



# CERTOLIZUMAB PEGOL

## WHAT ARE THE AIMS OF THIS LEAFLET?

This leaflet has been written to help you understand more about certolizumab pegol (Cimzia®). It tells you what it is, how it works, how it is used to treat skin conditions, and where you can find out more about it.

## WHAT IS CERTOLIZUMAB PEGOL AND HOW DOES IT WORK?

Certolizumab pegol is a biologic medicine. Biologic medicines are made using living cells, designed to reduce inflammation by acting on the immune system. They are used to treat inflammatory skin conditions including psoriasis. Certolizumab pegol specifically targets a chemical messenger (known as a 'cytokine') in the body. This cytokine is called 'tissue necrosis factor alpha' (TNFα). We know that TNFα is one of the main causes of inflammation in some skin conditions. By blocking it certolizumab pegol can improve symptoms in those conditions.

## WHAT SKIN CONDITIONS ARE TREATED WITH CERTOLIZUMAB PEGOL?

Certolizumab pegol is used to treat psoriasis.

## WHY HAVE I BEEN SELECTED FOR TREATMENT WITH CERTOLIZUMAB PEGOL?

The use of certolizumab pegol is reserved for a severe enough condition to require treatment based on national guidelines.

Usually, this is because your condition has not improved with other standard treatments, such as methotrexate. Alternatively, there may be safety reasons why you cannot receive these standard treatments, or they may have been tried but

caused you problems, so you had to stop them.

## HOW LONG WILL I NEED TO TAKE CERTOLIZUMAB PEGOL BEFORE IT HAS AN EFFECT?

Certolizumab pegol does not work immediately and you will be able to see improvement in the first few weeks of treatment. However, it can take 4 months to see the full benefit of the treatment. For example, in clinical trials, more than 23 out of 100 patients with psoriasis were clear or nearly clear of psoriasis by 4 months. If no significant improvement occurs the treatment will be stopped.

## HOW DO I TAKE CERTOLIZUMAB PEGOL?

Certolizumab pegol is given as an injection under your skin (subcutaneously) using a pre-filled pen or syringe device. A nurse or doctor will teach you how to use the pen or syringe to inject yourself, and details are also given in the package leaflet. Injections are made under the skin of the stomach, thighs or upper outer arms. You will be provided with a special bin so that you can dispose of your injections safely.

Certolizumab pegol must be stored in a refrigerator (between 2 to 8 °C). Keep the pre-filled syringe in its outer carton in order to protect it from light.

If you are travelling with your treatment, you should have a cool box or cool bag with icepacks to maintain the recommended temperature. Once certolizumab pegol has been removed from the refrigerator and has reached room temperature (up to 25 °C), it may be kept at room temperature for a single period of up to 10 days. After this, it must



either be used or thrown away – it should not be put back in the fridge.

## HOW SHOULD I TAKE CERTOLIZUMAB PEGOL?

Each syringe or pen contains 200 mg of certolizumab pegol.

You will need to give yourself **TWO injections** of certolizumab pegol for the first dose, and then inject **TWO injections 2 weeks later** (week 2), followed by **TWO injections after another 2 weeks** (week 4).

After this, you should inject **ONE injection once every 2 weeks**. If the treatment is effective, it can be continued in the long-term to control psoriasis. However, if not, your dermatologist may recommend a higher dose or more frequent injections after 16 weeks of treatment.

## WHAT ARE THE POSSIBLE SIDE EFFECTS OF CERTOLIZUMAB PEGOL?

Most of the side effects reported during clinical trials of certolizumab pegol were mild, easily manageable, and did not require discontinuation of the treatment.

### *Mild*

*Reactions at the injection sites* are usually mild and include redness, a rash, swelling, itching, or bruising. They usually go away within 3 to 5 days. If you have pain, redness or swelling around the injection site that doesn't go away, or gets worse, contact your dermatologist.

- Cold and flu symptoms, sore throat
- Urinary tract infections
- Mild fungal infections such as athlete's foot
- Skin infections (cellulitis)
- Cold sores (herpes simplex infections)
- Nausea
- Headaches (including migraine), dizziness
- Rashes, itching (pruritus)

### *Potentially severe*

Fewer than 2 out of every 100 individuals treated with certolizumab experience a serious adverse effect in the first 3 to 4 months of treatment.

