

# Medroxyprogesterone Sandoz®

medroxyprogesterone acetate tablets

## Consumer Medicine Information

### What is in this leaflet

This leaflet answers some common questions about Medroxyprogesterone Sandoz.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the benefits they expect it will have for you.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.** You may need to read it again.

### What Medroxyprogesterone Sandoz is used for

This medicine is used to treat:

- endometriosis, a condition in which material similar to the lining of the uterus (womb) grows outside the uterus, causing pain or bleeding.
- secondary amenorrhoea (a lack of menstrual bleeding not due to pregnancy). Medroxyprogesterone Sandoz, with or without an oestrogen, helps to re-establish a regular menstrual cycle.

- abnormal uterine bleeding, changed or irregular bleeding pattern. Medroxyprogesterone Sandoz helps to re-establish a regular menstrual cycle.
- symptoms of menopause in women with an intact uterus. Medroxyprogesterone Sandoz tablets are used in combination with oestrogen therapy to protect the lining of the uterus while the oestrogen relieves the symptoms.

It contains the active ingredient medroxyprogesterone acetate. Medroxyprogesterone acetate is a chemical similar to the natural hormone progesterone.

**Ask your doctor if you have any questions about why this medicine has been prescribed for you.**

Your doctor may have prescribed it for another reason.

There is no evidence that Medroxyprogesterone Sandoz is addictive.

### Before you take Medroxyprogesterone Sandoz

*When you must not take it*

**Do not take this medicine if you have an allergy to:**

- medroxyprogesterone acetate, the active ingredient, or to any of the other ingredients listed at the end of this leaflet under Product description
- any other similar medicines.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

**Do not take this medicine if you have or have had any of the following medical conditions:**

- blood clots
- pulmonary embolism
- swelling and redness along a vein which is extremely tender when touched
- stroke
- severe liver disease
- breast cancer or breast lumps not diagnosed by your doctor
- bleeding or discharge from your nipples
- uncontrolled high blood pressure
- unusual or irregular vaginal bleeding or blood in your urine that has not been diagnosed by your doctor.

**Do not take this medicine if you have had your uterus removed.**

**Do not take this medicine if you are pregnant.**

It may affect your developing baby if you take it during pregnancy.

**Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**

If it has expired or is damaged, return it to your pharmacist for disposal.

**If you are not sure whether you should start taking this medicine, talk to your doctor.**

## *Before you start to take it*

**Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.**

**Tell your doctor if you have or have had any of the following medical conditions:**

- heart or kidney problems
- migraine
- unusual or irregular vaginal bleeding
- asthma
- epilepsy (convulsions or seizures)
- diabetes or a family history of diabetes
- depression or a family history of depression
- osteoporosis
- genital or breast cancer.

**If you have not told your doctor about any of the above, tell him/her before you start taking Medroxyprogesterone Sandoz.**

## *Taking other medicines*

**Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.**

Some medicines and Medroxyprogesterone Sandoz may interfere with each other. These include:

- aminoglutethimide (Cytadren®), a medicine used to treat certain types of breast cancer.

This medicine may be affected by Medroxyprogesterone Sandoz or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Medroxyprogesterone Sandoz.

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## How to take Medroxyprogesterone Sandoz

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**Follow all directions given to you by your doctor or pharmacist carefully.**

They may differ from the information contained in this leaflet.

**If you do not understand the instructions, ask your doctor or pharmacist for help.**

## *How much to take*

**The dose of Medroxyprogesterone Sandoz will vary depending on the condition for which you are being treated. Medroxyprogesterone Sandoz should be used at the lowest effective dose to treat your condition.**

Your doctor may tell you to take this medicine every day or in repeating cycles with a break in between.

**Ask your doctor or pharmacist if you are unsure of the correct dose for you.**

They will tell you exactly how much to take.

**Follow the instructions they give you.**

If you take the wrong dose, Medroxyprogesterone Sandoz may not work as well and your problem may not improve.

## *How to take it*

**Swallow the tablets whole with a full glass of water.**

Medroxyprogesterone Sandoz tablets should not be broken or crushed.

## *When to take Medroxyprogesterone Sandoz*

**Take your medicine at about the same time each day.**

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

## *How long to take Medroxyprogesterone Sandoz*

**Continue taking your medicine for as long as your doctor tells you.**

Your doctor will prescribe this medicine for the shortest duration necessary to effectively treat your condition.

