



ספטמבר 2025

פיזור PFE פרמצבטיקה ישראל בע"מ
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רופא/ה, רוקח/ת נכבד/ה,
ברצוננו להודיעך על עדכון בעלון לרופא ובעלון לצרכן של SAYANA :

המרכיב הפעיל:

MEDROXYPROGESTERONE ACETATE 104 mg / 0.65 mL

Indicated for:

* SAYANA is indicated for long-term female contraception.

Each subcutaneous injection prevents ovulation and provides contraception for at least 13 weeks (+/- 1 week).

However, it should be taken into consideration that the return to fertility (ovulation) may be delayed for up to one year . Since loss of bone mineral density may occur in females of all ages who use SAYANA long-term, a risk/benefit assessment, which also takes into consideration the decrease in bone mineral density that occurs during pregnancy and/or lactation, should be considered.

* Use in Adolescents (12-18 years)

In adolescents, use of SAYANA is only indicated when other contraceptive methods are considered unsuitable or unacceptable, due to unknown long-term effects of bone loss associated with SAYANA during the critical period of bone accretion.

SAYANA has not been studied in women under the age of 18 years but data is available for intramuscular medroxyprogesterone acetate in this population.

להלן העדכונים העיקריים בעלון לרופא:

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

SAYANA® single-dose pre-filled syringe containing 104 mg depot medroxyprogesterone acetate (DMPA) in 0.65 ml suspension for injection.

Excipients with known effect:

Methyl parahydroxybenzoate – 1.04 mg per 0.65 ml

Propyl parahydroxybenzoate – 0.0975 mg per 0.65 ml

Sodium – 2.47 mg per 0.65 ml

Polysorbate 80 - 1.95 mg per 0.65 ml

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4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

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Precautions

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Excipients

As this product contains methyl parahydroxybenzoate and propyl parahydroxybenzoate, it may cause allergic reactions (possibly delayed), and exceptionally, bronchospasm. This medicinal product contains less than 1 mmol sodium (23 mg) per 104 mg/0.65 ml, i.e., essentially 'sodium-free'.

SAYANA contains polysorbate 80 (see section 2). Polysorbate 80 may cause hypersensitivity reactions.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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Meningioma

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Based on results from a matched case-control study from the United States, medroxyprogesterone acetate use was associated with increased odds of the presence of meningioma with evidence of increased odds with increasing duration of use. Data were obtained from the IBM MarketScan claims database for the years 2006–2022. A total of 117,503 cases and 1,072,907 matched controls were included in the analysis. For all meningiomas, the prevalence of oral exposure to medroxyprogesterone acetate was similar between cases (2.38%) and controls (2.29%). In both crude and adjusted models, medroxyprogesterone acetate exposure was not associated with being a case (adjusted OR 0.97, 95% CI 0.93–1.01); this null association persisted across all duration categories.

The prevalence of injection exposure to medroxyprogesterone acetate was nearly twice as high among cases (0.67%) than controls (0.39%); medroxyprogesterone acetate exposure was associated with 76% increased odds of being a case (OR 1.76, 95% CI 1.63–1.90), an association that persisted in the adjusted model (OR 1.53, 95% CI 1.40–1.67). There was evidence of increased odds by duration of exposure (linear trend, $p < 0.0001$). This association was notably specific to injection exposure to medroxyprogesterone acetate and cerebral meningiomas. No association was observed for oral medroxyprogesterone acetate exposure or for spinal meningiomas (for both oral and injection medroxyprogesterone acetate exposure).

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להלן העדכונים העיקריים בעלון לצרכן:

2. לפני השימוש בתרופה

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אין להשתמש בתרופה מבלי להיוועץ ברופא לפני התחלת הטיפול:

שומה בועית (Hydatidiform mole). אם עברת לאחרונה שומה בועית שהיא סוג של הריון לא תקין

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אזהרות מיוחדות הנוגעות לשימוש בתרופה:

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מידע חשוב על חלק מהמרכיבים של התרופה

סיאנה מכילה מתיל פארהידרוקסיבנזואט, פרופיל פארהידרוקסיבנזואט, פוליסורבט 80 ונתרן

• סיאנה מכילה את החומרים מתיל פארהידרוקסיבנזואט ופרופיל פארהידרוקסיבנזואט. חומרים אלה עלולים לגרום לתגובות אלרגיות (לעיתים תגובות מאוחרות).

• פוליסורבט 80: סיאנה מכילה 1.95 מ"ג פוליסורבט 80, בכל 0.65 מ"ל תרופה, כמות זהה ל 1.95 מ"ג פוליסורבט 80 בכל מנה של סיאנה. חומרים אלה עלולים לגרום לתגובות אלרגיות. עלייר לספר לרופא אם יש לך אלרגיות ידועות.

