Depo-Provera® 150mg/ml Sterile Suspension for Injection

(medroxyprogesterone acetate)

Your medicine is known by the above name, but will be referred to as Depo-Provera throughout this leaflet.

Patient Information Leaflet

Please 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 of the side effects, talk to your doctor, nurse or healthcare provider. 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 12 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 on 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) or if you are taking a medicine called aminoglutethimide that thins the blood (see section 2). 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). For a small number of patients that were followed-up, the average bone mineral density returned to average 1-3 years after they stopped using Depo-Provera. 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
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 is indicated for long-term female contraception for at least 12 weeks (+/- 5 days). This medicine contains the active substance medroxyprogesterone acetate (MPA), 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 (MPA) or any of the other ingredients (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.
- If you have had, or think you may have, hormone-dependent cancer of the breast or reproductive organs.
- If you have unexplained bleeding from the womb (uterus).
- If you have liver disease.
- 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).

Tell your doctor if any of the following conditions apply to you.

Warnings and precautions

Talk to your doctor or healthcare professional before using Depo-Provera.

Your doctor will ask about you and your family's medical problems, check your blood pressure and exclude the likelihood of you being pregnant. You may also need other checks, such as a breast examination, but only if these examinations are necessary for you, or if you have any special concerns.

It is important to tell your doctor or healthcare professional if you have, or have ever 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 clot in the leg, which may be called phlebitis)
- Blood clotting disorders such as deep vein thrombosis (blood clot in the legs), pulmonary embolus (blood clot in the lung) or a stroke you should not receive further injections of Depo-Provera
- Problems with your eyesight while using Depo-Provera; for example a sudden partial or complete loss of vision or double vision
- Past history of or current depression
- Problems with your liver or liver disease
- Problems with your kidneys or kidney disease
- History of heart disease or cholesterol problems including any family history
- If you have recently had a 'hydatidiform mole' which is a type of abnormal pregnancy
- Asthma
- Epilepsy
- If you are using certain medicines such as high dose glucocorticoids (steroids), antiepileptics, and thyroid hormones. 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.

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.

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 effect 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

Breast cancer is rare among women under 40 years of age whether or not they use hormonal contraceptives. Depo-Provera may increase the risk of breast cancer slightly compared with women who have never used it. However, any excess risk is small in relation to the overall risk of breast cancer, particularly in young women.

Older women have a higher baseline risk of breast cancer and therefore the increase in the number of cases due to Depo-Provera is greater in older women than in younger women.

In absolute terms this means that:

A 15 year old who uses Depo-Provera for 5 years increases her chance of developing breast cancer by a negligible amount by the age of 30.

A 25 year old who uses Depo-Provera for 5 years increases her chance of developing breast cancer by the age of 40 from 44 cases per 10,000 women (without Depo-Provera use) to up to 47 cases per 10,000 women i.e. an extra 3 cases/10,000.

A 35 year old who uses Depo-Provera for 5 years increases her chance of developing breast cancer by the age of 50 from 160 cases per 10,000 women (without Depo-Provera use) to 170 cases per 10,000 women i.e. an extra 10 cases/10,000.

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 other sexually transmitted infections.

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 pharmacist if you are taking, have recently taken or might take any other medicines.
- Tell your doctor or healthcare professional if you are taking a medicine called aminoglutethimide or other medicines that thin your blood (anticoagulants) as these may affect the way Depo-Provera works.
- Always tell your doctor or 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
- Your doctor will check that you are not pregnant before giving you the first injection and also if any following injection is delayed beyond 89 days (12 weeks and 5 days).
- 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.

Depo-Provera® 150mg/ml Sterile 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.)

Dosage:

Each ml of suspension contains 150 mg medroxyprogesterone acetate. 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 buttock or arm. Care should be taken to ensure that the depot injection is given into the muscle tissue, preferably the gluteus maximus, but other muscle tissue such as the deltoid may be used and the site of injection should be cleansed using standard methods prior to administration of the injection.

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.

Administration:

Adults

First injection: To provide contraceptive cover in the first cycle of use, an injection of 150 mg i.m. should be given during the first five days of a normal menstrual cycle. If the injection is carried out according to these instructions, no additional contraceptive cover is required.

