ALERT CARD FOR PATIENTS WITH NON ONCOLOGY DISEASES



Why have I been given this card?

This medicine may make you more likely to get infections. This card tells you:

- What you need to know before having Ruxience®.
- · What the signs of an infection are.

 What to do if you think you might be getting an infection It also includes your name and doctor's name and

phone number on the back.

What should I do with this card? Keep this card with you all the time - such as in

your wallet or purse. Show this card to any doctor, nurse or dentist

you see - not just the specialist who prescribes your Ruxience®.

Keep this card with you for 2 years after your last dose of Ruxience®. This is because side effects can develop several months after you have had treatment.

When should I not have Ruxience®?

Do not have Ruxience® if you have an active infection or a serious problem with your immune system.

Tell your doctor or nurse if you are taking or have previously taken medicines which may affect your immune system this includes chemotherapy.

What are the signs of getting an infection? Look out for the following possible signs of infection: Fever or cough all the time · Weight loss Pain without injuring yourself Feeling generally unwell or listless.

If you get any of these, tell a doctor or nurse straight away.

You should also tell them about your Ruxience® treatment.

What else do I need to know?

Rarely Ruxience® can cause a serious brain infection, called "Progressive Multifocal

- Leukoencephalopathy" or PML. This can be fatal.
- Signs of PML include:

- Confusion, memory loss or problems thinking.

- Loss of balance or a change in the way you walk or talk. - Decreased strength or weakness on one side
- of your body. Blurred vision or loss of vision.

If you get any of these, tell a doctor or nurse straight away. You should also tell them about your Ruxience® treatment

Patient's Name:
Doctor's Name:
Doctor's contact details:

Make sure you have a list of all your medicines when you see a health care professional.

Please talk to your doctor or nurse if you have any questions about the information in this card.

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 leaflet. You can also report side effects directly via:

ADR Reporting The Medicines Authority Post-Licensing Directorate Sir Temi Zammit Buildings, Malta Life Sciences Park, San Gwann SGN 3000, Malta Website. www.medicinesauthority.gov.mt

e-mail: postlicensing.medicinesauthority@gov.mt

Other Contact Information For any suspected adverse reactions you may also report such events promptly to Pfizer at:

Pfizer Hellas S.A., 243 Messoghion Ave. N.Psychiko, Athens GR-15451, Greece. Pfizer Hellas Pharmacovigilance Department contact details: +30 210 67 85 908 and +30 210 67 85 908 [24hour line]. fax: +30 210 81 99 996.