Please also read your patient information leaflet carefully before you start taking this medicine.

YOUR COPD TREATMENT PATIENT CARD

This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects using the Medicines Authority ADR reporting form, which is available online at

http://www.medicinesauthority.gov.mt/adrportal, and sent by post or email to;

P: Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority, Sir Temi Zammit Buildings, Malta Life Sciences Park, San Gwann SGN 3000

E: postlicensing.medicinesauthority@gov.mt

By reporting side effects, you can help provide more information on the safety of this medicine.

Dear Patient or Caregiver,

Your doctor has prescribed Daxas® for you as a treatment for your chronic obstructive pulmonary disease (COPD). Please tell your doctor if you have a history of any of the following conditions:

- · cancer, heart failure, use of immunosuppressive medicinal products
- · sleeplessness, anxiety, panic attack, depression, suicidal thoughts or behaviour
- multiple sclerosis (MS) or SLE (Systemic Lupus Erythematosus)
- infection with tuberculosis (TB), herpes, herpes zoster (Shingles), hepatitis, HIV
- progressive multifocal leukoencephalopathy, liver problems (e.g. hepatic impairment)

You should also inform your doctor if during treatment you develop symptoms related to:

- sleeplessness, anxiety, nervousness, panic attack (please describe all symptoms during the attack), depression, changes in mood or behaviour, suicidal thoughts or behaviour.
- · severe infection.

Please tell your doctor if you are taking any other medicines he/she doesn't know about.

In some patients, Daxas® may cause a decrease in body weight (not related to a diet or exercise programme) and it is recommended that you weigh yourself regularly and record your weight on the back of this patient information card.

To help your doctor manage your weight you should bring this card with you at each visit.

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