## *If you forget to take it*

Take your dose as soon as you remember, and continue to take it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

**Do not take a double dose to make up for the dose that you missed.**

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

## *If you take too much (overdose)*

**Immediately telephone your doctor or the Poisons Information Centre (telephone Australia 13 11 26 or New Zealand 0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Medroxyprogesterone Sandoz. Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

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## While you are taking Medroxyprogesterone Sandoz

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### *Things you must do*

Always follow your doctor's instructions carefully.

If you become pregnant while taking this medicine, tell your doctor immediately.

Medroxyprogesterone Sandoz should not be used during pregnancy.

Tell your doctor immediately if you have sudden partial or complete loss of vision or sudden onset of double vision or migraine.

You will need to be examined and may need to stop taking your medicine.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Medroxyprogesterone Sandoz.

If you are about to have any laboratory tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Regularly check your breasts for any lumps and have regular professional breast examinations and mammograms, as recommended by your doctor.

Tell your doctor if, for any reason, you have not taken this medicine exactly as prescribed.

Tell your doctor if you feel that your medicine is not helping your condition.

Always discuss with your doctor any problems or difficulties during or after taking Medroxyprogesterone Sandoz.

### *Things you must not do*

Do not take Medroxyprogesterone Sandoz to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not change your dose or stop taking Medroxyprogesterone Sandoz without your doctor's permission.

### *Things to be careful of*

Be careful driving or operating machinery until you know how Medroxyprogesterone Sandoz affects you.

This medicine may cause dizziness, drowsiness and fatigue in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

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## Side effects

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Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Medroxyprogesterone Sandoz.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

If you are over 65 years of age you may have an increased chance of getting side effects.

The use of oestrogen at the same time as Medroxyprogesterone Sandoz may also increase the risk of side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- nervousness, difficulty concentrating
- problems sleeping, drowsiness, fatigue
- shaking
- dizziness, headache, nausea or vomiting
- dry mouth
- depression or excitement
- tremor
- skin conditions, such as hives, itching, rash or acne
- unusual hair loss or thinning or increased hairiness
- constipation or diarrhoea
- changes in sexual drive
- fever
- leg cramps
- sweating
- irregular vaginal bleeding or spotting, unusual changes in vaginal secretions or lack of menstrual periods
- tenderness of the breast or unusual secretions of breast milk
- changes in your weight
- yellowing of the skin or eyes (jaundice)
- fluid retention - if you suffer from epilepsy (convulsions or seizures) or breathlessness, this increase in fluid retention may make symptoms worse.

These are the more common side effects of the medicine. Mostly, these are mild and short-lived.

Tell your doctor as soon as possible if you notice any of the following:

- confusion or memory loss
- changes in your breasts, for example lumps.

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- chest pain or shortness of breath
- painful swelling in a leg
- severe headaches or changes in speech or vision.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are not common.

**Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.**

Other side effects not listed above may also occur in some people.

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## After taking Medroxyprogesterone Sandoz

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### Storage

**Keep your medicine in the original container.**

If you take it out of its original container it may not keep well.

**Keep your medicine in a cool dry place where the temperature stays below 25°C.**

**Do not store Medroxyprogesterone Sandoz or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.**

Heat and dampness can destroy some medicines.

**Keep it where children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

### Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

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## Product description

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### *What it looks like*

Medroxyprogesterone Sandoz 10mg - white, round tablets, with a score notch on one side.

Available in blister packs of 30 tablets.

### *Ingredients*

Active ingredients:

- Medroxyprogesterone Sandoz 10mg - 10mg medroxyprogesterone acetate

Inactive ingredients:

- maize starch
- sodium starch glycollate
- lactose
- microcrystalline cellulose
- colloidal anhydrous silica
- magnesium stearate.

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

### *Supplier*

#### **Sandoz Pty Ltd**

ABN 60 075 449 553  
19 Harris St  
Pymont NSW 2009  
Tel: 1800 634 500

#### **Novartis New Zealand Ltd**

Private Bag 65904 Mairangi Bay  
Auckland 0754  
New Zealand  
Tel: 0800 354 335

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#### **Australian Register Number**

10mg tablets: AUST R 79252