Package leaflet: Information for the patient

Depo-Provera® 150 mg/ml Suspension for Injection
Medroxyprogesterone acetate

Read all of this leaflet carefully before you start using this medicine because it contains important information for you

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

IMPORTANT INFORMATION YOU SHOULD KNOW ABOUT DEPO-PROVERA
Depo-Provera is a very effective injectable contraceptive which gives 12 weeks' continuous contraception with each injection. The effect is not reversible once the injection is given.

- You must have injections of this contraceptive regularly every 3 months (12 – 13 weeks), otherwise you may risk becoming pregnant (see section 3).
- Depo-Provera may not be suitable for every woman. You will need to discuss with your doctor or healthcare professional providing your contraception whether it is suitable for you, especially if you wish to use it for more than 2 years (see section 1).
- Depo-Provera may not be suitable for you if you have a history of certain medical conditions (see section 2 under 'Before you use Depo-Provera') or if you are taking a medicine called aminoglutethiamide that thins the blood (see section 2 under 'Other medicines and Depo-Provera'). Your doctor or nurse should take a full medical history before prescribing Depo-Provera.
- Regular use of Depo-Provera causes a gradual loss of bone mineral density (see section 4). It is not known whether this may lead to bone thinning (osteoporosis) in later life. Teenagers who are rapidly developing their bones may be at particular risk and should only use Depo-Provera if other methods of contraception have been discussed and considered unsuitable or unacceptable.
- Your doctor may plan to conduct a general medical as well as a gynaecological examination before they decide to prescribe Depo-Provera for you and may request you to visit the clinic for similar examinations at appropriate intervals thereafter.

What is in this leaflet

1. What Depo-Provera is and what it is used for

Depo-Provera is a long acting contraceptive. This medicine contains medroxyprogesterone acetate (DMPA), which is one of a group of medicines called 'Progestogens'. It is similar to (but not the same as) the natural hormone progesterone that is produced in the ovaries during the second half of your menstrual cycle.

Depo-Provera acts by preventing an egg from fully developing and being released from the ovaries during your menstrual cycle. If an egg is not released it cannot become fertilised by

sperm and result in pregnancy. Depo-Provera also causes changes in the lining of your womb that makes it less likely for pregnancy to occur. It also thickens the mucus at the entrance of the womb, making it more difficult for sperm to enter.

Depo-Provera can be used:

- For long-term contraception where you and the person who provides your contraception (e.g. your doctor or healthcare professional) have decided that this method is the most suitable for you.
- If you wish to use Depo-Provera for more than 2 years, your doctor or healthcare professional may wish to re-evaluate the risks and benefits of using Depo-Provera to make sure that it is still the best option for you.
- In teenagers, only after other methods of contraception have been discussed with the healthcare professional who provides your contraception and considered to be unsuitable or unacceptable.
- For just one or two occasions in the following cases:
  - if your partner is undergoing a vasectomy, to give you protection until the vasectomy becomes effective;
  - if you are being immunised against rubella, to prevent pregnancy during the period of activity of the virus;
  - if you are awaiting sterilisation.

2. What you need to know before you use Depo-Provera

Do not use Depo-Provera

- If you are allergic (hypersensitive) to the active ingredient (DMPA) or any of the other ingredients of this medicine (listed in section 6). There is a small risk of a severe allergic reaction to Depo-Provera that will require emergency medical treatment.
- If you think you may be pregnant. You may be required to have a negative pregnancy test before you are given your first dose of this medicine.
- If you have had, or think you may have, hormone-dependent cancer of the breast or sex organs.
- If you have, or have had, a blood clotting disorder such as deep vein thrombosis (blood clot in the legs) or pulmonary embolism (blood clot in the lung).
- If you have unexplained vaginal bleeding.
- If you have a severe liver disease such as jaundice (yellowing of the skin) or abnormal liver function.
- If you have not yet started your periods.
- If you have meningioma or have ever been diagnosed with a meningioma (a usually benign tumour of the tissue layer surrounding the brain and spinal cord).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Depo-Provera.

Before your doctor or healthcare professional prescribes Depo-Provera, you may need to have a physical examination. It is important to tell your doctor or healthcare professional if you have, or have had in the past, any of the following conditions. Your doctor will then discuss with you whether Depo-Provera is suitable for you.

