

# Methylprednisolone Alphapharm

contains the active ingredient methylprednisolone sodium succinate

## Consumer Medicine Information

### What is in this leaflet

This leaflet answers some common questions about Methylprednisolone Alphapharm.

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

All medicines have benefits and risks. Your doctor has weighed the risks of you being treated with Methylprednisolone Alphapharm against the benefits it is expected to have for you.

Follow the instructions given to you by your doctor and the advice contained in this leaflet.

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

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

### What Methylprednisolone Alphapharm is used for

Your doctor has prescribed Methylprednisolone Alphapharm for the treatment of one or more of the following:

- 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

Your doctor may have prescribed Methylprednisolone Alphapharm for another reason.

#### How your medicine works

Methylprednisolone sodium succinate, the active ingredient in Methylprednisolone Alphapharm, belongs to a group of medicines called corticosteroids.

Methylprednisolone Alphapharm acts in the body by reducing 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 Methylprednisolone Alphapharm has been prescribed for you.**

Methylprednisolone Alphapharm is available only with a doctor's prescription.

There is no evidence that Methylprednisolone Alphapharm is addictive.

### Before you start treatment with Methylprednisolone Alphapharm

#### When Methylprednisolone Alphapharm must not be used

Methylprednisolone Alphapharm must not be used if you have an allergy to:

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

Some symptoms of an allergic reaction (anaphylactic reactions) may include

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

If you are not sure if you have or have had an allergic reaction to Methylprednisolone Alphapharm, check with your doctor.

**Do not start treatment with Methylprednisolone Alphapharm, if you have a severe fungal infection.**

Your doctor will advise whether use of Methylprednisolone Alphapharm is appropriate in those particular circumstances. Methylprednisolone Alphapharm must not be used with certain types of vaccines.

**Tell your doctor if you have recently been vaccinated or immunised.**

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

Methylprednisolone Alphapharm must be administered by intravenous or intramuscular injection.

**Do not administer Methylprednisolone Alphapharm in the spinal cord (intrathecal or epidural) or by local injection due to the risk of serious side effects.**

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

**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 if you should start treatment with this medicine, talk to your doctor.**

#### Before treatment with Methylprednisolone Alphapharm

**Tell your doctor if you are allergic to any other medicines or any other substances such as foods, preservatives or dyes.**

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

- disease of the heart, e.g., high blood pressure (hypertension) or congestive heart failure
- condition or tumour of the adrenal and/or pituitary glands
- stomach ulcers
- thin or weak bones, or bones that tend to break easily (osteoporosis)
- kidney or liver disease
- underactive thyroid gland
- emotional and mental disorder
- myasthenia gravis (ongoing chronic fatigue and muscle weakness)
- tuberculosis (TB)
- herpes simplex of the eye
- any pus producing infections
- disease of the bowel, e.g., ulcerative colitis or diverticulitis
- recent head injuries
- fits or convulsions
- diabetes or increased sugar in your blood

- blood clots.

If you are scheduled to have any laboratory tests, e.g., blood or urine, tell your doctor that you are being treated with Methylprednisolone Alphapharm.

The use of Methylprednisolone Alphapharm may disguise the signs of infections due to a decrease in the body's response to the infection. If you are in any doubt please consult your doctor.

**Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.**

Your doctor can discuss with you the risks and benefits involved.

#### Children

Long term treatment with corticosteroids can affect growth and development in children. It can also increase the risk of high pressure in the brain. Your doctor will monitor your child closely if your child needs long term treatment with Methylprednisolone Alphapharm.

#### Elderly

If you are over 65 years old, you may have an increased chance of side effects such as bone weakness possibly leading to fractures. You may also experience fluid retention which may lead to increased blood pressure.

