PT. PFIZER INDONESIA
Local Product Document

Generic Name: Medroxyprogesterone Acetate
Trade Name: PROVERA®
CDS Effective Date: May 13, 2025
Supersedes: December 08, 2023

WARNINGS
CARDIOVASCULAR AND OTHER RISKS

Estrogens with progestins should not be used for the prevention of cardiovascular disease or dementia.

The Women's Health Initiative (WHI) estrogen plus progestin sub study reported increased risks of myocardial infarction, stroke, invasive breast cancer, pulmonary emboli, and deep vein thrombosis (DVT) in postmenopausal women (50 to 79 years of age) during 5.6 years of treatment with daily oral conjugated estrogens (CE 0.625 mg) combined with medroxyprogesterone acetate (MPA 2.5 mg) relative to placebo.

The Women's Health Initiative Memory Study (WHIMS), a sub study of the WHI study, reported increased risk of developing probable dementia in postmenopausal women 65 years of age or older during 4 years of treatment with daily CE 0.625 mg combined with MPA 2.5 mg, relative to placebo. It is unknown whether this finding applies to younger postmenopausal women.

In the absence of comparable data, these risks should be assumed to be similar for other doses of CE and MPA and other combinations and dosage forms of estrogens and progestins. Because of these risks, estrogens with or without progestins should be prescribed at the lowest effective doses and for the shortest duration consistent with treatment goals and risks for the individual woman.

DESCRIPTION

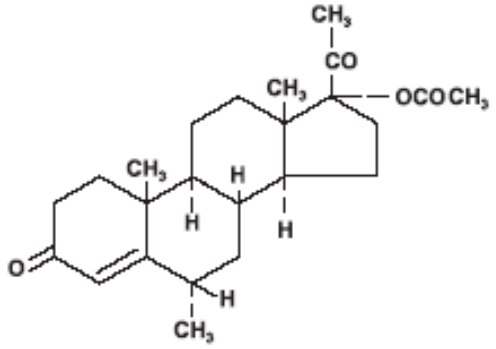
PROVERA tablets contain medroxyprogesterone acetate, which is a derivative progesterone.

List of excipients:
Microcrystalline cellulose, maize starch, gelatin, macrogol 400, sodium starch glycolate, magnesium stearate, docusate sodium (85%) with sodium benzoate (15%).

It is a white round, flat, one side scored tablets marked "U 467" on the other one, odorless crystalline powder, stable in air, melting between 200°C and 210°C. It is freely soluble in chloroform, soluble in acetone and in dioxane, sparingly soluble in alcohol and in methanol, slightly soluble in ether, and insoluble in water.

DISETUJUI OLEH BPOM: 05/02/2026 ID: EREG10024112500331

The chemical name for medroxyprogesterone acetate is pregn-4-ene-3, 20-dione, 17-(acetyloxy)-6-methyl-, (6α)-. The structural formula is:



Each PROVERA tablet for oral administration contains 100 mg medroxyprogesterone acetate.

ACTIONS

Medroxyprogesterone acetate, administered orally or parenterally in the recommended doses to women with adequate endogenous estrogen, transforms proliferative into secretory endometrium. The drug is progestational agent devoid of estrogenic activity. Minimal androgenic and anabolic effects may occur. While parenterally administered medroxyprogesterone acetate inhibits gonadotropin production, which in turn prevents follicular maturation and ovulation, available data indicate that this does not occur when the usually recommended oral dosage is given as single daily doses. The anti-cancer activity of PROVERA at pharmacologic doses in the case of specific forms of hormone-dependent cancers may be due to its effect on the hypothalamic-pituitary-gonadal axis, estrogen receptors and the metabolism of steroids at the tissue level.

Administration with food increases the bioavailability of MPA. A 10 mg dose of oral MPA, taken immediately before or after a meal, increased average MPA C_{max} (51% and 77%, respectively) and average AUC (18 and 33%, respectively). The half-life of MPA was not changed with food.

Meningioma

Based on results from a French epidemiological case-control study, an association between medroxyprogesterone acetate and meningioma has been observed. This study was based on data from the French national health data system (SNDS – Système National des Données de Santé) and included a population of 18,061 women who had intracranial surgery for meningioma and 90,305 women without meningioma. The exposure to medroxyprogesterone acetate 150 mg/3 mL injectable was compared between women who had intracranial surgery for meningioma and women without meningioma. Analyses showed an excess risk of meningioma with the use of medroxyprogesterone acetate 150 mg/3 mL (9/18,061 (0.05%) v 11/90,305 (0.01%), OR 5.55 (95% CI 2.27–13.56)). This excess risk seems to be driven primarily by prolonged use of medroxyprogesterone acetate.

DISETUJUI OLEH BPOM: 05/02/2026 ID: EREG10024112500331

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).