*Serious infections.* Certolizumab pegol may decrease your ability to fight infection. Your doctor will ask you about any current or past infections (particularly tuberculosis), or if you are prone to infections such as cold sores or urinary tract infections. If you develop any symptoms of tuberculosis (for example, a dry cough that doesn't go away, weight loss, fever, night sweats) call your doctor. Your doctor will also ask if you have or have ever had any disease that affects your immune system, such as cancer, human immunodeficiency virus (HIV) infection or viral hepatitis. It is advisable to avoid close contact with anyone with a bad cold, flu or chest infections, and wash your hands frequently during the course of treatment.

*Allergic reactions.* It is possible that some patients could experience an allergic reaction to certolizumab pegol. Severe reactions requiring emergency treatment (for example, anaphylaxis) are very rare.

The needle shield inside the removable caps of the prefilled certolizumab pegol syringe and pen contain a derivative of latex. There is a potential risk of allergic reactions in people with a severe latex allergy.

*Blood problems.* Some patients taking certolizumab pegol may be unable to produce enough of the blood cells that help to fight infections or to stop bleeding.

*Nervous system diseases.* Certolizumab has rarely been reported to cause problems with the nervous system. Symptoms of this include numbness or tingling; problems with vision; weakness in the arms and/or legs; and dizziness. You will be asked if you have experienced any of these symptoms or been affected by a neurological condition, such as multiple sclerosis, Guillain-Barre syndrome or have experienced seizures. If you have, certolizumab pegol may not be appropriate for you.



*Liver problems.* Rarely, patients taking certolizumab pegol may experience inflammation of the liver (hepatitis). Your dermatologist will monitor your liver enzymes as part of your routine blood tests while on this treatment. If there are small increases in liver enzymes, you will not necessarily need to stop taking the medication.

*Heart problems.* Your dermatologist will ask you if you have ever been treated for heart failure. If you have, certolizumab pegol may not be appropriate for you.

*Lupus-like reactions.* Some people taking certolizumab pegol and other medicines which block TNF $\alpha$  have developed symptoms (such as rash and joint pains) that resemble lupus erythematosus, and these usually go away when treatment is stopped.

*Cancers:* Biologics affect parts of the immune system. Careful safety studies have been ongoing over recent years to check if these drugs increase the risk of cancer. So far, these studies are reassuring and do not show any increase in risk of cancer. We advise everyone, including people taking biologics, to participate in appropriate cancer screening programmes, which can be accessed via your GP. You should also wear sunscreen and regularly check your skin for any new spots or changes in freckles or moles. Ask your dermatologist if you have any concerns about this.

## HOW CAN THE RISK OF SIDE EFFECTS BE MINIMISED?

*Before you start taking certolizumab pegol* you will have a thorough consultation with your dermatologist/team including a clinical examination and a number of blood tests. Additional investigations may be required depending on your medical history (for example, a chest X-ray or other imaging).

Your dermatologist will go through the below checklist. These situations do not necessarily mean that you cannot be treated with certolizumab pegol but may mean that other precautions are needed for you to have this

treatment safely. Your dermatologist would discuss your individual situation and explain more about this.

- *Tuberculosis* or close contact with someone who has had it.
- *Hepatitis or an HIV infection*, or if you think you are at risk of having these.
- *Infection and vaccination history.* If you are scheduled to have *any type of vaccination*.
- *Numbness or tingling* or a disease that affects your nervous system like multiple sclerosis.
- If you are being treated for *congestive heart failure*
- If you are scheduled to have *major surgery*.
- If you are *pregnant or breastfeeding or are planning a family*.

You are encouraged to take part in any *National Health screening programmes* at the routine time points recommended (for example, with cervical smears, mammograms).

*During your treatment with certolizumab pegol* you will be asked about side effects and have blood tests from time to time (for example every 6 months) at your clinic appointments. Keep your own doctor and/or your dermatology team informed at all times of changes to your medications, planned procedures and surgery or health problems including:

- If you get an infection, or any symptom or sign of an infection that doesn't go away, including fever, lethargy, cough, 'flu-like symptoms, burning on passing urine, dental problems, night sweats. Your dermatologist may suggest stopping certolizumab pegol temporarily.
- If you bruise or bleed very easily or look very pale.
- If you develop swelling of your feet or have shortness of breath when active or when lying down.



- If you experience numbness or tingling; problems with vision; weakness in the arms and/or legs; and dizziness
- If you develop signs of a severe allergic reaction, such as a swollen face/tongue, throat tightness or difficulty with breathing (known as anaphylaxis), **dial 999 for an ambulance immediately** and go to a hospital Accident and Emergency department. Afterwards you should make sure that your dermatologist has been informed.