- Migraine headaches – if you develop migraine you should consult your doctor before receiving further injections of Depo-Provera
- Diabetes, or a family history of diabetes
- Severe pain or swelling in the calf (indicating a possible thromboembolic disorder)

- Problems with your eyesight while using Depo-Provera; for example a sudden partial or complete loss of vision or double vision
- If you have a history of depression, or are currently receiving treatment for depression
- Problems with your liver or liver disease
- Problems with your kidneys or kidney disease
- If you, or another member of your family, have a history of heart disease or cholesterol problems
- If you have a personal history or a family history of osteoporosis (see section 4, 'Possible effects on your bones')
- Asthma
- Epilepsy
- If you are using certain medicines such as high dose glucocorticoids (steroids), tell the person who provides your contraception if you are taking these or any other medicines - they may recommend a more suitable method of contraception.

Psychiatric disorders
Some women using hormonal contraceptives including Depo-Provera have reported depression or depressed mood. Depression can be serious and may sometimes lead to suicidal thoughts. If you experience mood changes and depressive symptoms contact your doctor for further medical advice as soon as possible.

Possible effects on your periods
Depo-Provera will usually disturb the pattern of a woman's period.
After the first injection, it is most likely that you will have irregular, possibly lengthy bleeding or spotting. This will continue in some women. This is quite normal and nothing to worry about.
One third of women will not have any bleeding at all after the first injection. After 4 injections, most women find that their periods have stopped completely. Not having periods is nothing to worry about.

If you experience very heavy or prolonged bleeding you should talk to your doctor. This happens rarely but can be treated.

When you stop taking Depo-Provera your periods will return to normal in a few months.

Possible effects on your bones
Depo-Provera works by lowering levels of oestrogen and other hormones. However, lower oestrogen levels can cause bones to become thinner (by reducing bone mineral density). Women who use Depo-Provera tend to have lower bone mineral density than women of the same age who have never used it. The effects of Depo-Provera are greatest in the first 2-3 years of use. Following this, bone mineral density tends to stabilise and there appears to be some recovery of bone density when Depo-Provera is stopped. It is not yet possible to say whether Depo-Provera increases the risk of osteoporosis (weak bones) and fractures in later life (after the menopause).

The following are risk factors in the development of osteoporosis in later life. You should discuss with your doctor before starting treatment if you have any of the following as an alternative contraceptive may be more suitable to your needs;
- Chronic alcohol and/or tobacco use
- Chronic use of drugs that can reduce bone mass, e.g. epilepsy medication or steroids
- Low body mass index or eating disorder, e.g. anorexia nervosa or bulimia
- Previous low trauma fracture that was not caused by a fall
- Strong family history of osteoporosis

Teenagers (up to 18 years)
Normally, the bones of teenagers are rapidly growing and increasing in strength. The stronger the bones are when adulthood is reached, the greater the protection against osteoporosis in later life. Since Depo-Provera may cause teenage bones to become thinner at a time when they should be growing, its effect may be particularly important in this age group. Bones start to recover when Depo-Provera is stopped, but it is not yet known whether the bone mineral density reaches the same levels as it would have if Depo-Provera had never been used. **You should therefore discuss whether another form of contraception might be more suitable for you with the person who provides your contraception before starting Depo-Provera.**

If you use Depo-Provera, it may help your bones if you take regular weight-bearing exercise and have a healthy diet, including an adequate intake of calcium (e.g. in dairy products) and vitamin D (e.g. in oily fish).

Possible risk of cancer
Studies of women who have used different forms of contraception found that women who used Depo-Provera for contraception had no increase in overall risk of developing cancer of the ovary, womb, cervix or liver.

Possible risk of breast cancer
Every woman is at risk of breast cancer whether or not she receives injections of medicines like Depo-Provera. Breast cancer is rare under 40 years of age, but the risk increases as a woman becomes older.

There seems to be a slightly increased risk of breast cancer in women who take injectable contraceptives compared to women of the same age who do not. It is not certain whether Depo-Provera causes the increased risk of breast cancer or whether women receiving it are examined more often, so that breast cancer is noticed earlier. The breast cancer seems less likely to have spread when found in women who receive medicines like Depo-Provera than in women who do not.

The risk of finding breast cancer is not affected by how long a woman is on the injection, but by the age at which she stops. This is because the risk of breast cancer strongly increases as a woman becomes older. Ten years after stopping hormonal contraceptive injections, the risk of finding breast cancer is the same as for women who have never used hormonal contraceptives.

