Depo-Provera 150 mg/ml (medroxyprogesterone acetate)

ABBREVIATED PRESCRIBING INFORMATION (UK)

Please refer to the SmPC before prescribing Depo-Provera 150 mg/ml.

**Presentation:** 1 ml Disposable syringe, containing 150 mg medroxyprogesterone acetate in a Sterile suspension for injection.

**Indication:** Long-term contraceptive agent, in women who have been counselled concerning the likelihood of menstrual disturbance, potential delay in return to full fertility and risks of bone mineral density losses. Short-term contraception for the following (i) for partners of men undergoing vasectomy, until the vasectomy becomes effective, (ii) in women who are being immunised against rubella (iii) in women awaiting sterilisation. May only be used in adolescents (12-18 years) after other methods of contraception were considered to be unsuitable.

**Dosage:**
- **First injection:** 150mg intramuscular injection during the first 5 days of a normal menstrual cycle.
- **Post Partum:** Within 5 days post-partum if not breast-feeding. Women in puerperium can experience prolonged and heavy bleeding, therefore caution is required, and women should be advised accordingly. If the puerperal woman will breast-feed, the initial injection should be no sooner than 6 weeks post partum.
- **Further doses:** These should be given at 12 week intervals, however as long as the injection is given no later than 5 days after the 12 week interval, no additional contraception measures are required. For partners of men undergoing vasectomy, a second injection 12 weeks after the first may be necessary in a small proportion of patients where the partner's sperm count has not fallen to zero. If the dose repeat interval is greater than 89 days (12 weeks and 5 days) for any reason, then pregnancy should be excluded before the next injection is given and the patient should use additional contraceptive measures (e.g. barrier) for fourteen days after this subsequent injection.

**Elderly:** Not appropriate. Children: Depo-Provera is not indicated before menarche. Data in adolescent females (12-18 years) is available, Refer to the Summary of Product Characteristics for further information. Other than concerns about loss of BMD, the safety and effectiveness of Depo-Provera is expected to be the same for adolescents after menarche and adult females. Depo-Provera may be poorly metabolised in patients with severe liver insufficiency. No dosage adjustment is required for renal insufficiency.

**Administration:** By deep intramuscular injection. The sterile aqueous suspension should be vigorously shaken just before use to ensure the dose being given represents a uniform suspension.

**Contraindications:** Known hypersensitivity to medroxyprogesterone acetate or any of its excipients. Pregnancy. Known or suspected hormone-dependent malignancy of breast or genital organs. Patients with presence or a history of severe hepatic disease whose liver function has not returned to normal. Patients with abnormal uterine bleeding, whether administered alone or in combination with oestrogen until a definite diagnosis has been established and the possibility of genital tract malignancy eliminated.

**Special Warnings and Precautions:** Use of Depo-Provera reduces serum oestrogen levels and is associated with significant loss of BMD due to the known effect of oestrogen deficiency on the bone remodelling system. Bone loss is greater with increasing duration of use, however BMD appears to increase after Depo-Provera is discontinued and ovarian oestrogen production increases. In adolescents and women with significant lifestyle and/or medical risk factors for osteoporosis, other methods of contraception should be considered before using Depo-Provera. The administration of Depo-Provera usually causes disruption of the normal menstrual cycle. Bleeding patterns can include amenorrhoea. Women should be counselled that there is a potential for delay in return to full fertility following use of the method, regardless of the duration of use. Long-term case-controlled surveillance of Depo-Provera users found no
overall increased risk of ovarian, liver, or cervical cancer and a prolonged, protective effect of reducing the risk of endometrial cancer in the population of users. Refer to the Summary of Product Characteristics for further information. There is a tendency for women to gain weight while on Depo-Provera therapy. Reports of anaphylactic responses (anaphylactic reactions, anaphylactic shock, anaphylactoid reactions) have been received. Should the patient experience pulmonary embolism, cerebrovascular disease or retinal thrombosis while receiving Depo-Provera, the drug should not be re-administered. Patients with a history of endogenous depression should be carefully monitored. Some patients may complain of premenstrual type depression while on Depo-Provera therapy. As with any intramuscular injection, especially if not administered correctly, there is a risk of abscess formation at the site of injection, which may require medical and/or surgical intervention. Patients with a history of the following conditions should be carefully monitored: endogenous depression (including premenstrual-type depression), migraine or unusually severe headaches, acute visual disturbances of any kind, pathological changes in liver function or hormone levels. Diabetic patients should be carefully monitored while receiving DMPA; increases and decreases in total cholesterol, triglycerides and low-density lipoprotein (LDL) cholesterol have been observed. DMPA have been associated with a 15-20% reduction in serum high density lipoprotein (HDL) cholesterol levels. Potential for an increased risk of coronary disease should be considered prior to use. Doctors should carefully consider the use of DMPA in patients with recent trophoblastic disease before levels of human chorionic gonadotrophin have returned to normal. Pathologists should be informed of the patient's use of Depo-Provera if endometrial or endocervical tissue is submitted for examination. Results of certain laboratory tests may be affected. Refer to the Summary of Product Characteristics for further information.

