Checklist for Prescribers –

cyproterone acetate/ethinylestradiol (Dianette®)

Please use this checklist in conjunction with the Summary of Product Characteristics and at regular intervals.

Healthcare Professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

Indication for which Dianette® is prescribed:

Treatment of moderate to severe acne related to androgen sensitivity (with or without seborrhoea) and/or hirsutism in women of reproductive age. For the treatment of acne, Dianette® should only be used after topical therapy or systemic antibiotic treatments have failed.
Since Dianette® is also a hormonal contraceptive, it should not be used in combination with other hormonal contraceptives.

- Thromboembolism (e.g. deep vein thrombosis, pulmonary embolism, heart attack and stroke) is a rare but important risk with use of cyproterone acetate/ethinylestradiol (Dianette®).
- A woman's risk will also depend on her baseline risk of thromboembolism. The decision to use cyproterone acetate/ethinylestradiol (Dianette®) should therefore take into consideration the contraindications and a woman's risk factors, particularly those for thromboembolism – see boxes below and the Summary of Product Characteristics.
- The risk of a thromboembolism with cyproterone acetate/ethinylestradiol (Dianette®) is higher:
  - during the first year of use
  - when re-starting use after an intake break of 1 month or more.
- The decision to use cyproterone acetate/ethinylestradiol (Dianette®) should be taken only after a discussion with the woman to ensure she understands
  - the effect of any intrinsic risk factors on her risk of thrombosis
  - the risk of thromboembolism with Dianette®
  - that she must be alert for signs and symptoms of a thrombosis

Please be reminded to consider the possibility of a thromboembolic event in healthy women of reproductive age also in case of non-distinct, unexplained complaints like pain in the leg, cough/dyspnoea, or headache.

Date of Preparation: Apr 2017

Do not prescribe cyproterone acetate/ethinylestradiol (Dianette®) if you tick any of the boxes in this section. Does the woman have:

- ☐ Concomitant use with another hormonal contraceptive?
- ☐ Current or personal history of a thromboembolic event (e.g. deep vein thrombosis, pulmonary embolism, heart attack, stroke, transient ischaemic attack, angina pectoris)?
- ☐ Knowledge of predisposition for a blood clotting disorder personally?
- ☐ History of migraine with aura?
- ☐ Diabetes mellitus with vascular complications?
- ☐ Very high blood pressure (e.g. systolic ≥160 or diastolic ≥100 mm Hg)?
- ☐ Very high blood lipids?
- ☐ Major surgery or a period of prolonged immobilisation coming up? If so, advise the patient to stop using Dianette and to use a non-hormonal treatment for their skin condition and, if necessary, a non-hormonal method of contraception for at least 4 weeks beforehand and two weeks after full ambulation*.

Discuss the suitability of cyproterone acetate/ethinylestradiol (Dianette®) with the woman if you tick any of the boxes in this section:

- ☐ Is her BMI over 30 kg/m²?
- ☐ Is she aged over 35 years?
- ☐ Is she a smoker? If yes and also over the age of 35 she should be strongly advised to stop smoking or use a non-hormonal treatment for her acne and/or hirsutism.
- ☐ Does she have high blood pressure (e.g. systolic 140–159 or diastolic 90–99 mm Hg)?
- ☐ Does she have a close relative (e.g. parent or sibling) who has had a thromboembolic event (see above list) at a young age (e.g. before 50)?
- ☐ Does she or someone in her immediate family have high blood lipids?
- ☐ Does she get migraines?
- ☐ Does she have a cardiovascular condition such as atrial fibrillation, arrhythmia, coronary heart disease, cardiac valve disease?
- ☐ Does she have diabetes mellitus?
- ☐ Has she given birth in the last few weeks?
- ☐ Does she have any other medical conditions that might increase the risk of thrombosis (e.g. cancer, systemic lupus erythematosus, sickle cell disease, Crohn's disease, ulcerative colitis, haemolytic uraemic syndrome)?
- ☐ Is she taking any other medicines that can increase the risk of thrombosis (e.g. corticosteroids, neuroleptics, antipsychotics, antidepressants, chemotherapy, etc.)?

More than one risk factor may mean cyproterone acetate/ethinylestradiol (Dianette®) should not be used.
Don't forget, a woman's risk factors may change over time and might need to be revisited at regular intervals.

*This should be weighed against the risk of VTE after stopping CPA/EE for 4 weeks or more

Date of Preparation: Apr 2017

Please make sure your patient understands that she should tell a Healthcare Professional she is taking cyproterone acetate/ethinylestradiol (Dianette®) if she:

- Needs an operation
- Needs to have a period of prolonged immobilisation (e.g. because of an injury or illness, or if her leg is in a cast)

→ In these situations it would be best to discuss discontinuing cyproterone acetate/ethinylestradiol (Dianette) until the risk returns to normal.

Please also tell your patient that the risk of a blood clot is increased if she:

- Travels for extended periods (e.g. on long-haul flights)
- Develops one or more of the above risk factors for cyproterone acetate/ethinylestradiol (Dianette®)
- Has given birth within the last few weeks

→ In these situations your patients should be particularly alert for any signs and symptoms of a thromboembolism.

Please **advise your patient to tell you** if any of the above situations change or get much worse.

Please strongly encourage women to read the Patient Information Leaflet that accompanies each pack of Dianette®. This includes the symptoms of blood clots that she must watch out for.

To order additional copies of the Dianette® patient information card and/or prescriber checklist, please contact Bayer Limited on +353 1 2999313 or go to www.bayer.ie.

Date of Preparation: Apr 2017