INDICATION AND USAGE

PROVERA tablets are indicated:
1. As adjunctive and/or palliative treatment of recurrent and/or metastatic endometrial or renal carcinoma; and
2. In the treatment of hormonally-dependent, recurrent breast cancer in post-menopausal women.

CONTRAINDICATIONS

1. Known sensitivity to medroxyprogesterone acetate.
2. Undiagnosed vaginal bleeding.
3. Undiagnosed urinary tract bleeding.
4. Undiagnosed breast pathology.
5. Liver dysfunction or active liver disease.
6. Thrombophlebitis, thromboembolic disorders or cerebral apoplexy, or patients with a past history of these conditions.
7. Pregnancy (either for diagnosis or therapy), see Warnings.

WARNINGS

PROVERA, especially in the high doses used for cancer therapy, may cause weight gain and fluid retention. With this in mind, caution should be exercised in treating any patient with a pre-existing medical condition that might be adversely affected by weight gain or fluid retention.

The high doses of PROVERA used in the treatment of cancer patients may, in some cases, produce Cushingoid symptoms, e.g., moon faces, fluid retention, glucose intolerance, and blood pressure elevation.

DISETUJUI OLEH BPOM: 05/02/2026 ID: EREG10024112500331

In the treatment of carcinoma of breast occasionally cases of hypercalcaemia have been reported.

Any patient who develops an acute impairment of vision, proptosis, diplopia, or migraine headache should be carefully evaluated ophthalmologically to exclude the presence of papill-oedema or retinal vascular lesions before continuing medication.

Medroxyprogesterone acetate and/or its metabolites are secreted in breast milk but there is no evidence to suggest that this presents any hazards to the child.

The use of PROVERA during the first four months of pregnancy is not recommended.

The administration of large doses to pregnant women has resulted in the observation of some instances of female foetal masculinisation. Doctors should therefore check that patients are not pregnant before commencing treatment.

The physician should be alert to the earliest manifestation of thrombotic disorders (thrombophlebitis, cerebrovascular disorders, pulmonary embolism, and retinal thrombosis).

Should any of these occur or be suspected, the drug should be discontinued immediately.

MPA has not been causally associated with the induction of thrombotic or thromboembolic disorders, however MPA is not recommended in any patient with a history of venous thromboembolism (VTE). Discontinuation of MPA is recommended in patients who develop VTE while undergoing therapy with MPA.

Additional Warnings and Precautions for Specific Use or Formulation

Breast Cancer

The use of combined estrogen/progestin by postmenopausal women has been reported to increase the risk of breast cancer. Results from a randomized placebo-controlled trial, the WHI trial, and epidemiological studies have reported an increased risk of breast cancer in women taking estrogen/progestin combinations for HT for several years. In the WHI conjugated equine estrogens (CEE) plus MPA trial and observational studies, the excess risk increased with duration of use (see section **DOSAGE AND ADMINISTRATION**). The use of estrogen plus progestin has been reported to result in an increase in abnormal mammograms requiring further evaluation.

In several epidemiologic studies no overall increased risk for breast cancer was found among users of injectable depot progestogens in comparison to non-users. However, an increased relative risk (e.g., 2.0 in one study) was found for women who currently used injectable depot progestogens or had used them only a few years before. It is not possible to infer from these data whether this increased rate of breast cancer diagnosis among current users is due to increased surveillance among current users, the biological effects of injectable progestogens, or a combination of reason.

DISETUJUI OLEH BPOM: 05/02/2026 ID: EREG10024112500331

Cardiovascular Disorders

Estrogens with or without progestins should not be used for the prevention of cardiovascular disease. Several randomized, prospective trials on the long-term effects (see section **DOSAGE AND ADMINISTRATION**) of a combined estrogen/progestin regimen in postmenopausal women have reported an increased risk of cardiovascular events such as myocardial infarction, coronary heart disease, stroke, and venous thromboembolism.

- Coronary Artery Disease

There is no evidence from randomized controlled trials of cardiovascular benefit with continuous combined conjugated estrogen and medroxyprogesterone acetate (MPA). Two large clinical trials [WHI CEE/MPA and Heart and Estrogen/progestin Replacement Study (HERS)] showed a possible increased risk of cardiovascular morbidity in the first year of use and no overall benefit.

In the CEE/MPA substudy of WHI, an increased risk of coronary heart disease (CHD) events (defined as nonfatal myocardial infarction and CHD death) was observed in women receiving CEE/MPA compared to women receiving placebo (37 vs. 30 per 10,000 person years).

- Stroke

In the same substudy of WHI, an increased risk of stroke was observed in women receiving CEE/MPA compared to women receiving placebo (29 vs. 21 per 10,000 person-years). The increase in risk was observed in year one and persisted over the observation period (see section **DOSAGE AND ADMINISTRATION**).

