should also be reported to Wyeth on 0845 367 0098.

ZENB2213. Date of preparation: June 2009.

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