• נתרן: סיאנה מכילה כמות קטנה מ 1 מילימול (23 מ"ג) של נתרן לכל 104 מ"ג / 0.65 מ"ל, היא בעיקרון "נטולת נתרן".

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מידע לציוות הרפואי:

The following information is intended for medical or healthcare professionals only:

SAYANA suspension for injection

medroxyprogesterone acetate 104 mg/0.65 mL

INSTRUCTIONS FOR ADMINISTRATION: PREPARING AND GIVING A SUBCUTANEOUS INJECTION OF SAYANA

Introduction

SAYANA should be administered by a person (such as your doctor, nurse or healthcare professional) trained in administering subcutaneous injections.

The following instructions explain how to prepare and inject SAYANA. The instructions should be read carefully and followed step-by-step.

The injection should not be mixed with any other medicine.

Instructions for Administration of SAYANA for Subcutaneous Use

Getting ready

Do not refrigerate. Ensure that the medication is **at room temperature** prior to injection (to ensure appropriate viscosity of the suspension). Make sure the following components (Diagrams 1 and 2) are available.

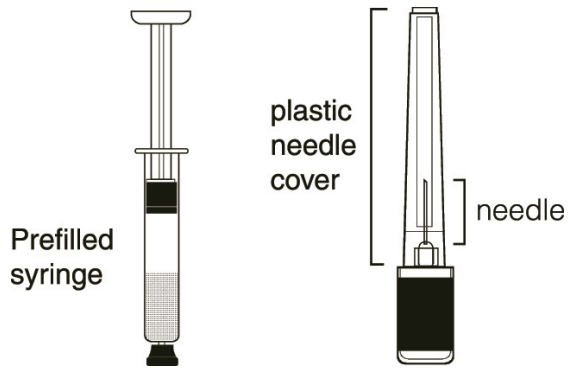


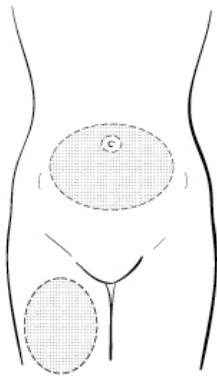
Diagram 1

Diagram 2

SAYANA, as with other parenteral drug products, should be inspected visually for particulate matter and discoloration prior to administration.

Step 1: Choosing and preparing the injection area.

Choose the injection area in either the upper thigh or abdomen, see shaded areas (Diagram 3). Avoid bony areas and the umbilicus.



Upper thigh or abdomen

Diagram 3

Use an alcohol pad to wipe the skin in the injection area you have chosen. Allow the skin to dry.

Step 2: Syringe preparation

Gently twist off the protective end cap from the needle to break the seal (Diagram 4). Set aside.

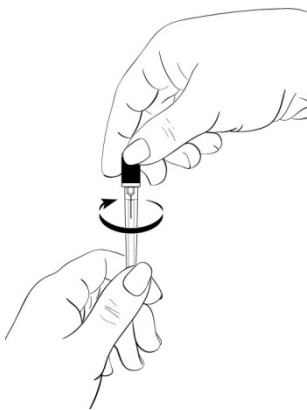
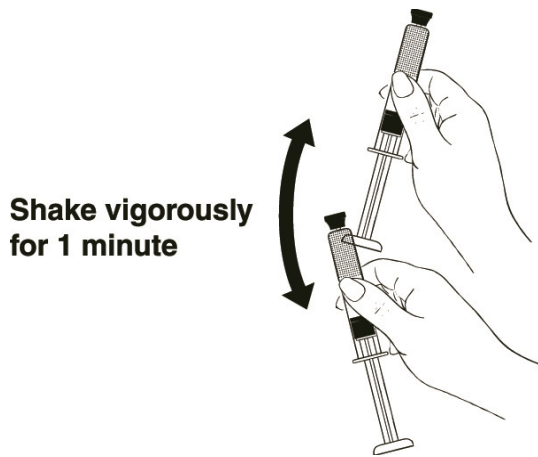


Diagram 4

While holding the syringe firmly by the barrel pointing upward, shake it vigorously for at least 1 minute to thoroughly mix the medication (Diagram 5).



Shake vigorously for 1 minute

Then remove the protective cap from the tip of the syringe barrel.

Diagram 5

While holding the syringe barrel, attach the needle to the barrel of the syringe firmly by pushing the plastic needle cover down fully with a slight twisting movement (Diagram 6).

