Template for letter to other treating physicians
Revlimid®

Dear Dr

Re: Patient……

……

Your patient (named above) has been prescribed lenalidomide

Physician to add treatment details

……

Safety information

Lenalidomide belongs to a group of drugs called 'immunomodulatory drugs' (IMiDs).

Lenalidomide is structurally related to thalidomide, which is a known human teratogen that causes severe life-threatening birth defects. Lenalidomide induced malformations in monkeys similar to those described for thalidomide. Therefore if lenalidomide is taken during pregnancy a teratogenic effect in humans is expected:

- Female patients are advised to avoid pregnancy whilst taking lenalidomide. Any female of child-bearing potential, must use one form of effective contraception as described in the lenalidomide Summary of Product Characteristics starting 4 weeks before, during and continuing for 4 weeks after stopping lenalidomide. In addition a monthly pregnancy test must be taken to confirm that she is not pregnant.
- Male patients are advised that they must use a condom every time they have sexual contact with a pregnant woman or a female of childbearing potential who is not using effective contraception whilst on treatment, during dose interruptions and for one week after discontinuation of treatment.

Lenalidomide therapy is associated with neutropenia and thrombocytopenia. This should be born in mind if the patient presents with signs and symptoms suggestive of infection. Patients should have their full blood-count checked, every week for the first 8 weeks of therapy and at least once a month thereafter. This will be done by the hospital unless otherwise arranged.

There is an increased risk of venous and arterial thromboembolic events (predominantly deep vein thrombosis, pulmonary embolism, myocardial infarctions and cerebrovascular events). Venous thromboembolism was seen to a lesser extent with lenalidomide in combination with melphalan and prednisone in newly diagnosed multiple myeloma and with monotherapy in myelodysplastic syndrome. In patients with myelodysplastic

syndromes, treatment with lenalidomide monotherapy was also associated with a risk of venous thromboembolism (predominantly deep vein thrombosis and pulmonary embolism), but to a lesser extent than in patients with multiple myeloma Patients and doctors are advised to be observant for the signs and symptoms of thrombosis. The combined oral contraceptive, hormone replacement therapy and erythropoetic agents are thus not recommended. Some patients may be prescribed prophylactic anti-coagulant/platelet drugs.

Other most commonly reported adverse events are: constipation, diarrhoea, nausea, pruritus, rash, fatigue and muscle spasms.

Lenalidomide is not metabolised by cytochrome p450 enzymes and does not induce or inhibit these enzymes. In addition warfarin interaction studies were negative. Lenalidomide does interact with digoxin to produce a small increase (14%) in C_{max} – routine monitoring of digoxin is advised.

Further information on lenalidomide (Revlimid®) can be found in the SmPC

Should you require any further information please do not hesitate to contact (Medical team contact):……
on:……

Kind regards,