- Venous Thromboembolism/Pulmonary Embolism

HT is associated with a higher relative risk of developing venous thromboembolism (VTE), i.e., deep vein thrombosis or pulmonary embolism. In the CEE/MPA substudy of WHI, a 2-fold greater rate of VTE, including deep venous thrombosis and pulmonary embolism was observed in women receiving CEE/MPA compared to women receiving placebo. The increase in risk was observed in year one and persisted over the observation period.

Dementia

Pooling data from the Women's Health Initiative Memory Study (WHIMS), a substudy of WHI, for CEE-alone and CEE/MPA reported an increased risk of developing probable dementia and mild cognitive impairment (MCI) in postmenopausal women 65 years of age or older. Use of HT to prevent dementia or MCI in women is not recommended.

Ovarian Cancer

Current use of estrogen only or estrogen plus progestin products in post-menopausal women for five or more years, has been associated with an increased risk of ovarian

DISETUJUI OLEH BPOM: 05/02/2026 ID: EREG10024112500331

cancer in some epidemiological studies. Past users of estrogen only or estrogen plus progestin products were at no increased risk for ovarian cancer. Other studies did not show a significant association. The WHI CEE/MPA trial reported that estrogen plus progestin increased the risk of ovarian cancer, but this risk was not statistically significant. In one study, women who use HRT are at increased risk of fatal ovarian cancer.

History and Physical Exam Recommendation
A complete medical and family history should be taken before the initiation of any hormone therapy. Pretreatment and periodic physical examinations should include special reference to blood pressure, breasts, abdomen, and pelvic organs, including cervical cytology.

Oncology
- MPA may produce cushingoid symptoms.
- Some patients receiving MPA may exhibit suppressed adrenal function. MPA may decrease ACTH and hydrocortisone blood levels.

The physician/laboratory should be informed that in addition to the endocrine biomarkers listed in Special Warnings and Special Precautions for Use (see section **WARNINGS**), the use of MPA in oncology indications may also cause partial adrenal insufficiency (decrease in pituitary-adrenal axis response) during metyrapone testing. Thus the ability of adrenal cortex to respond to ACTH should be demonstrated before metyrapone is administered.

Oral Formulations and High Dose Parenteral Formulations (e.g., oncology use in pre-menopausal women)
Decrease in Bone Mineral Density
There are no studies on the bone mineral density (BMD) effects of orally administered MPA or the high doses of parenteral MPA (e.g., for oncology use). An evaluation of BMD may be appropriate in some patients who use MPA long-term.

PRECAUTIONS
Patients with a history of treatment for mental depression should be carefully monitored while receiving PROVERA therapy. Some patients may complain of premenstrual like depression while on PROVERA therapy.

Pathologists should be informed of the patients ingestion of PROVERA if endometrial or endocervical tissue is submitted for examination.

The following laboratory tests may be affected by the use of PROVERA: Gonadotropin levels, plasma progesterone levels, urinary pregnanediol levels, plasma testosterone levels (in the male), plasma estrogen levels (in the female), plasma cortisol levels, glucose tolerance test, metyrapone test and sex-hormone-binding-globulin.

Aminoglutethimide administered concomitantly with PROVERA may significantly depress the bioavailability of PROVERA.

DISETUJUI OLEH BPOM: 05/02/2026 ID: EREG10024112500331

A decrease in glucose tolerance has been observed in some patients on progesterone. The mechanism of this decrease is obscure. For this reason diabetic patients should be carefully observed while receiving progesterone therapy.

Before using PROVERA the general medical condition of the patient should be carefully evaluated.

This product should be used under the supervision of a specialist and the patients kept under regular surveillance.

Occasional uterine bleeding may occur in patient with high dose therapy.

Animal studies show that PROVERA possesses adrenocorticoid activity. This has also been reported in man, therefore patients receiving large doses continuously and for long period should be observed closely.

Treatment with progesterone in the premenopausal patient may mask the onset of the climacteric.

The pretreatment physical examination should include special reference to breast and pelvic organs, as well as papanicolaou smear.

Because progestogens may cause some degree of fluid retention, conditions which might be influenced by this factor, such as epilepsy, migraine, asthma, cardiac or renal dysfunction, require careful observation.

In cases of breakthrough bleeding, as in all cases of irregular bleeding per vaginum, non functional causes should be borne in mind. In cases of undiagnosed vaginal bleeding, adequate diagnostic measures are indicated.

Meningioma

Meningiomas have been reported following long-term administration of MPA. Patients treated with MPA should be monitored for signs and symptoms of meningiomas in accordance with clinical practice. If a patient is diagnosed with meningioma, the need for further treatment with MPA should be carefully considered on a case-by-case basis taking into account individual benefits and risks. Caution is advised when recommending MPA to patients with a history of meningioma.

