



The Society of Obstetricians
and Gynaecologists of Canada
La Société des obstétriciens
et gynécologues du Canada



Canadian Dermatology Association
Association canadienne de dermatologie



Federation of Medical
Women of Canada
Fédération des femmes
médecins du Canada



CANADIAN
PHARMACISTS
ASSOCIATION

ASSOCIATION DES
PHARMACIENS
DU CANADA

PATIENT FACT SHEET on DIANE® 35

July 2005

The Society of Obstetricians and Gynaecologists of Canada, the Canadian Dermatology Association, the Federation of Medical Women of Canada and the Canadian Pharmacists Association wishes to outline a few facts regarding DIANE® 35 following the Health Canada Advisory issued May 12, 2005

- DIANE® 35 is a medication prescribed to women for treatment of severe acne, hirsutism (facial hair) and other signs of androgenization (excess of male hormones).
- DIANE® 35 is NOT indicated for use as an oral contraceptive (birth control pill) alone and should not be prescribed as such. However, when taken as recommended for the above indications, DIANE® 35 will provide reliable contraception. Women taking DIANE® 35 should not be prescribed an additional hormonal contraceptive.
- Use of any estrogen/progestin combination oral contraceptives (birth control pill) increases your risk of venous thromboembolism (VTE-blood clot), including blood clots in the legs and lungs as compared with no use. However, the absolute risk to any individual user is low. It is estimated that 1-3 of every 10,000 users will have a blood clot in a year. This is approximately the same risk for blood clot that results from smoking cigarettes or being obese and is less than one half of the risk of blood clots associated with a normal pregnancy.
- The medical conditions of hyperandrogenism (excess of male hormones), hirsutism (facial hair) and severe acne are in themselves associated with an increase in blood clots, even without treatment.
- DIANE® 35 can be appropriately prescribed if deemed necessary by the physician and if it is well tolerated.
- We recommend that you do not make any changes to your existing treatment without first consulting with your physician.