### WHAT WILL HAPPEN IF I NEED AN OPERATION OR DENTAL SURGERY?

Certolizumab pegol comes under the category of an 'immune suppressant' and therefore may increase your risk of getting an infection after a surgical procedure. For planned procedures, you may be advised to stop certolizumab pegol prior to the surgery. Please discuss this with your doctor or dentist.

### CAN I HAVE IMMUNISATIONS (VACCINATIONS) WHILST ON CERTOLIZUMAB PEGOL?

*People on certolizumab pegol treatment should not get vaccinated with 'live' vaccines.*

These include:

- the flu vaccine administered through the nose
- measles, mumps and rubella (MMR)
- yellow fever
- Bacillus Calmette-Guérin (BCG)
- rotavirus
- oral typhoid
- varicella (chickenpox)
- herpes zoster (shingles).

If you require immunisation with a live vaccine, you should stop certolizumab pegol for at least 12 months before getting vaccinated. You should then wait for 4 weeks after the vaccination before you can restart certolizumab pegol treatment. You will be able to discuss this further with your dermatology team.

'Inactivated' vaccines are safe and recommended. Some examples include Pneumovax, the COVID-19 vaccine and the annual flu vaccine administered by injection.

Shingrix® is an inactivated version of the shingles vaccine. British Association of Dermatologists patient information leaflet on [shingles](#).

Keep up to date with COVID-19 vaccine schedules according to national policy.

It is important to always discuss your immunisation plan with your healthcare professional. You must always inform them that you are on certolizumab pegol treatment.

For more detailed information see the British Association of Dermatologists patient information leaflet on [immunisations](#)).

### DOES CERTOLIZUMAB PEGOL AFFECT PREGNANCY?

Data collected by the manufacturer shows that certolizumab pegol has been used in more than 1000 pregnancies without causing harm to the unborn baby. Studies indicate that low levels of certolizumab pegol, if any, cross the placenta during pregnancy due to its chemical structure. For this reason, if you need a biologic for your skin condition, you may be switched to certolizumab pegol for pregnancy.

Certolizumab pegol used in later pregnancy can potentially affect the baby's immune system for up to six months after birth. Because of this, live vaccines in the baby should be avoided during this time.

Although the risk of certolizumab pegol causing harm to the pregnancy or unborn baby appears to be very low, it cannot be completely ruled out. If you are pregnant or are planning to become pregnant, please discuss with your dermatologist as they will be able to advise on your individual circumstances.



No effects on the breastfed newborns/infants are expected. Therefore, certolizumab pegol can be used during breastfeeding.

### **CAN I TRAVEL ABROAD WHILE TAKING CERTOLIZUMAB PEGOL?**

Please discuss with your dermatologist if you are planning to travel abroad. Depending on where you are travelling, precautions may need to be taken against infections. Depending on the length of your travel plans, you may need a cool box to take the medication with you.

### **MAY I DRINK ALCOHOL WHILE TAKING CERTOLIZUMAB PEGOL?**

There is no known interaction between alcohol and certolizumab pegol.

### **CAN I TAKE OTHER MEDICINES AT THE SAME TIME AS CERTOLIZUMAB PEGOL?**

Most medicines are safe to take with certolizumab pegol. However, it is important that your GP and other doctors are aware that you are taking it.

#### **The BAD Biologic Interventions Register (BADBIR)**

You may be asked to take part in a national register if a biologic medicine is prescribed for you. This register will collect valuable information on side effects and benefits of the drug. It will also inform doctors on how best to use biologic drugs. No information will be passed to the register without your informed consent.

### **WHERE CAN I GET MORE INFORMATION ABOUT CERTOLIZUMAB PEGOL?**

This information sheet does not list all of the side effects of certolizumab pegol. If you wish to find out more about certolizumab pegol please speak to your doctor, specialist nurse or pharmacist.

For further details, see the drug information sheet which comes as an insert with your prescription for certolizumab pegol.

Or visit the website to view the patient information leaflet online:

<https://www.medicines.org.uk/emc/product/7387/pil>

This leaflet aims to provide accurate information about the subject and is a consensus of the views held by representatives of the British Association of Dermatologists: individual patient circumstances may differ, which might alter both the advice and course of therapy given to you by your doctor.

*This leaflet has been assessed for readability by the British Association of Dermatologists' Patient Information Lay Review Panel*

**BRITISH ASSOCIATION OF DERMATOLOGISTS**

**PATIENT INFORMATION LEAFLET**

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