

# METHYLPRED

*methylprednisolone sodium succinate powder for injection*

## Consumer Medicine Information

### What is in this leaflet

This leaflet answers some common questions about METHYLPRED. 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 being given METHYLPRED against the benefits they expect it will have for you.

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

**Keep this leaflet with the medicine.**

You may need to read it again.

### What METHYLPRED is used for

METHYLPRED contains methylprednisolone (as methylprednisolone sodium succinate) as the active ingredient. It belongs to a group of medicines called corticosteroids.

It is used for the treatment of one or more of the following conditions:

- skin diseases
- allergic reactions
- inflammation of the eyes
- respiratory diseases and certain respiratory infections
- diseases of the gut (gastrointestinal tract)
- multiple sclerosis
- rheumatic disorders
- diseases of the blood
- treatment of certain glandular conditions and tumours of the immune system.

METHYLPRED reduces inflammation (pain, swelling, redness and heat) which is one of the body's reactions to injury and by reducing the body's reaction to infection.

**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 purpose.

It is available only with a doctor's prescription.

There is no evidence that it is addictive.

### Before you are given it

*When you must not be given it*

**You must not be given METHYLPRED if you have an allergy to:**

- any medicine containing methylprednisolone sodium succinate
- any of the ingredients listed at the end of this leaflet.

The METHYLPRED 40 mg product contains lactose from cow's milk.

**Tell your doctor if you are allergic or suspect you are allergic to cow's milk or to any other dairy products.**

Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty in breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

**You must not be given this medicine if you have a current serious or uncontrolled fungal infection.**

Your doctor will advise you whether use of METHYLPRED is appropriate in those particular circumstances.

**You must not be given this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**

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

*Before you are given 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:**

- unusually high stress due to trauma or infection
- stomach ulcers
- thin or weak bones, or bones that tend to break easily (osteoporosis)
- high blood pressure (hypertension)
- kidney or liver disease
- underactive thyroid gland
- mental disorder
- myasthenia gravis (ongoing chronic fatigue and muscle weakness)
- tuberculosis
- herpes simplex of the eye
- ulcerative colitis (disease of the bowel).

**Tell your doctor that you are being treated with METHYLPRED if you are scheduled to have any laboratory tests (e.g. blood or urine).**

The use of METHYLPRED may disguise the signs of infections due to a decrease in the body's response to the infection.

**Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.**

Your doctor can discuss with you the benefits and possible risks of being given this medicine during pregnancy or breastfeeding.

**If you have not told your doctor about any of the above, tell them before you start being given METHYLPRED.**

*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 METHYLPRED may interfere with each other. These include:

- salicylates e.g. aspirin
- respiratory medicines e.g. salbutamol
- neuromuscular blocking drugs, e.g. pancuronium
- some antibiotics e.g. erythromycin
- some antifungal agents e.g. ketoconazole
- blood pressure medicines
- some medicines for heart disease e.g. digoxin
- some diuretics e.g. frusemide
- anticonvulsants e.g. phenobarbitone, phenytoin
- anticoagulants e.g. heparin, warfarin

- antidiabetic medicines e.g.
- insulin, glibenclamide, metformin
- immunosuppressants e.g. methotrexate, cyclosporin
- some immunisations, inoculations or vaccinations.

These medicines may be affected by METHYLPRED 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 being treated with this medicine.

### How it is given

*How much is given*

Your doctor will decide what dose you will receive. This depends on the condition being treated and your response to the treatment.

Your doctor may change the dose and frequency of your medicine as your condition changes.

*How it is given*

METHYLPRED is a sterile powder which is dissolved and diluted with suitable sterile fluids.

It is given by direct injection either into a vein or muscle or less frequently via an intravenous (I.V. line) line.

It must not be given intrathecally, epidurally or by local injection due to the risk of serious side effects.

**Do not administer this medicine to yourself.**

Your doctor or nurse will prepare METHYLPRED for you.

*If you are given too much (overdose)*

As METHYLPRED is given to you under the supervision of your doctor, it is extremely unlikely that you will be given too much.

**However, if you experience any side effects after being given METHYLPRED, tell your doctor or nurse immediately.**

Ask your doctor or pharmacist if you have any concerns.

### Side effects

**Tell your doctor or nurse as soon as possible if you do not feel well while you are being treated with METHYLPRED.**

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

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

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

- fluid retention (causes an increase in weight)
- muscle weakness or loss of muscle mass
- increased sweating
- headache or dizziness
- changes in your menstrual periods
- mood changes

- nausea and vomiting
- itchy skin
- thin fragile skin or bruising
- facial redness
- persistent hiccups.

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

**Tell your doctor immediately if you notice any of the following:**

- bone weakness possibly leading to fractures
- wounds that will not heal
- deterioration in the control of diabetes mellitus.

**Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital if you notice any of the following symptoms:**

- signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers
- allergic-type reactions e.g. skin rash, itching and difficulty breathing, wheezing or coughing (anaphylactic reactions)
- severe stomach pains
- convulsions or fits
- blurred vision or loss of vision
- passing large amounts of urine, increased thirst and appetite.

These side effects are serious and may need urgent medical attention.

Long term treatment with corticosteroids such as METHYLPRED may also cause:

- chemical imbalances in the blood
- swelling of the pancreas (pancreatitis)
- bleeding in the stomach
- masking of infections
- increased risk of infection
- hormone changes
- metabolic changes
- changes in liver enzymes
- increased blood pressure
- cataracts and other eye diseases.

**Tell your doctor if you notice anything else that is making you feel unwell, even if you think the problems are not connected with this medicine and are not referred to in this leaflet.**

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

**Do not be alarmed by this list of side effects.**

You may not experience any of them.

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## Product description

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### *What it looks like*

METHYLPRED is available in four strengths:

- 40 mg
- 125 mg
- 500 mg
- 1.0 g.

All strengths are a white to off white powder in a vial. The powder is dissolved and diluted with suitable sterile fluids before it is used.

Available in the following pack sizes:

- 40 mg: packs of 5 vials
- 125 mg: packs of 1 vial
- 500 mg: packs of 1 vial
- 1.0 g: packs of 1 vial.

### *Ingredients*

#### **Active ingredients:**

Each vial contains either 40 mg, 125 mg, 500 mg or 1.0 g of methylprednisolone (as methylprednisolone sodium succinate).

#### **Inactive ingredients:**

- sodium phosphate - dibasic anhydrous
- sodium phosphate - monobasic anhydrous
- lactose (40 mg only).

### *Sponsor*

METHYLPRED is supplied in Australia by:

#### **Alphapharm Pty Limited**

(ABN 93 002 359 739)

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

Phone: (02) 9298 3999

www.mylan.com.au

Australian Registration Numbers:

40 mg: AUST R 145028

125 mg: AUST R 145102

500 mg: AUST R 145103

1.0 g: AUST R 161750.

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## After using it

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### *Storage*

Normally your doctor will get METHYLPRED from the hospital pharmacy or their consulting rooms. If you take your METHYLPRED from the pharmacy to your doctor, it is important to store it in a safe place, away from heat and light, where the temperature stays below 25°C.

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

If for any reason you take your METHYLPRED home, always ensure that it is stored in a place where children cannot reach it.