CIMZIA®

PATIENT ALERT CARD

cimzia®
(certolizumab pegol)

Keep this card with you at all times and show this card to any doctor you see for medical treatment.

Infections

CIMZIA® increases the risk of getting infections. Infections may progress more rapidly and be more severe. This includes tuberculosis (TB), which occurs mainly in the lungs (pulmonary TB), in some cases TB can occur in another organ (extra-pulmonary TB) or in more than one organ at the same time (disseminated TB).

Prior to treatment with CIMZIA®:

- You must not be treated with CIMZIA® if you have a serious infection.
- You should be screened for hepatitis B infection. If you are a carrier of hepatitis B infection you should be closely monitored for the signs and symptoms of active hepatitis B infection.

CIMZIA® should be discontinued in patients who develop active hepatitis B infection.

- You should be screened for TB. It is very important that you tell your doctor if you have ever had TB, or if you have been in close contact with someone who has had TB, or if you have visited a country with a high prevalence of TB.

Please record the dates of the last screening for TB below:

Tuberculin test/IGRA:_____

Chest x-ray: _____

During CIMZIA® treatment:

- If you develop symptoms suggestive of an infection, such as fever, persistent cough, weight loss, or tiredness, seek medical attention immediately.

Heart Failure

Prior to treatment with CIMZIA®

- Physicians should exercise caution in patients with heart failure. You must not use CIMZIA® if you have moderate to severe heart failure.

During CIMZIA® treatment:

- If you develop symptoms that can potentially be related to heart failure (e.g. shortness of breath or swelling of the feet) seek medical attention immediately.

Allergic Reactions

If you experience symptoms that could be due to allergic reactions such as chest tightness, wheezing, dizziness, swelling or rash, stop using CIMZIA® and contact your doctor immediately. Some of these reactions could occur after the first administration of CIMZIA®.

Patients receiving vaccinations:

- Please be aware that live or live-attenuated vaccines should not be administered concurrently with CIMZIA®.

Patients requiring surgery:

- If you require surgery on CIMZIA® you should be closely monitored for infection and appropriate action taken as necessary.

Malignancies

- Patients with severe chronic inflammatory diseases, such as rheumatoid arthritis (RA), may be at increased risk of cancer. The use of anti-TNF therapy may also increase the risk of cancer. However, in RA studies, cancers were reported in a similar number of patients treated with CIMZIA® compared to the control group not treated with CIMZIA®.

Reporting of side effects - If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in the patient information leaflet. You can also report side effects directly via the Yellow Card Scheme, website: http://yellowcard.mhra.gov.uk/, if you are in the UK and in Republic of Ireland to the HPRA at HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6767836. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. Please also report AE to UCB Pharma at UCBCares: +44(0) 1753 777100 (UK) or + 353 1463 2371 (Ireland). By reporting side effects you can help provide more information on the safety of this medicine.

Assay Interaction

Please inform your doctors if you are receiving anti-coagulant therapy or if you have a clotting test performed.

Interference with certain tests of blood clotting (coagulation assays) has been detected in patients treated with CIMZIA®. CIMZIA® may erroneously cause these tests to indicate prolonged clotting time when none exists. This effect has been observed with the PTT-LA and STA-PTT A tests from Diagnostica Stago and the HemosIL APTT-SP liquid and HemosIL APTT lyophilised silica tests from Instrumentation Laboratories. Other aPTT assays may be affected as well.Interference with thrombin time (TT) and prothrombin time (PT) assays have not been observed. There is no evidence that CIMZIA® therapy has an effect on blood clotting (in vivo coagulation).

Any prescriber providing medical treatment to this patient should refer to the CIMZIA® SmPC.

Dates of CIMZIA® Treatment

1st injection:_____

Following injections:_____

_____

Patient's Name: _____

GP's Name and Phone:_____

Specialists Name and Phone: _____

- See the Patient Information Leaflet for more information.
- Please make sure you also have a list of all your other medicines with you at any visit to a health care professional.

Please keep this card with you for 5 months after your last CIMZIA® dose, since side effects may occur a long time after your last dose.

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This alert card contains important safety information that you need to be aware of before you are given CIMZIA and during treatment with CIMZIA.

Please refer to the Patient Information Leaflet that comes with your CIMZIA pre-filled syringes for further safety information