In 10,000 women who receive injections like Depo-Provera for up to 5 years, but stop taking it by the time they are aged 20, it is estimated that less than 1 additional case of breast cancer would be found up to 10 years afterwards, compared with the number found in 10,000 women who had never had the injection.

For 10,000 women who are on injections like Depo-Provera for 5 years and stop it by the age of 30, there would be 2 or 3 extra cases of breast cancer found up to 10 years afterwards. These are in addition to the 44 cases of breast cancer found in 10,000 women in this age group who had never had the injection.

For 10,000 women who take Depo-Provera for 5 years and stop it by the age of 40, there would be about 10 extra cases found up to 10 years afterwards. These are in addition to 160 cases of breast cancer found in 10,000 women in this age group who had never had the injection.

Meningioma

Use of medroxyprogesterone acetate has been linked to the development of a usually benign tumour of the tissue surrounding the brain and spinal cord (meningioma). The risk increases especially when you use it for longer duration (several years). If you are diagnosed with meningioma, your doctor will stop your treatment with Depo-Provera (see section 'Do not use Depo-Provera'). If you notice any symptoms such as changes in vision (e.g. seeing double or blurriness), hearing loss or ringing in the ears, loss of smell, headaches that worsen with time, memory loss, seizures, weakness in your arms or legs, you must tell your doctor straightaway.

Possible risk of forming an abscess at the injection site
As with any intramuscular injection, there is a risk of an abscess forming at the site of injection. This may require medical or surgical attention.

Possible risk of weight gain
Some women gained weight while using Depo-Provera. Studies show that over the first 1-2 years of use, the average weight gain was 5-8 lbs. Women completing 4-6 years of therapy gained an average of 14-16.5 lbs.

Cervical smear testing
The results of a cervical smear and some laboratory tests could also be affected if you are using Depo-Provera so it is important that you tell your doctor.

Protection against sexually transmitted infections:
Depo-Provera does not protect against HIV infection e.g. AIDS and any other sexually transmitted infections. Depo-Provera is a sterile injection and, when used as directed, will not expose you to sexually transmitted infections by itself.

Safer sex practices, including correct and consistent use of condoms, reduce the transmission of sexually transmitted infections through sexual contact, including HIV.

You should seek advice from your healthcare professional on how to decrease your risk of catching sexually transmitted infections including HIV.

Other medicines and Depo-Provera
- Tell your doctor or healthcare professional if you are taking a medicine called aminoglutethiamide, or other medicines that thin your blood (anticoagulants), as these may affect the way Depo-Provera works.
- Always tell your doctor, or any healthcare professional who treats you, that you are using Depo-Provera as a contraceptive if you are taking or have recently taken any other medicines, even those you bought yourself without a prescription, because medicines can sometimes interact with each other.

Pregnancy, breast-feeding and fertility

- Depo-Provera must not be taken if you are pregnant as hormonal medicines can affect the developing baby.
- If you think you may have become pregnant while using Depo-Provera for contraception, tell your doctor immediately.

Effect on future fertility
- Your usual level of fertility will return when the effect of the injection has worn off.
- This takes different amounts of time in different women, and does not depend on how long you have been using Depo-Provera.
- In most women the effect will have worn off 4 to 31 months after the last injection and the average time for conceiving is 10 months.

If you are breast-feeding

- Depo-Provera does not prevent the breast from producing milk so nursing mothers can use it. However, it is better for the baby that for the first few weeks after birth its mother's milk contains no traces of any medicines, including Depo-Provera.
- Your doctor or healthcare professional may advise that you wait until at least 6 weeks after your baby has been born before you start using Depo-Provera for contraception.
- If a baby is exposed to Depo-Provera in the breast milk, no harmful effects have been seen in babies and children.

Driving and using machines
No effects on the ability to drive or use machines have been seen with Depo-Provera.

Depo-Provera contains methyl parahydroxybenzoate, propyl parahydroxybenzoate and sodium
Methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) may cause allergic reactions (possibly delayed), and exceptionally, bronchospasm.
This medicinal product contains less than 1 mmol sodium (23 mg) per 150 mg/ml, i.e. essentially 'sodium free'.

3. How to use Depo-Provera

This medicine will be given to you by your doctor or healthcare professional.
(The last section of this leaflet contains instructions for your doctor or healthcare professional on how they should do this.)

Depo-Provera is given every 3 months (12-13 weeks) as a single intramuscular injection of 1 ml (150 mg medroxyprogesterone acetate) into the buttock or upper arm. The injection is given during the first 5 days after the beginning of a normal menstrual period.

