Package leaflet: Information for the user

Depo-Provera 150 mg/mL suspension for injection
Depo-Provera 150 mg/mL suspension for injection, pre-filled syringe

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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet
1. What Depo-Provera is and what it is used for
2. What you need to know before you use Depo-Provera
3. How to use Depo-Provera
4. Possible side effects
5. How to store Depo-Provera
6. Contents of the pack and other information

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

Depo-Provera contains medroxyprogesterone acetate. Medroxyprogesterone acetate is a synthetic hormone similar to the naturally occurring hormone progesterone (a luteal hormone). An injection of medroxyprogesterone acetate prevents ovulation, and it is then impossible to get pregnant. The protection against pregnancy is strengthened by the fact that medroxyprogesterone acetate makes the mucous membrane of the womb impervious to a fertilised egg and affects the mucus in the neck of the womb, making it impenetrable to sperm.

Depo-Provera is used as a contraceptive, but also for symptomatic relief of endometriosis, treatment of various gynaecological diseases or for treatment of breast and uterine cancer.

Depo-Provera should only be used by young women (< 18 years) when other contraceptive methods are inappropriate.

Medroxyprogesterone acetate, which is contained in Depo-Provera, may also be authorised to treat other illnesses, which are not mentioned in this leaflet. Ask your doctor, pharmacist or other healthcare professional if you have further questions and always follow their instructions.

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

Do not use Depo-Provera:
- if you are allergic to medroxyprogesterone acetate or any of the other ingredients of this medicine (listed in section 6)
- if you are pregnant or if you suspect you are pregnant.

Warnings and precautions
Talk to your doctor or pharmacist before using Depo-Provera if you:

- have a liver disease
- have previously had diabetes in connection with a pregnancy
- normally have infrequent menstruation. Also, inform your doctor if you have had abnormal bleeding between your menstruations. Depo-Provera should not be used if your doctor does not know the cause of the intermenstrual bleeding
- have experienced depression during prior use of contraceptive pills or another medicine containing progesterone.

Effect on your menstruation
If the bleeding pattern deviates from what is expected during treatment with Depo-Provera, you should contact a gynaecologist. This applies especially if heavy and prolonged bleeding occurs after a long time without bleeding.

Effect on your skeleton
Depo-Provera functions by reducing the levels of oestrogen and other hormones. Low oestrogen levels may lead to brittle bones (by reducing bone density). Women who use Depo-Provera tend to have lower bone density than women who have never used this medicine. The effect of Depo-Provera is greatest during the first two to three years after the start of treatment. Bone density then appears to stabilise and recover once the treatment has ended. It is not known whether Depo-Provera increases the risk of brittle bones and fractures later in life (after menopause, i.e. the time when menstruation definitively ceases).

The use of Depo-Provera may involve an increased risk of brittle bones in women with risk factors for brittle bones. You should therefore discuss with your doctor before you start treatment if any of the below apply to you:
- high alcohol consumption and/or smoking
- long-term use of other medicines that may reduce bone density (e.g. medicines for seizures and corticosteroids)
- low weight (low BMI) or an eating disorder (anorexia or bulimia)
- previous fractures that were not caused by a fall/injury
- inherited disposition to osteoporosis

Adolescents aged 12-18 years
Normally, the skeleton both rapidly grows and increases in strength in adolescents. A strong skeleton at an adult age results in better protection against brittle bones later in life. As Depo-Provera can reduce bone density in growing teenagers, this effect may be relevant for this age group. The bone density recovers when treatment with Depo-Provera ends; however, it is unknown whether bone density reaches the same levels as if Depo-Provera had not been used.

You should therefore discuss with your doctor whether alternative treatment methods exist before you start treatment with Depo-Provera.

After discontinuation of treatment with Depo-Provera, there will be a certain delay before ovulation and the start of menstrual bleeding occur again. Only then will it be possible to get pregnant again. This time period varies from one woman to another, but in most women ovulation occurs 6-8 months after the last injection of Depo-Provera. In some women, ovulation may occur very soon after the expected protective effect of 3 months is over. In exceptional cases, there may be a delay of up to 1.5 years before it is possible to get pregnant again.

This medicine does not protect against HIV infection (AIDS) or other sexually transmitted infections. Only condoms protect against HIV and other sexual diseases.

Psychiatric disorders:
Some women who use hormonal contraception, including Depo-Provera, have reported depression or dejection. Depression may be severe, and may sometimes lead to suicidal thoughts. If you experience changes in mood and symptoms of depression, you must contact your doctor as soon as possible for advice.

Other medicines and Depo-Provera
Tell your doctor, midwife or pharmacist if you are using, have recently used or might use any other medicines.

Some medicines may reduce the effect of hormonal contraceptives. Some examples are medicines for treatment of epilepsy (e.g. primidone, phenobarbital, phenytoin, carbamazepine), some antibiotics (rifampicin and rifabutin) and herbal remedies containing St John's wort *(Hypericum perforatum)*.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Depo-Provera should not be given during pregnancy. Should pregnancy occur during on-going treatment, treatment should immediately be discontinued.

