

**To uncover the new way of healing severe female acne when antibiotics have failed, mail this card : Diane cyproterone acetate and ethinyloestradiol.**

**Contributors**

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TO UNCOVER THE NEW WAY OF  
HEALING SEVERE FEMALE ACNE  
WHEN ANTIBIOTICS HAVE  
FAILED, MAIL THIS CARD.

(Please print clearly)

Doctor \_\_\_\_\_

Address \_\_\_\_\_  
\_\_\_\_\_

Signature \_\_\_\_\_

SCL.D.GP30.RA1.Mar



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# DIANE

cyproterone acetate and ethinylloestradiol

**A REMARKABLE NEW  
THERAPY THAT CAN HEAL  
SEVERE FEMALE ACNE WHEN  
ANTIBIOTICS HAVE FAILED.**



### Diane - Abbreviated prescribing information

**Presentation** The memopack holds 21 pink, sugar-coated tablets, containing 2 mg cyproterone acetate and 0.05 mg ethinyloestradiol.

**Uses** In women only: (a) Severe acne, refractory to prolonged oral antibiotic therapy and (b) Idiopathic hirsutism of mild to moderate degree. Diane blocks androgen receptors and reduces androgen synthesis.

Diane also acts as an oral contraceptive, but should be reserved for women requiring treatment for acne and/or hirsutism. In very severe cases long treatment may be necessary. Treatment should be withdrawn when resolution is complete, but may be repeated if necessary.

**Dosage and Administration** One tablet daily for 21 days, the first course starting on the 5th day of the menstrual cycle. Seven tablet-free days follow each 21-day course. When contraception with Diane is also required, non-hormonal contraceptives (except the rhythm, temperature or cervical mucus methods) must be used during the first 14 days. If withdrawal bleeding fails to occur, the possibility of pregnancy must be excluded before the next course is started.

**Contra-indications, warnings, etc.** Pregnancy. Lactation. Thrombotic disorders and a history of these conditions, sickle-cell anaemia, disorders of lipid metabolism. Other conditions whenever known or suspected to entail a much increased risk of thrombosis. Acute or severe chronic liver disease. Dubin-Johnson syndrome. Rotor syndrome. History, during pregnancy, of idiopathic jaundice or severe pruritus. History of herpes gestationis. Mammmary or endometrial carcinoma, or a history of these conditions. Abnormal vaginal bleeding of unknown cause. Deterioration of otosclerosis during pregnancy.

**Warnings** Like many other steroids, Diane, in very high doses for most of the animal's life span, has increased the incidence of tumours, including carcinoma, in the liver of rats. The relevance to humans is unknown. Diane has shown good liver tolerance in women. In animals, feminisation of male foetuses may occur if cyproterone acetate is given during differentiation of the external genitalia. The possibility must be considered that administration of Diane to women after the 45th day of pregnancy could cause feminisation of male foetuses. Hence, pregnancy is an absolute contra-indication, and must be excluded before Diane is given. Diane shares many properties with combined oral contraceptives. There is evidence of a statistical association between combined oral contraceptives and (1) arterial and venous thromboembolism and infarction of major organs (2) subarachnoid haemorrhage. Other risk factors for thrombosis to be considered before prescribing Diane are smoking and obesity, varicose veins, cardiovascular diseases, diabetes and migraine. The risk of arterial thrombosis associated with combined oral contraceptives increases with age, and this risk is aggravated by cigarette smoking. The possibility cannot be ruled out that certain chronic diseases may occasionally deteriorate.

**Reasons for stopping medication immediately** Pregnancy, because of (1) possible risk to male foetus (see above), (2) suggestions that oral contraceptives may slightly increase the risk of foetal malformations in general; thrombosis, phlebitis, or symptoms suggestive of abnormal risk of incipient thrombosis, including exacerbation or first-ever attack of migraine; unusually frequent or severe headaches; acute visual disturbances; jaundice; six weeks before elective surgery; immobilization; significant hypertension; exacerbation of conditions capable of deteriorating during oral contraception or pregnancy.

**Precautions** Regular monitoring of blood-pressure, genital organs, breasts and all pre-existing diseases, especially those that may deteriorate during pregnancy. The treatment of acne with ultraviolet lamps or prolonged exposure to sunlight increases the risk of the deterioration of chloasma.

**Possible Side-effects** Nausea, vomiting, headaches, breast tension, changed body weight or libido, depressive moods, chloasma, etc.

**Legal Category** POM

**Product Licence Number** DIANE 0053/0116.

**Product Licence Holder** Schering Chemicals Ltd., Pharmaceutical Division, The Brow, Burgess Hill, West Sussex RH15 9NE.

**Basic NHS Price** 3 x 21 tablets: £9.90.

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Pharmaceuticals

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