Interactions with Other Medicaments and Other Forms of Interaction

Aminoglutethimide administered concomitantly with high doses of MPA may significantly depress the serum concentrations of medroxyprogesterone acetate. Users of

DISETUJUI OLEH BPOM: 05/02/2026 ID: EREG10024112500331

high-dose MPA should be warned of the possibility of decreased efficacy with the use of aminoglutethimide.

MPA is metabolized *in-vitro* primarily by hydroxylation via 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.

Fertility, Pregnancy and Lactation
Pregnancy
MPA is contraindicated in women who are pregnant.

Some reports suggest under certain circumstances, an association between intrauterine exposure to progestational drugs in the first trimester of pregnancy and genital abnormalities in fetuses.

If the patient becomes pregnant while using this drug, the patient should be apprised of the potential hazard to the fetus.

Lactation
MPA and its metabolites are excreted in breast milk. There is no evidence to suggest that this presents any hazard to the nursing child.

Effects on Ability to Drive and Use Machines
The effect of MPA on the ability to drive and use machinery has not been systematically evaluated.

UNDESIRABLE EFFECTS
ONCOLOGY:

The table below provides a listing of adverse drug reactions with frequency based on all-causality data from 1337 patients who received MPA in 4 pivotal studies that evaluated efficacy and safety of MPA for oncology indications.

System Organ Class	Common ≥ 1/100 to < 1/10	Uncommon ≥ 1/1000 to < 1/100	Rare ≥ 1/10,000 to < 1/1000	Frequency Not Known (cannot be estimated from the available data)
Immune system disorders		Angioedema	Drug hypersensitivity	Anaphylactic reaction, Anaphylactoid reaction
Endocrine disorders		Corticoid-like effects		Prolonged anovulation
Metabolism and nutritional disorders	Weight fluctuation, Increased appetite	Diabetes mellitus exacerbated, Hypercalcaemia		
Psychiatric disorders	Insomnia	Depression, Euphoria, Changes in libido	Nervousness	Confusion

DISETUJUI OLEH BPOM: 05/02/2026 ID: EREG10024112500331

System Organ Class	Common ≥ 1/100 to < 1/10	Uncommon ≥ 1/1000 to < 1/100	Rare ≥ 1/10,000 to < 1/1000	Frequency Not Known (cannot be estimated from the available data)
Nervous system disorders	Headache, Dizziness, Tremors		Cerebral infarction, Somnolence	Loss of concentration, Adrenergic-like effects
Eye disorders				Retinal embolism and thrombosis, Cataract diabetic, Visual impairment
Cardiac disorders		Cardiac failure congestive	Myocardial infarction	Tachycardia, Palpitations
Vascular disorders		Thrombophlebitis	Embolism and thrombosis	
Respiratory, thoracic and mediastinal disorders		Pulmonary embolism		
Gastrointestinal disorders	Vomiting, Constipation, Nausea	Diarrhoea, Dry mouth		
Hepatobiliary disorders			Jaundice	
Skin and subcutaneous tissue disorders	Hyperhidrosis	Acne, Hirsutism	Alopecia, Rash	Lipodystrophy acquired*, Urticaria, Pruritus
Musculoskeletal and connective tissue disorders		Muscle spasms		
Renal and urinary system disorders				Glycosuria
Reproductive system and breast disorders	Erectile dysfunction	Dysfunctional uterine bleeding (irregular, increase, decrease, spotting), Breast pain		Amenorrhoea, Uterine cervical erosions, Cervical discharge, Galactorrhoea
General disorders and administration site conditions	Oedema /fluid retention, Fatigue		Malaise, Pyrexia	
Investigations			Glucose tolerance decreased, Blood pressure increased	Liver function test abnormal, White blood cell count increased, Platelet count increased

*ADR identified post-marketing

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via:
Pusat Farmakovigilans/MESO Nasional

DISETUJUI OLEH BPOM: 05/02/2026 ID: EREG10024112500331

Direktorat Pengawasan Keamanan, Mutu, dan Ekspor Impor Obat, Narkotika, Psikotropika, Prekursor dan Zat Adiktif
Badan Pengawas Obat dan Makanan
Jl. Percetakan Negara No. 23, Jakarta Pusat, 10560
Email: pv-center@pom.go.id
Phone: +62-21-4244691 Ext.1079
Website: https://e-meso.pom.go.id/ADR

PT Pfizer Indonesia
Email: IDN.AEReporting@pfizer.com
Website: www.pfizersafetyreporting.com

OVERDOSE
Overdosage of estrogen plus progestin therapy may cause nausea and vomiting, breast tenderness, dizziness, abdominal pain, drowsiness/fatigue and withdrawal bleeding may occur in women. Treatment of overdose consists of discontinuation of CE/MPA together with institution of appropriate symptomatic care.