Medroxyprogesterone acetate enters breast milk but is unlikely to affect a breast-fed child. However, ask your doctor for advice if Depo-Provera is used more than occasionally during breast-feeding.

Driving and using machines
Depo-Provera has no effect on the ability to drive and use machines.

Depo-Provera contains methyl parahydroxybenzoate and propyl parahydroxybenzoate
It can cause allergic reaction (potentially delayed) and, exceptionally, bronchospasm.

Depo-Provera contains sodium
This medicine contains less than 1 mmol (23 mg) sodium per dose, i.e. it is essentially "sodium free".

3. How to use Depo-Provera

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Depo-Provera should be injected deeply into a muscle (intramuscularly) by a healthcare professional.

Recommended dose:
Contraceptive: 150 mg every three months. The first injection should be given within the first three days of the menstrual cycle or, in women who are not breast-feeding, within three weeks after the birth at the latest. In women who are breast-feeding, the first injection should be given 6 weeks after birth at the earliest. In this way, you will get maximum protection against pregnancy from the very first day of injection. If the injection is given later in the menstrual cycle, then there is a risk that you may already be pregnant or that the protection is not at the maximum level during the first few weeks after the injection.

Relief of symptoms in endometriosis: 100 mg every other week for at least 6 months.

Treatment of breast cancer: 500 mg per day for 4 weeks (loading dose), then 1,000 mg per week as maintenance therapy. This dose can be divided as 500 mg twice per week. The maintenance therapy should be continued for as long as the tumour responds to treatment.

Treatment of uterine cancer: 1,000 mg per week. The treatment is continued for life. After a year or more of lasting tumour size reduction, the dose may be reduced to 500 mg per week.

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

4. Possible side effects

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

The following side effects may occur when Depo-Provera is used as a contraceptive

At the start of the treatment irregular bleeding usually occurs at unpredictable intervals.

Contact your doctor immediately if you experience any of the following symptoms, which may be due to an anaphylactic reaction; this is a serious side effect *(may affect up to 1 in 1,000 users)***:**
- itching
- skin rash
- local fluid swelling (oedema)
- difficulty breathing

Other side effects

Very common (may affect more than 1 in 10 users):
- headache
- stomach pains, gastrointestinal symptoms
- weight gain

Common (may affect up to 1 in 10 users):

- depression
- reduced libido
- nausea
- acne (spots)
- hair loss
- skin rash
- back pains
- weakness
- tender breasts

Uncommon (may affect up to 1 in 100 users):

- increased libido
- insomnia
- unpredictable vaginal bleeding (irregular, increased, reduced, spotting)

Rare (may affect up to 1 in 1,000 users):

- anxiety
- change in body shape due to redistribution of fat
- bone pains
- joint pain
- missed menstruation
- fever
- local reaction at the injection site (pain, reduced tissue under the skin, bumps under the skin)

The following side effects may occur when Depo-Provera is used in cancer treatment

Common (may affect up to 1 in 10 users):

- weight gain
- shaking (tremor)
- sweating
- fluid accumulation in the body
- local reaction at the injection site

Uncommon (may affect up to 1 in 100 users):

- rounding of the face (moon face)
- inflammation in a superficial blood vessel
- unpredictable vaginal bleeding (irregular, increased, reduced, spotting)
- local reaction at the injection site (pain, tenderness)

Rare (may affect up to 1 in 1,000 users):

- fever

Not known (cannot be estimated from the available data):

- change in body shape due to redistribution of fat
- brittle bones, including brittle bone fractures

- local reaction at the injection site (reduced tissue under the skin, bumps under the skin)
- incorrect results of liver tests

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Läkemedelsverket, PO Box 26, 751 03 Uppsala, Sweden www.lakemedelsverket.se

5. How to store Depo-Provera

Keep this medicine out of the sight and reach of children.
The injection vial must be stored in a standing position. Do not refrigerate. Do not freeze.
Do not use this medicine after the expiry date which is stated on the carton 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 substance is medroxyprogesterone acetate 150 mg/mL.
- The other ingredients are macrogol, polysorbate, sodium chloride, the methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), sodium hydroxide/hydrochloride acid, water for injection.

What Depo-Provera looks like and contents of the pack
Suspension for injection: 1 mL, 10×3.3 mL, 10×6.7 mL in a glass vial
Suspension for injection, pre-filled syringe: 1 mL in a single-dose syringe

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Pfizer AB, 191 90 Sollentuna, Sweden. Tel.: 08-550 520 00. E-mail: eumedinfo@pfizer.com

This leaflet was last revised in May 2021

The following information is intended for healthcare professionals only:

The suspension must be shaken well before use and be given deep into a muscle.

- To decrease the risk of blockage in the cannula/needle upon injection, it is important that the syringe or bottle be shaken well before injection.
- Since Depo-Provera is secreted much more slowly from fatty tissue, it is essential that the preparation be injected deep into a muscle.