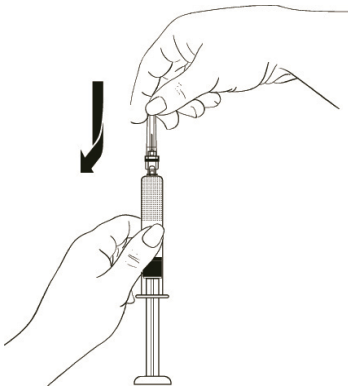


Diagram 6

While continuing to hold the syringe barrel firmly, remove the protective plastic needle cover from the needle without twisting, making sure the needle is still firmly attached to the syringe (Diagram 7).

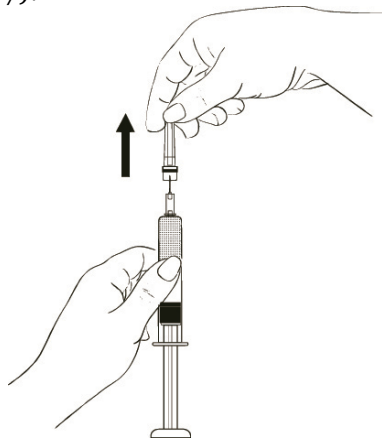


Diagram 7

While holding the syringe with the needle pointing upward, gently push in the plunger until the medicine is up to the top of the syringe. There should be no air within the barrel (Diagram 8).

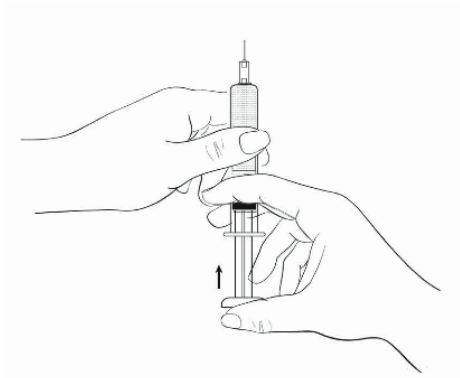


Diagram 8

Step 3: Injecting the dose.

Gently grasp and squeeze a large area of skin in the chosen injection area between the thumb and fore-finger, pulling it away from the body. Insert the needle at a 45 degree angle so that most of the needle is in the fatty tissue. The plastic hub of the needle should be nearly or almost touching the skin (Diagram 9).

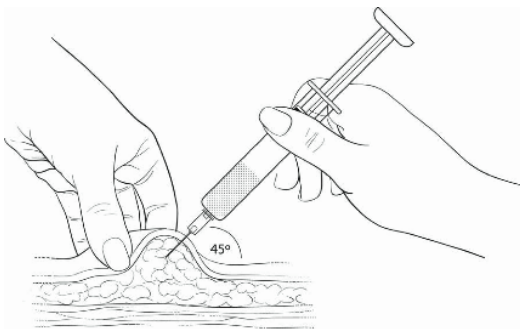
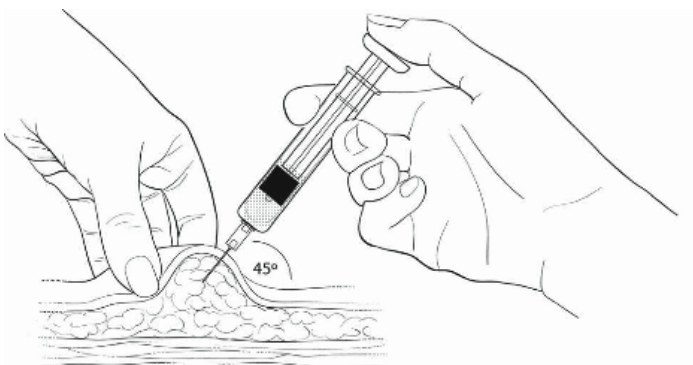


Diagram 9

Inject the medication slowly until the syringe is empty (Diagram 10).

- This should take about 5-7 seconds.
- It is important that the entire dose of Sayana is given



Inject slowly (5-7 seconds)
Diagram 10

When the entire dose is completely injected, gently pull the needle out of the skin.

Use a clean cotton pad to press lightly on the injection area for a few seconds. **Do NOT rub the area.**

DISPOSING OF SUPPLIES

The syringe and needle should **NEVER** be reused.


Any unused product should be disposed of safely after use, in accordance with local guidance for the disposal of sharps.

השינויים המודגשים ברקע צהוב מהווים החמרה. כמו כן, בוצעו שינויים נוספים הכוללים תוספת מידע, השמטת מידע ועדכוני נוסח שאינם מהווים החמרה. העלונים המעודכנים זמינים באתר משרד הבריאות.

<https://israeldrugs.health.gov.il/#!/byDrug>

לחילופין, לקבלת עלון מלא מודפס ניתן לפנות לחברת פיזר PFE פרמצבטיקה ישראל בע"מ, שנקר 9, ת.ד. 12133 הרצליה פיתוח, 46725.

בברכה,
עידית שלם אבידר
רוקחת ממונה

DocuSigned by:

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