

Diane 35[®] {Ethinyl estradiol 35 ug; Cyproterone 2mg}

1. What is Diane 35[®]?

Diane 35[®] is a unique combination hormone product containing per tablet, 35ug of ethinyl estradiol along with 2 mg of cyproterone, an anti-androgenic progestin (also found in Androcur[®]). It is formulated and packaged in a similar fashion to birth control pills. In Canada, Diane 35[®] is officially indicated of women with **severe acne**, unresponsive to oral antibiotic and other available treatments, **with associated symptoms of androgenization**, including seborrhea and mild hirsutism. (NOTE: will also provide reliable contraception when taken as recommended. See product monograph.)

2. How does Diane 35[®]'s contraceptive effect compare to other OCs?

Although not sanctioned solely for this use in Canada, Diane 35[®] is approved and used in some other countries as a contraceptive.¹ Diane 35[®] provides effective birth control comparable to other combined oral contraceptives (OCs) but because of its unique formulation it is used to best advantage in women with the aforementioned conditions. Both the estrogen and cyproterone components have documented contraceptive effects.² In otherwise healthy women, other OCs would be more rational and appropriate choices. Should pregnancy occur while on Diane 35[®], the potential risk to the fetus appears to be minimal, though this is not well understood compared to other OCs.²

3. What is its role in treatment of acne relative to other OCs?

Although targeted for use in moderate to severe unresponsive acne, it is unclear whether Diane 35[®] offers any benefit over other OCs in cases uncomplicated by other androgen-dependent conditions. All OCs have beneficial effects in acne due to the estrogen-induced increase in sex-hormone-binding-globulin (SHBG) which also overrides any supposed androgen-like effect of the progestin component. In theory the new progestins (norgestimate, desogestrel) are supposed to be more beneficial because of their reduced androgenicity and greater SHBG production/testosterone binding but this has yet to be proven in clinical trials.³ Good comparative trials are few and difficult to compare as each define acne and its severity differently...**overall no product appears superior** and it is interesting to note that the putatively "androgenic" progestins are often associated with the least acne and have comparable beneficial effects in established cases.⁴ In studies comparing Diane 35 with other OCs in acne, results are equivocal. One study comparing Diane 50[®] with Triphasil[®] (levonorgestrel) showed similar reduction in acne after 6 months²; another found no difference between groups treated for 4 months with either Diane 35[®] or a biphasic OC containing desogestrel.⁵ Other studies have found Diane 35[®] to produce more favorable results although generally these have been in women with additional androgenization symptoms.⁶ From a cost perspective, **Diane 35[®] is more expensive than most other OCs**; a 2 month supply costs over \$50 or about \$330 per year as compared to \$160-230 annually for other OC brands. An initial trial of another combination OC may be considered in some cases before trying Diane 35[®] for the hormonal treatment of acne.

¹ New Zealand website for Diane 35[®]: <http://www.dermnet.org.nz/adverts/diane35/ad7.diane35.html>

² Micromedex Computer Drug Data Base, 2000.

³ Sherif K. Benefits and risks of oral contraceptives. Am J Obstet Gynecol 1999; 180: S343-8.

⁴ Thorneycroft I. Update on androgenicity. Am J Obstet Gynecol 1999; 180: S288-94.

⁵ Dieben TO et al. Effects of CTR-24 a biphasic OC compared to Diane 35 in women with acne. Contraception 1994;50:373-82.

⁶ Erkkola R et al. Ovulation inhibitors containing cyproterone or desogestrel in the treatment of hyperandrogenic symptoms. Acta Obstet Gynecol Scand 1990; 69:61-5.