DOSAGE AND ADMINISTRATION
Recurrent endometrial and renal cancer: 200 mg to 400 mg per day.

Recurrent breast cancer in postmenopausal women: 400 to 800 mg per day.

Doses of 1000 mg daily have been given although the incidence of minor side effects, such as indigestion and weight gain, increase with the increase in dose response to hormonal therapy may not be evident until after at least 8 – 10 weeks of therapy.

HOW SUPPLIED
PROVERA tablets are available in the following strengths and package sizes:
100 mg, Boxes of 10 blisters @ 10 tablets; Reg. No. DKI0054200210D1

Store at maximum temperature 30°C

HARUS DENGAN RESEP DOKTER

Manufactured by:
Pfizer Italia S.r.l., Ascoli, Italy

Imported by:
PT. Pfizer Indonesia
Jakarta, Indonesia

DISETUJUI OLEH BPOM: 05/02/2026 ID: EREG10024112500331

Leaflet kemasan: Informasi untuk pengguna

Provera®
Tablet 100 mg
Medroksiprogesteron Asetat

Baca semua bagian leaflet ini dengan cermat sebelum mulai menggunakan obat ini karena berisi informasi penting bagi Anda.
- Simpan leaflet ini. Anda mungkin perlu membacanya kembali.
- Jika Anda memiliki pertanyaan lebih lanjut, tanyakan kepada dokter, apoteker, atau perawat Anda.
- Obat ini telah diresepkan hanya untuk Anda. Jangan berikan kepada orang lain. Obat ini dapat membahayakan mereka, sekalipun tanda-tanda penyakit mereka sama dengan Anda.
- Jika Anda mengalami efek samping apa pun, konsultasikan dengan dokter atau perawat Anda. Termasuk setiap kemungkinan efek samping yang tidak tercantum dalam leaflet ini. Lihat bagian 13.

Isi leaflet ini:

1. Nama obat
Provera®

2. Bentuk sediaan
Tablet

DISETUJUI OLEH BPOM: 05/02/2026 ID: EREG10024112500331

3. Deskripsi obat

Provera® mengandung zat aktif medroksiprogesteron asetat, yang merupakan salah satu golongan obat yang disebut "progestogen". Progestogen mirip dengan hormon alami perempuan yaitu progesteron.

Tablet berwarna putih bulat, datar, di satu sisi diberi tanda "U 467"

Daftar eksipien:
Mikrokristalin selulosa, pati jagung, gelatin, makrogol 400, glikolat pati natrium, magnesium stearat, natrium dokusat (85%) dengan natrium benzoat (15%).

4. Apa kandungan obat ini?

Setiap Tablet Provera® untuk administrasi oral mengandung 100 mg medroksiprogesteron asetat.

5. Kekuatan obat

100 mg.

6. Apa kegunaan obat ini?

Tablet Provera® digunakan untuk pengobatan tambahan dan/atau paliatif kanker pada ginjal (pada laki-laki dan perempuan) dan kanker pada dinding rahim (kanker endometrium) yang telah menyebar ke bagian tubuh lainnya (kanker metastasis).

Obat ini juga digunakan untuk mengobati kanker payudara berulang yang berhubungan dengan hormone pada perempuan pascamenopause (perempuan yang telah berhenti mendapatkan menstruasi).

7. Berapa banyak dan seberapa sering Anda seharusnya menggunakan obat ini? Apa yang harus dilakukan jika ada dosis yang terlewat?

Selalu gunakan obat ini dengan tepat sesuai anjuran dokter atau apoteker Anda. Tanyakan kepada dokter atau apoteker jika Anda merasa tidak yakin.

Anda akan dipantau secara ketat dan diperiksa secara rutin sebelum dan selama pengobatan menggunakan Tablet Provera, khususnya jika dosis tablet yang tinggi diresepkan untuk Anda.

Kanker endometrium (dinding rahim) dan ginjal:
Dosis yang umum adalah 200 mg hingga 400 mg setiap hari.

Kanker payudara pada perempuan pascamenopause:
Dosis yang umum adalah 400 mg hingga 800 mg setiap hari.

Peluang untuk mengalami efek samping kecil, seperti gangguan pencernaan dan kenaikan berat badan akan bertambah jika dosis ditingkatkan.

Mungkin diperlukan pengobatan selama 8 hingga 10 minggu sebelum efeknya dapat dirasakan.

DISETUJUI OLEH BPOM: 05/02/2026 ID: EREG10024112500331

Telan tablet secara utuh. Minumlah tablet Anda pada waktu yang sama setiap hari. Patuhi arahan dokter Anda. Jika Anda tidak yakin, tanyakan kepada dokter Anda.

