Depo-subQ provera 104™: Clinical brief

BACKGROUND

Depo-subQ provera 104™ (depo-subQ) is a new formulation of the injectable contraceptive Depo-Provera.* Administered through subcutaneous injection, depo-subQ contains 30 percent less depot medroxyprogesterone acetate (DMPA) than the intramuscular presentation (DMPA IM, 150 mg/mL medoxyprogesterone acetate sterile aqueous suspension). Depo-subQ’s contraceptive efficacy and safety profiles are equivalent to that of DMPA IM. Depo-subQ is indicated for the prevention of pregnancy in women of childbearing potential and for management of endometriosis-associated pain.

In addition to providing three months of contraception, other known benefits of DMPA IM also apply to depo-subQ, including:

- Rapid onset of efficacy—no backup contraceptive method required during first cycle of use.
- Efficacy—not compromised by body mass index (BMI).
- Convenient administration—easy to use.
- Privacy—women can use this contraceptive method without telling their spouses or families.
- Safety—for women for whom contraceptive use of estrogen is ill-advised or contraindicated.¹

Depo-subQ will soon be available in the Uniject™ injection system (Uniject), which is a prefilled, autodisable injection device containing 0.65 mL (104 mg) of medroxyprogesterone acetate (MPA) sterile aqueous suspension.²

HOW IT WORKS

Depo-subQ provera 104 mg/0.65 mL contains MPA, a derivative of progesterone, as its active ingredient. When depo-subQ is administered to women every three months (12 to 14 weeks), it inhibits the secretion of gonadotropins, preventing follicular maturation and ovulation and causing endometrial thinning. Because DMPA is absorbed more slowly when administered subcutaneously, a 30 percent lower dose of depo-subQ allows for a lower peak MPA concentration and above-minimum serum MPA levels for suppressed ovulation over a targeted three months in comparison with DMPA IM.³

EFFECTIVENESS

As the following clinical evidence suggests, depo-subQ's efficacy, safety, and immediacy of onset are equivalent to DMPA IM’s and the product effectively suppresses ovulation for at least 13 weeks regardless of race, ethnicity, or BMI:

- In a randomized, evaluator-blinded study comparing efficacy, safety, and acceptability of depo-subQ with DMPA IM over two years with an optional third year among 225 women in Brazil, Canada, and the United States depo-subQ was well tolerated and provided comparable contraceptive efficacy and bone mineral density outcomes to that of DMPA IM.¹
- No pregnancies were reported among two large, open-label, Phase 3 studies that assessed the one-year contraceptive efficacy, safety, and patient satisfaction with depo-subQ.³ The studies—one in North and South...
America and the other in Europe and Asia—including 16,023 women-cycles of exposure to depo-subQ and many overweight and obese women.

- In a randomized, prospective, evaluator-blinded, single-center trial conducted in Los Angeles, California, with 20 African American and 38 Caucasian women, depo-subQ demonstrated the same contraceptive efficacy, pharmacokinetics, and pharmacodynamics over 12 months as DMPA IM among a broad range of women, regardless of race and BMI.¹

- In a single-center, single-dose, open-label depo-subQ trial conducted in Singapore with 24 Asian women, ovulation suppression was maintained for at least 91 days regardless of ethnicity and injection site. The pharmacokinetic parameters for MPA in these Asian women were similar to those previously reported in Caucasian women.²

- The combined results of the Singapore and Los Angeles trials suggest that consistent suppression of ovulation with depo-subQ is independent of both ethnicity and injection site.²

ADMINISTRATION AND DOSAGE

Depo-subQ is administered once every three months (12 to 14 weeks). It is indicated for subcutaneous injection into the anterior thigh or abdomen. The back of the upper arm as an injection site is being evaluated, as many other types of subcutaneous injections are delivered in the arm. Depo-subQ is not formulated for intramuscular injection and dosage does not need to be adjusted for body weight.³

CONTRAINDICATIONS AND SIDE EFFECTS

Depo-subQ is expected to have equivalent—if not improved—tolerability in comparison with the DMPA IM formulation because side effects are generally dose dependent.³ Contraindications are identical to those of DMPA IM. Common side effects for both products include headache; bleeding irregularities (including amenorrhea, irregular spotting or bleeding, prolonged spotting or bleeding, and heavy bleeding—irregular bleeding typically decreases over time, and amenorrhea becomes more common); increased weight; and injection site reactions—typically mild injection-site pain, granuloma or atrophy. While use of DMPA IM and depo-subQ is associated with decreased bone mineral density, no evidence suggests that use of DMPA leads to significantly increased risk of bone fracture.⁴ Bone loss associated with DMPA use is reversible, and prior use of DMPA is not likely to be an important risk factor for low bone density or fracture in older women many years after discontinuation.⁵⁶

REFERENCES


2 Pfizer Inc. Depo-subQ provera 104™ medroxyprogesterone acetate injectable suspension 104 mg/0.65 mL. Physician information. New York: Pharmacia & Upjohn Company - Division of Pfizer Inc.; revised October 2007.


For more information regarding this project, please visit our web page: www.path.org/projects/uniject-dmpa.php.

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