Drug interactions: Aminoglutethimide administered concurrently may significantly depress bioavailability. The possibility of interaction (including oral anticoagulants) should be borne in mind in patients receiving concurrent treatment with other drugs. Medroxyprogesterone acetate (MPA) is metabolized in-vitro primarily by hydroxylation via the CYP3A4. Specific drug-drug interaction studies evaluating the clinical effects with CYP3A4 inducers or inhibitors on MPA have not been conducted and therefore the clinical effects of CYP3A4 inducers or inhibitors are unknown.

Pregnancy and Lactation: Check for pregnancy before initial injection, and also if administration of subsequent injection is delayed beyond 89 days (12 weeks and 5 days).

Effects on ability to drive and use machines: Depo-Provera may cause headaches and dizziness. Patients should be advised not to drive or operate machinery if affected.

Side-effects: Very common (≥1/10): nervousness, abdominal pain or discomfort, headache, weight increased or decreased. Common (≥1/100 to <1/10): depression, libido decrease, nausea, abdominal distention, alopecia, acne, rash, back pain, dizziness, pain in extremity, vaginal discharge, breast tenderness, dysmenorrhea, genitourinary tract infection, oedema/fluid retention, asthenia. Uncommon (≥1/1000 to <1/100): drug hypersensitivity, increased or decreased appetite, insomnia, seizure, somnolence, paraesthesia, hot flush, dyspnoea, hepatic function abnormal, hirsutism, urticaria, pruritus, chloasma, dysfunctional uterine bleeding (irregular, increased, decreased, spotting), galactorrhoea, pelvic pain, dyspareunia, suppressed lactation, chest pain. Other side effects include: breast cancer, anaemia, anaphylactic reaction, anaphylactoid reaction, angioedema, anorgasmia, emotional disturbance, affective disorder, irritability, anxiety, migraine, paralysis, syncope, vertigo, tachycardia, embolism and thrombosis, deep vein thrombosis, thrombophlebitis, hypertension, varicose veins, pulmonary embolism, rectal haemorrhage, gastrointestinal disorder, jaundice, hepatic enzyme abnormal, lipodystrophy acquired, dermatitis, ecchymosis, scleroderma, skin striae, arthralgia, muscle spasms, osteoporosis, osteoporotic fractures, vaginitis, amenorrhea, breast pain, metrorrhagia, menometrorrhagia, menorrhagia, vulvovaginal dryness, breastatrophy, ovarian cyst, premenstrual syndrome, endometrial hyperplasia, breast mass, nipple exudate bloody, vaginal
cyst, breast enlargement, lack of return to fertility, sensation of pregnancy, pyrexia, fatigue, injection site reaction, dysphonia, VIIth nerve paralysis, axillary swelling, glucose tolerance decreased, cervical smear abnormal.

Refer to the Summary of Product Characteristics for more detailed information on side-effects.

Package Quantities and Basic NHS Cost: Single 1ml Syringe pack: £6.01. Legal Category: POM. Marketing Authorisation Number and Holder: PL 00057/0965, Pfizer Limited, Ramsgate Road, Sandwich, CT13 9NJ, UK. Last Updated: May 2016

Further information is available on request from: Medical Information at Pfizer Limited, Walton Oaks, Dorking Road, Tadworth, Surrey, KT20 7NS, UK. Tel: +44 (0) 1304 616161

Ref: DP 14_0

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Pfizer Medical Information on 01304 616161.