Jika Anda lupa meminum Provera®
Jika Anda lupa untuk meminum tablet, minumlah dosis berikutnya pada waktu yang seharusnya. **Jangan meminum dosis ganda untuk mengejar dosis yang tertinggal.**

Jika Anda berhenti meminum Provera®
Jangan berhenti meminum obat Anda atau mengubah dosis yang Anda minum saat ini tanpa berkonsultasi dengan dokter Anda terlebih dahulu. Anda perlu terus meminum obat ini.

Jika Anda memiliki pertanyaan lebih lanjut seputar penggunaan obat ini, tanyakan kepada dokter atau apoteker Anda.

8. Kapan seharusnya Anda tidak menggunakan obat ini?

Jangan menggunakan Provera®

- jika Anda alergi terhadap medroksiprogesteron asetat atau terhadap bahan lain yang terkandung dalam obat ini
- jika Anda sedang hamil atau ada kemungkinan hamil. Dokter Anda dapat meminta Anda melakukan tes kehamilan sebelum memulai pengobatan atau jika Anda tidak mengalami menstruasi selama pengobatan.
- jika Anda sedang atau pernah mengalami t romboflebitis (proses inflamasi yang menyebabkan terbentuknya bekuan darah dan menyumbat satu atau beberapa pembuluh vena, biasanya di tungkai Anda), kelainan tromboemboli apopleksi serebral (bekuan darah dalam otak (‘stroke’))
- jika Anda menderita gangguan hati
- jika Anda mengalami perdarahan vagina yang tidak terdiagnosis
- jika Anda mengalami perdarahan saluran kencing yang tidak terdiagnosis
- jika Anda mengalami masalah pada payudara yang tidak terdiagnosis

9. Apa pertimbangan saat menggunakan obat ini?

Provera® mungkin tidak sesuai untuk semua perempuan. Harap baca daftar berikut ini dengan saksama untuk melihat apakah ada poin yang sesuai dengan Anda. Konsultasikan dengan dokter Anda jika Anda merasa tidak yakin.

Konsultasikan dengan dokter Anda sebelum menggunakan Provera® jika Anda mengalami kondisi berikut ini untuk membantunya memutuskan apakah Provera® sesuai untuk Anda:

- Gangguan penglihatan yang tiba-tiba
- Penyakit yang memengaruhi jantung dan pembuluh darah (penyakit kardiovaskular)
- Retensi cairan
- Epilepsi
- Sakit kepala migrain
- Asma
- Gangguan jantung
- Gangguan ginjal
- Diabetes

DISETUJUI OLEH BPOM: 05/02/2026 ID: EREG10024112500331

- Depresi atau riwayat depresi
- Tekanan darah tinggi
- Meningioma (tumor yang biasanya jinak yang terbentuk pada lapisan jaringan yang membungkus otak dan sumsum tulang belakang Anda)

Meningioma
Penggunaan medroksiprogresteron asetat telah dikaitkan dengan berkembangnya tumor yang umumnya jinak pada jaringan yang membungkus otak dan sumsum tulang belakang (meningioma). Risiko akan meningkat khususnya jika Anda menggunakannya untuk durasi yang lebih lama (beberapa tahun). Jika Anda didiagnosis menderita meningioma, dokter Anda akan menghentikan pengobatan dengan Provera® (lihat bagian 8). Jika Anda mengalami gejala apa pun, seperti perubahan penglihatan (misalnya penglihatan ganda atau penglihatan kabur), hilangnya pendengaran atau telinga berdenging, hilangnya penciuman, sakit kepala yang memburuk seiring waktu, hilangnya memori, kejang, lengan atau tungkai Anda melemah, segera beri tahu dokter Anda.

Provera®, khususnya dengan dosis tinggi, dapat menyebabkan penambahan berat badan dan retensi cairan.

Risiko Tromboemboli Vena (VTE)
Semua perempuan memiliki peluang kecil mengalami bekuan darah dalam pembuluh vena di kaki, paru, atau bagian tubuh lainnya. Peluang untuk mengalami bekuan darah menjadi sangat sedikit lebih tinggi jika Anda meminum obat hormon seperti Provera®. Kemungkinan Anda untuk mengalami bekuan darah menjadi lebih tinggi, baik Anda meminum Provera® atau tidak, jika Anda:

- memiliki berat badan yang sangat berlebih
- pernah mengalami bekuan darah dalam pembuluh vena atau paru sebelumnya
- memiliki kerabat yang pernah mengalami bekuan darah
- tidak dapat bergerak untuk jangka waktu yang lama (misalnya setelah operasi)
- mengalami cedera serius atau menjalani pembedahan besar
- memiliki riwayat keguguran berulang kali

Beri tahu dokter Anda jika Anda baru saja menjalani operasi atau jika Anda akan menjalani operasi selama menggunakan Provera®.

