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Depo-Provera (Medroxyprogesterone)

??? ??????: 30 ?????2/????? 2017

The following important adverse reactions observed with the use of Depo-Provera CI are discussed in greater detail in the Warnings and Precautions section (5):

-] **WARNINGS AND PRECAUTIONS** Loss of Bone Mineral Density [see
-] **WARNINGS AND PRECAUTIONS** Thromboembolic disease [see
-] **WARNINGS AND PRECAUTIONS** Breast Cancer [see
-] **WARNINGS AND PRECAUTIONS** Anaphylaxis and Anaphylactoid Reactions [see
-] **WARNINGS AND PRECAUTIONS** Bleeding Irregularities [see
-] **WARNINGS AND PRECAUTIONS** Weight Gain [see

Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical studies of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

In the two clinical trials with Depo-Provera CI, over 3,900 women, who were treated for up to 7 years, reported the following adverse reactions, which may or may not be related to the use of Depo-Provera CI. The population studied ranges in age from 15 to 51 years, of which 46% were White, 50% Non-White, and 4.9% Unknown race. The patients received 150 mg Depo-Provera CI every 3-months (90 days). The median study duration was 13 months with a range of 1-84 months. Fifty eight percent of patients remained in the study after 13 months and 34% after 24 months.

Table 1 : Adverse Reactions that Were Reported by More than 5% of Subjects

Adverse Reactions (Incidence (%))	Body System*
Headache (16.5%) Abdominal pain/discomfort (11.2%)	Body as a Whole
Increased weight > 10lbs at 24 months (37.7%)	Metabolic/Nutritional
Nervousness (10.8%) Dizziness (5.6%) Libido decreased (5.5%)	Nervous
Menstrual irregularities: (bleeding (57.3% at 12 months, 32.1% at 24 months) amenorrhea (55% at 12 months, 68% at 24 months)	Urogenital
* Body System represented from COSTART medical dictionary.	

Table 2 : Adverse Reactions that Were Reported by between 1 and 5% of Subjects

Adverse Reactions (Incidence (%))	Body System*
Asthenia/fatigue (4.2%) Backache (2.2%) Dysmenorrhea (1.7%) Hot flashes (1.0%)	Body as a Whole
Nausea (3.3%) Bloating (2.3%) Edema (2.2%)	Digestive Metabolic/Nutritional
Leg cramps (3.7%) Arthralgia (1.0%)	Musculoskeletal
Depression (1.5%) Insomnia (1.0%) Acne (1.2%) No hair growth/alopecia (1.1%) Rash (1.1%)	Nervous Skin and Appendages
Leukorrhea (2.9%) Breast pain (2.8%) Vaginitis (1.2%)	Urogenital
* Body System represented from COSTART medical dictionary.	

bleeding (8.2%), amenorrhea (2.1%), weight gain (2.0%) :of subjects %2 ? **Adverse reactions leading to study discontinuation in**

Post-marketing Experience

The following adverse reactions have been identified during post approval use of Depo-Provera CI. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

There have been cases of osteoporosis including osteoporotic fractures reported post-marketing in patients taking Depo-Provera CI.

Table 3 : Adverse Reactions Reported during Post-Marketing Experience

Adverse Reactions	Body System*
Chest pain, Allergic reactions including angioedema, Fever, Pain at injection site, Chills, Axillary swelling	Body as a Whole
Syncope, Tachycardia, Thrombophlebitis, Deep vein thrombosis, Pulmonary embolus, Varicose veins	Cardiovascular
Changes in appetite, Gastrointestinal disturbances, Jaundice, Excessive thirst, Rectal bleeding	Digestive
Anemia, Blood dyscrasia	Hematologic and Lymphatic
Osteoporosis	Musculoskeletal
Paralysis, Facial palsy, Paresthesia, Drowsiness	Nervous
Dyspnea and asthma, Hoarseness	Respiratory
Hirsutism, Excessive sweating and body odor, Dry skin, Scleroderma	Skin and Appendages
Cervical cancer, Breast cancer, Lack of return to fertility, Unexpected pregnancy, Prevention of lactation, Changes in breast size, Breast lumps or nipple bleeding, Galactorrhea, Melasma, Chloasma, Increased libido, Uterine hyperplasia, Genitourinary infections, Vaginal cysts, Dyspareunia	Urogenital

* Body System represented from COSTART medical dictionary.