Postpartum: To increase assurance that the patient is not pregnant at the time of first administration, this injection should be given within 5 days postpartum if not breast-feeding.

There is evidence that women prescribed Depo-Provera in the immediate puerperium can experience prolonged and heavy bleeding. Because of this, the drug should be used with caution in the puerperium. Women who are considering use of the product immediately following delivery or termination should be advised that the risk of heavy or prolonged bleeding may be increased.

Doctors are reminded that in the non breast-feeding postpartum patient, ovulation may occur as early as week 4. If the puerperal woman will be breast-feeding, the initial injection should be given no sooner than six weeks postpartum, when the infant's enzyme system is more fully developed. Further injections should be given at 12 week intervals.

Effect on future fertility
- Your usual level of fertility should 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 studies, over 80% of women trying to get pregnant conceived within 15 months of the last injection; however this varied from 4 months after the last injection to more than two years.
- Some women have got pregnant as early as 14 weeks after their last injection.

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
Depo-Provera may cause headaches and dizziness. Therefore be careful until you know whether this medicine affects your ability to drive or use machines. If you have any concerns discuss them with your doctor.

Depo-Provera contains methyl parahydroxybenzoate, propyl parahydroxybenzoate, polysorbate 80 and sodium
Methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) may cause allergic reactions (possibly delayed), and exceptionally, bronchospasm.
Depo-Provera contains 2.4 mg of polysorbate 80 in each ml which is equivalent to 2.4 mg of polysorbate 80 per dose of Depo-Provera. Polysorbates may cause allergic reactions. Tell your doctor if you have any known allergies.
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 12 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** breast-feeding.

Provided that the injection is given at the times stated 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 every 12 weeks. Make sure that you or your doctor makes your next appointment for 12 weeks time.

The risk of heavy or pro‑longed vaginal bleeding may be increased if Depo-Provera is used immediately following childbirth or termination of pregnancy.

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 12 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 or healthcare professional.

4) Possible side effects

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

Seek medical help immediately if you notice any of the following side effects:
- Hypersensitivity (allergic) reaction (it is not known how frequently this occurs) Symptoms include: sudden skin rash, swelling of the face, lips, tongue or throat, wheezing or difficulty in breathing.
- A blood clot in the lungs (this occurs **rarely** - may affect up to 1 in 1000 people) Symptoms include:
  - Shortness of breath
  - Breath-related chest pains
  - Coughing up blood
- A blood clot in the leg (this occurs **rarely** - may affect up to 1 in 1000 people)

Deep vein thrombosis (DVT) is a condition in which a blood clot forms in one of your deep veins, usually in your leg.
These are symptoms of a **deep‑vein thrombosis (DVT):**
- You have pain, tenderness or swelling in your calf, ankle or foot
- You have painful or inflamed veins in your leg
- You find it difficult to put full weight on the affected leg
- You have purple discolouration of the skin of the leg or the skin becomes red and warm to touch.
- Jaundice (yellowing of the skin or the whites of the eyes).

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 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.

Other side-effects include:

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
- back pain
- vaginal discharge
- breast tenderness
- difficult or painful period
- urinary tract infection
- oedema/fluid retention
- weakness
- pain in extremity

Uncommon: may affect up to 1 in 100 people
- appetite increased or decreased
- difficulty sleeping
- convulsions (fits)
- drowsiness
- tingling
- hot flush
- liver disorder
- facial hair growth
- nettle rash or hives
- itchy skin
- temporary brown patches
- unexpected or unusual vaginal bleeding or spotting
- milky discharge from the breast when not pregnant or breastfeeding
- pelvic pain
- painful intercourse
- prevention of lactation