Pengobatan dengan Provera® dapat menyebabkan Anda mengalami gejala yang dikaitkan dengan sindrom Cushing's.

Tes Laboratorium:
Beri tahu dokter Anda jika Anda perlu menjalani tes darah atau pemeriksaan ginekologi, karena Provera® dapat memengaruhi hasilnya.

10. Apa saja obat lain atau makanan yang harus dihindari selama menggunakan obat ini?

Beri tahu dokter atau apoteker Anda jika Anda sedang meminum, baru-baru ini meminum, atau mungkin akan meminum obat-obatan lainnya:

- Aminoglutetimid

DISETUJUI OLEH BPOM: 05/02/2026 ID: EREG10024112500331

- Pemicu atau penghambat CYP3A4

11. Apakah obat tersebut aman bagi ibu hamil dan menyusui?

Kehamilan

Jika Anda sedang hamil atau menduga diri Anda hamil, atau berencana untuk hamil, Anda harus menghubungi dokter sebelum meminum Provera®.

Provera® tidak boleh diminum saat Anda hamil karena obat-obatan hormonal dapat memengaruhi perkembangan bayi. Penting bagi Anda untuk menggunakan metode kontrasepsi lainnya (misalnya kondom) selama meminum Provera®, karena obat ini tidak bersifat kontraseptif.

Menyusui

Beri tahu dokter Anda jika Anda akan menyusui selama meminum Provera® karena obat ini dapat dialirkan ke dalam ASI.

Jika Anda sedang menyusui, konsultasikan dengan dokter Anda yang akan menyarankan apakah Anda sebaiknya menggunakan metode pemberian asupan makanan alternatif bagi bayi Anda.

12. Apakah pasien diizinkan mengemudi dan mengoperasikan mesin saat menggunakan obat ini?

Efek Provera® terhadap kemampuan mengemudi dan mengoperasikan mesin belum dievaluasi secara sistematis.

13. Apa saja potensi efek yang tidak diinginkan dari penggunaan obat ini

Seperti semua obat-obatan yang ada, obat ini bisa menimbulkan efek samping, meskipun tidak semua orang mengalaminya.

Alasan menghentikan pengobatan Provera® dengan segera

Meskipun jarang terjadi, Provera® dapat menyebabkan reaksi alergi berat yang dalam beberapa kasus dapat mengancam jiwa. Anda bisa mengalami sebagian atau semua gejala berikut ini: mengi, kesulitan bernapas, merasa lemah, pembengkakan wajah atau lidah, telapak tangan, dan telapak kaki, ruam kulit yang sangat gatal. Jika Anda merasakan reaksi yang negatif terhadap obat ini, dapatkan penanganan medis darurat **secepatnya**.

Jika Anda mengalami gejala mana pun berikut ini, Anda harus **berhenti meminum** tablet dan mengunjungi dokter Anda **secepatnya**.

Ini merupakan gejala **adanya bekuan darah di paru** yang semuanya dapat terjadi bersamaan:

- Rasa nyeri yang tajam, parah, dan muncul tiba-tiba dalam dada Anda
- Batuk darah
- Anda tiba-tiba merasa sesak napas
- Jantung Anda berdenyut lebih cepat

Ini dapat menjadi gejala **adanya bekuan darah dalam otak ('stroke'):**

- Anda mengalami sakit kepala yang luar biasa parah atau berkepanjangan

DISETUJUI OLEH BPOM: 05/02/2026 ID: EREG10024112500331

- Anda mengalami gangguan penglihatan
- Anda kesulitan berbicara
- Anda roboh atau pingsan
- Ada bagian dari tubuh Anda yang terasa lemah atau kebas

Ini merupakan gejala **trombosis vena dalam (DVT):**

- Anda mengalami nyeri yang parah, nyeri tekan, atau pembengkakan pada betis, pergelangan kaki, atau telapak kaki
- Anda mengalami perubahan warna kulit kaki menjadi keunguan atau kulit memerah dan hangat saat disentuh

Beri tahu dokter Anda jika Anda mengalami efek samping lain yang dilaporkan sehubungan dengan penggunaan Provera® yang dapat mencakup efek samping berikut ini:

Umum**:** dapat dialami hingga 1 di antara 10 orang

- fluktuasi berat badan
- peningkatan nafsu makan
- sulit tidur
- sakit kepala
- pusing
- tremor
- muntah
- sembelit
- merasa mual
- berkeringat
- impotensi
- edema/retensi cairan
- kelelahan