Following childbirth the first Depo-Provera injection can be given within 5 days after childbirth if you are **not** breastfeeding.

Provided that the injection is given at the times states above, then you are protected from pregnancy straight away and there is no need to take extra precautions.

Depo-Provera works as a contraceptive for 12 weeks in your body. There is no way of reversing the injection once it is given.

For effective contraceptive cover Depo-Provera **must** be given at 3 month intervals. Make sure that you or your doctor makes your next appointment for 3 months time.

The risk of heavy or prolonged vaginal bleeding may be increased if Depo-Provera is used immediately following childbirth.

If you forget an injection of Depo-Provera
If you forget your injection or are late getting your next injection (i.e. wait longer than 13 weeks between injections), there is a greater risk that you could become pregnant. Ask your doctor or healthcare professional to find out when you should receive your next injection of Depo-Provera and which type of contraception should be used in the meantime.

Switching from other methods of contraception

When you switch from other contraceptive methods, your doctor will make sure you are not at risk of becoming pregnant by giving you your first injection at the appropriate time. If you switch from oral contraceptives, you should have your first injection of Depo-Provera within 7 days after taking your last pill.

If you have any further questions on the use of this medicine ask your doctor, pharmacist or nurse.

4. Possible side effects
Like all medicines, this medicine can cause side effects although not everybody gets them.

Contact your doctor immediately if you notice any of the following side effects as you must not receive any more injections of Depo-Provera:

- Painful or inflamed veins in your leg, possible signs of a blood clot forming in a leg.
- Shortness of breath, breath-related chest pains or coughing up blood, possible signs of a blot clot in a lung.
- Hypersensitivity (allergic) reactions, such as a sudden skin rash, swelling of the face or tongue, wheezing or difficulty in breathing.
- Jaundice (yellowing of the skin or the whites of the eyes).
- Sight problems, such as double vision, sudden, partial or complete loss of vision.

Tell your doctor if you get any other side effects reported with Depo-Provera which may include the following:

Very common: may affect more than 1 in 10 people

- nervousness
- headache
- stomach pain or discomfort
- weight increase or decrease

Common: may affect up to 1 in 10 people

- depression
- libido decreased (reduced sex drive)
- dizziness
- feeling sick
- feeling bloated
- hair loss
- acne
- rash
- back pain
- vaginal discharge
- breast tenderness
- fluid retention
- weakness

Uncommon: may affect up to 1 in 100 people

- severe allergic reaction to the drug (e.g. wheezing, difficulty breathing)
- difficulty sleeping
- convulsions (fits)
- drowsiness
- hot flush
- liver disorder

- Facial hair growth
- nettle rash or hives
- itchy skin
- unexpected or unusual vaginal bleeding or spotting
- milky discharge from the breast when not pregnant or breastfeeding
- pelvic pain

Rare: may affect up to 1 in 1,000 people
- severe allergic reaction (anaphylactic reaction)
- swelling in face/throat which may cause difficulty breathing
- delayed egg release with longer menstrual cycle (periods)
- moon face
- difficulty reaching orgasm
- migraine
- sudden, partial or complete loss of vision
- bulging of the eye
- double vision
- swelling of the optic nerve (papilloedema)
- Retinal abnormality
- swelling in the veins due to blood clots
- tenderness or swelling in your calf, ankle or foot
- yellowing of the skin or whites of the eye (jaundice)
- accumulation of fat (at injection site)
- pain in a joint
- muscular cramps
- reduced bone density (osteoporosis)
- vaginal pain or inflammation
- stopping or extended break of your periods
- breast pain
- fever
- tiredness
- injection site pain or tenderness
- injection site lump or dimple
- decreased sugar tolerance

Not known: frequency cannot be estimated from the available data
- Usually benign tumour of the tissue surrounding the brain and spinal cord (meningioma) (see section 2 “Warnings and precautions”).

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance; Website: www.hpra.ie
By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Depo-Provera

Keep this medicine out of the sight and reach of children.
Do not store above 25ºC. Do not freeze.

Do not mix with other agents. For single use only. Discard any unused contents.
Do not use Depo-Provera after the expiry date which is stated on the carton label and pre-filled syringe after 'EXP'. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Depo-Provera contains
The active ingredient is medroxyprogesterone acetate (DMPA). Each pre-filled syringe contains 1ml of suspension containing 150mg of medroxyprogesterone acetate.