Rare: may affect up to 1 in 1,000 people
- breast cancer
- reduction in red blood cell
- blood disorder
- difficulty reaching orgasm
- behavior change
- mood change
- irritability
- anxiety
- migraine
- paralysis
- fainting
- feeling of dizziness or spinning
- heart beats more rapidly
- high blood pressure
- varicose veins
- rectal bleeding
- digestive disorder
- liver enzyme disorder
- accumulation of fat (at injection site)
- inflammation of the skin
- scar tissue formation
- stretch marks
- pain in a joint
- muscular cramps
- bone density decreased (osteoporosis)
- vaginal pain or inflammation
- stopping or extended break of your periods
- breast pain
- inflammation of the vagina
- uterine bleeding or excessive bleeding
- periods with abnormally heavy or prolonged bleeding
- vaginal dryness
- change in breast size
- ovarian or vaginal cyst
- premenstrual syndrome
- excessive thickening of the lining of the womb
- breast lump
- nipple bleeding
- delayed egg release with longer menstrual cycles (periods)
- feel pregnant
- fever
- tiredness
- injection site pain or tenderness
- injection site lump or dimple
- feeling thirsty
- hoarseness
- facial nerve paralysis
- decreased sugar tolerance
- abnormal smear
- ecchymosis (bruising)
- axillary swelling (swelling in the armpit)

Not known: cannot be estimated from available data
- meningioma (a usually benign tumour of the tissue surrounding the brain and spinal cord) (see section 2 "Warnings and precautions")

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects you can help provide more information on the safety of this medicine.

5) How to store Depo-Provera

- **Keep out of the sight and reach of children.**
- Do not store above 25°C. Do not refrigerate or freeze. For vials only: store upright.
- Do not use Depo-Provera after the last day of the month shown in the expiry date stated on the pre-filled syringe label and the carton after EXP. The expiry date is the last day of that month.
- Do not throw away 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.
- If the medicine becomes discoloured or shows any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.

6) Contents of the pack and other information

What Depo-Provera contains
The active substance in Depo-Provera is medroxyprogesterone acetate (MPA). Each dose (1 millilitre) of Depo-Provera contains 150 mg of medroxyprogesterone acetate. Depo-Provera also contains methyl parahydroxybenzoate (E218), Macrogol 3350, polysorbate 80, propyl parahydroxybenzoate (E216), sodium chloride and water. 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. It is supplied as 1 ml suspension for injection in a pre-filled glass syringe with halobutyl rubber plunger stopper and halobutyl rubber tip cap, packed singly and/or
1 ml suspension for injection in glass vials with halobutyl rubber stopper and aluminum cap with a plastic flip off in pack sizes of 1 vial.

Not all pack sizes may be marketed.

PL 46420/0450 Depo-Provera 150mg/ml Sterile Suspension for Injection **POM**

Who makes and repackages your medicine?
Your medicine is manufactured by Pfizer Manufacturing Belgium N.V./S.A., Rijksweg 12, 2870 Puurs, Belgium. Procured from within the EU and repackaged by the Product Licence holder: Suerte Pharma Ltd, 4/5 Northolt Trading Estate, Belvue Road, Northolt, Middlesex, UB5 5QS.

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For any information about this medicine or to request for a copy of this leaflet in Braille, large print or audio, please call the PL holder: Suerte Pharma Ltd on 020 8839 3000.

Further doses: These should be given at 12 week intervals, however, as long as the injection is given no later than five days after this time, no additional contraceptive measures (e.g. barrier) are required.
(NB For partners of men undergoing vasectomy a second injection of 150 mg i.m. 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 interval from the preceding injection is greater than 89 days (12 weeks and five 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.

Paediatric population (12‑18 years): Depo-Provera is not indicated before menarche. Data in adolescent females (12‑18 years) is available. 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.

Switching from other Methods of Contraception: Depo-Provera should be given in a manner that ensures continuous contraceptive coverage. This should be based upon the mechanism of action of other methods (e.g. patients switching from oral contraceptives should have their first injection of Depo-Provera within 7 days of taking their last active pill).

Hepatic Insufficiency: The effect of hepatic disease on the pharmacokinetics of Depo-Provera is unknown. As Depo-Provera largely undergoes hepatic elimination it may be poorly metabolised in patients with severe liver insufficiency (see Contraindications).

Renal Insufficiency: The effect of renal disease on the pharmacokinetics of Depo-Provera is unknown. No dosage adjustment should be necessary in women with renal insufficiency, since Depo-Provera is almost exclusively eliminated by hepatic metabolism.

For patient records:

Date of administration of Depo-Provera: _ _ /_ _ /_ _ _ _ (DD/MM/YYYY)

Date for next dose, if required
(date above + 12 weeks): _ _ /_ _ /_ _ _ _ (DD/MM/YYYY)

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