Tidak Umum**:** dapat dialami hingga 1 di antara 100 orang

- pembengkakan pada wajah/tenggorokan yang dapat menyebabkan kesulitan bernapas
- efek seperti kortikoid
- peningkatan gejala diabetes melitus (misalnya merasa haus, buang air kecil lebih sering)
- peningkatan kadar kalsium dalam darah (hiperkalsemia)
- depresi
- euforia (perasaan sejahtera dan senang yang berlebihan)
- perubahan libido (dorongan seksual)
- gagal jantung (misalnya sesak napas, pembengkakan di kaki)
- bekuan darah, termasuk bekuan di dalam paru (misalnya nyeri dan pembengkakan di kaki, sesak napas yang muncul tiba-tiba)
- diare
- mulut kering
- jerawat
- pertumbuhan bulu pada wajah

DISETUJUI OLEH BPOM: 05/02/2026 ID: EREG10024112500331

- kram otot
- perdarahan atau flek darah pada vagina yang tidak diduga atau tidak biasa
- nyeri dan nyeri tekan pada payudara

Jarang**:** dapat dialami hingga 1 di antara 1000 orang
- reaksi alergi terhadap obat (misalnya mengi, sulit bernapas)
- kegelisahan
- stroke
- mengantuk
- serangan jantung
- kulit atau bagian putih pada mata menguning atau gangguan pada hati
- rambut rontok
- ruam
- merasa tidak enak badan
- demam
- penurunan toleransi gula
- peningkatan tekanan darah

Tidak diketahui: frekuensi tidak dapat diperkirakan dari data yang tersedia
- reaksi alergi berat (reaksi anafilaksis)
- tertundanya pelepasan sel telur disertai siklus menstruasi yang lebih panjang
- kebingungan
- hilangnya konsentrasi
- efek seperti adrenergik
- gangguan penglihatan, penglihatan ganda, pembesaran bola mata yang terjadi tiba-tiba, hilangnya penglihatan
- penglihatan keruh
- jantung berdenyut lebih cepat
- palpitasi
- lipodistrofi dapatan
- ruam jelatang atau kaligata
- gatal-gatal pada kulit
- air kencing mengandung gula
- menstruasi terhenti atau tertunda untuk waktu yang lama
- erosi serviks pada rahim
- keputihan
- cairan putih susu yang keluar dari payudara saat tidak hamil atau menyusui
- hasil tes fungsi hati abnormal
- peningkatan hitungan sel darah putih dan trombosit

Beri tahu dokter atau perawat Anda jika teramati adanya efek samping yang tercantum di atas.

Melaporkan efek samping
Jika Anda mengalami efek samping apa pun, konsultasikan dengan dokter, apoteker, atau perawat Anda. Termasuk setiap kemungkinan efek samping yang tidak tercantum dalam

DISETUJUI OLEH BPOM: 05/02/2026 ID: EREG10024112500331

leaflet ini. Dengan melaporkan efek samping, Anda bisa membantu memberikan informasi lebih lanjut mengenai keamanan obat ini.

Untuk melaporkan efek samping, hubungi www.pfizersafetyreporting.com atau email di IDN.AEReporting@pfizer.com

14. Tanda-tanda dan gejala-gejala overdosis
Mual dan muntah, nyeri tekan payudara, pusing, nyeri perut, mengantuk/kelelahan, dan perdarahan *withdrawal* mungkin saja terjadi.

15. Apa yang harus dilakukan jika Anda menggunakan lebih dari dosis yang dianjurkan?
Jika Anda tanpa sengaja meminum terlalu banyak tablet Provera®, segera hubungi dokter Anda atau datangi unit gawat darurat di rumah sakit terdekat.

Bawa selalu kemasan obat berlabel, baik yang masih ada tablet Provera® yang tersisa di dalamnya atau tidak.

Jangan meminum tablet lagi hingga dokter Anda memerintahkan Anda.

16. Bagaimana cara menyimpan obat ini?
Jauhkan obat ini dari pandangan dan jangkauan anak-anak.

Jangan gunakan obat ini setelah melewati tanggal kedaluwarsa yang tertera pada wadahnya.

Simpan pada suhu di bawah 30 °C.

17. Nomor otorisasi pemasaran
Provera® 100 mg: Dus berisi 10 blister @ 10 Tablet, No. Reg.: DKI0054200210D1

18. Nama dan alamat pemohon dan/atau pemilik obat sesuai dengan ketentuan yang berlaku

Diproduksi oleh:
Pfizer Italia S.r.l.
Ascoli, Italy

Diimpor oleh:
PT. Pfizer Indonesia
Jakarta, Indonesia

19. Tanggal revisi
08/2025

20. Peringatan khusus
HARUS DENGAN RESEP DOKTER

DISETUJUI OLEH BPOM: 05/02/2026 ID: EREG10024112500331