The other ingredients in Depo-Provera are methyl parahydroxybenzoate (E218), macrogol 3350, polysorbate 80, propyl parahydroxybenzoate (E216), sodium chloride and water for injections. Hydrochloric acid or sodium hydroxide may also be added when the product is being made to adjust the acidity or alkalinity of the product to the correct level.

What Depo-Provera looks like and contents of the pack
Depo-Provera is a white sterile suspension for injection. Each syringe contains 1 millilitre (ml) of Depo-Provera. Depo-Provera is supplied in cartons containing one prefilled syringe.

Marketing Authorisation Holder
Pfizer Healthcare Ireland Unlimited Company
The Watermarque Building
Ringsend Road,
Dublin 4,
D04 K7N3,
Ireland.

Manufacturer
Pfizer Manufacturing Belgium NV
Rijksweg 12
2870 Puurs-Sint-Amands
Belgium

Company Contact Address
For further information on your medicine contact Medical Information at Pfizer Healthcare Ireland Unlimited Company, The Watermarque Building, Ringsend Road, Dublin 4, D04 K7N3, Ireland.
Telephone 1800 633 363

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Depo-Provera® 150 mg/ml
Suspension for Injection
Medroxyprogesterone acetate

The following information is intended for medical or healthcare professionals only:
(For further information, consult the Summary of Product Characteristics.)

Assembly of syringe for single use:
1. Remove tip cap.
2. Position needle using aseptic technique.
3. Remove needle shield. The syringe is now ready for use.

Posology and method of administration:
The sterile aqueous suspension of Depo-Provera should be vigorously shaken just before use to ensure that the dose being given represents a uniform suspension of Depo-Provera.

Doses should be given by deep intramuscular injection into the gluteal or deltoid muscle. The gluteal muscle is the optimal site if sufficiently well developed.

Contraception
All potential users of Depo-Provera should have a negative pregnancy test before first administration.

Because of the risk of heavy or prolonged bleeding in some women, the drug should be used with caution in the puerperium.

The recommended dose is 150 mg of depot medroxyprogesterone acetate (DMPA) injectable suspension every 3 months (12-13 weeks) administered by intramuscular injection in the gluteal or deltoid muscle. The gluteal muscle is the optimal site, however the deltoid muscle may be used if sufficiently well developed. The initial injection should be given during the first 5 days after the onset of a normal menstrual period; within 5 days postpartum if not breast-feeding; or, if exclusively breast-feeding, at or after 6 weeks postpartum.

For second and subsequent injections, if the time interval between IM injections is greater than 13 weeks, pregnancy should be ruled out before administering the next IM injection.

As with other hormonal contraceptives, regular consideration should be given to whether the previous treatment has resulted in: first-time migraine or unusually severe headaches, visual disturbances, reappearance of depression, pathological changes in liver function tests.

Paediatric population
DMPA IM is not indicated before menarche.

Data regarding the effects of DMPA on BMD in adolescent females (12-18 years) is available (please consult section 4.4 and section 5.1 of the Summary of Product Characteristics). Other than concerns about loss of BMD, the safety and effectiveness of DMPA IM are expected to be the same for postmenarcheal adolescent and adult females.

Switching from other Methods of Contraception
When switching from other contraceptive methods, (DMPA IM or SC) should be given in a manner that ensures continuous contraceptive coverage based upon the mechanism of action of both methods, (e.g.,

patients switching from oral contraceptives should have their first injection of DMPA within 7 days after taking their last active pill).

Hepatic Insufficiency
No clinical studies have evaluated the effect of hepatic disease on the pharmacokinetics of DMPA. However, DMPA is almost exclusively eliminated by hepatic metabolism and steroid hormones may be poorly metabolized in patients with severe liver insufficiency (please consult section 4.3 of the Summary of Product Characteristics).

Renal Insufficiency
No clinical studies have evaluated the effect of renal disease on the pharmacokinetics of DMPA. However, since DMPA is almost exclusively eliminated by hepatic metabolism, no dosage adjustment should be necessary in women with renal insufficiency.

Marketing Authorisation Holder
Pfizer Healthcare Ireland Unlimited Company, The Watermarque Building, Ringsend Road, Dublin 4, D04 K7N3, Ireland.

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Further information is available to the medical and allied professions on request from:
Pfizer Healthcare Ireland Unlimited Company, The Watermarque Building, Ringsend Road, Dublin 4, D04 K7N3, Ireland; Telephone 1800 633 363