**If you have not told your doctor about any of the above, tell them before you start treatment with Methylprednisolone Alphapharm.**

#### Taking other medicines

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

Some medicines and food and Methylprednisolone Alphapharm may interfere with each other. These include:

- nonsteroidal anti-inflammatory such as salicylates or aspirin, medicines used to relieve pain, swelling and other symptoms of inflammation including arthritis.
- neuromuscular blocking drugs, e.g., pancuronium
- some antibiotics, e.g., erythromycin
- medicines used to treat TB, e.g. isoniazid
- some anti-fungal agents, e.g., ketoconazole, amphotericin
- medicines to treat HIV, e.g., indinavir, ritonavir
- some medicines to treat blood pressure, heart conditions and stroke, e.g., digoxin and diltiazem
- some diuretics e.g., frusemide, a medicine to help kidneys get rid of salt and water by increasing the amount of urine produced
- medicine for nausea, e.g., aprepitant, fosaprepitant
- oral contraceptives
- medicines used for myasthenia gravis, glaucoma, Alzheimer's disease
- medicines for psychiatric disorders
- medicines to treat anxiety

- bronchodilators (a type of medicine that opens up the airways in the lungs) used to treat asthma, bronchitis, emphysema, and other lung diseases, e.g., salbutamol
- medicines to treat breast cancer or hormone disorder
- anticonvulsants e.g., phenytoin, phenobarbitone
- anticoagulants e.g., heparin, warfarin
- antidiabetic medicines e.g., insulin, glibenclamide and metformin
- immunosuppressants e.g., methotrexate and cyclosporin (a medicine used in kidney transplant patients)
- some immunisations, inoculations or vaccinations
- grapefruit juice.

You may need different amounts of Methylprednisolone Alphapharm or you may need to take different medicines.

Your doctor or pharmacist can tell you what to do if you are taking any of these medicines. They also have a more complete list of medicines to be careful with or avoid while being treated with Methylprednisolone Alphapharm.

**Ask your doctor or pharmacist if you are not sure if you are taking any of these medicines.**

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## How to use Methylprednisolone Alphapharm

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This medicine will be administered under medical supervision.

Methylprednisolone Alphapharm must be administered by intravenous or intramuscular injection. It must not be given in the spinal cord (intrathecal or epidural) or by local injection due to the risk of serious side effects.

**You must not administer this medicine to yourself.**

Methylprednisolone Alphapharm powder is reconstituted with Sterile Water for Injections by your doctor or pharmacist.

### *How much you should be given*

The dose and how often you are treated with will depend on your medical condition and also on your weight. Your doctor may change the dose and how many times a day you have it, as your condition changes.

### *How long you should be given Methylprednisolone Alphapharm*

Your doctor will continue giving you Methylprednisolone Alphapharm for as long as your condition requires.

### *If you are given too much (overdose)*

Methylprednisolone Alphapharm will be administered under medical supervision so an overdose is unlikely.

However, repeated frequent doses over a long period of time may cause an increase in side effects.

**Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much Methylprednisolone Alphapharm. Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

**Keep the telephone numbers for these services handy.**

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## While being treated with Methylprednisolone Alphapharm

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### *Things you must do*

**Tell your doctor immediately if you notice any unusual symptoms.**

**If you are about to start taking any new medicines, tell your doctor or pharmacist that you are being treated with Methylprednisolone Alphapharm.**

**Tell any doctor, dentist or pharmacist who treats you that you are being treated with Methylprednisolone Alphapharm.**

**Tell your doctor immediately if you become pregnant while taking this medicine.**

**If you are about to have any blood test, tell your doctor that you are taking Methylprednisolone Alphapharm.**

It may interfere with some of the results.

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

### *Things to be careful of*

**Avoid drinking grapefruit juice while you are being treated with Methylprednisolone Alphapharm.**

Grapefruit may interact with Methylprednisolone Alphapharm and affect the way your body uses the medicine.

**Be careful when driving or operating machinery until you know how Methylprednisolone Alphapharm affects you.**

Methylprednisolone Alphapharm may cause dizziness, light headedness, visual disturbances, and fatigue in some patients.

**Do not drive or operate machinery or do anything else that could be dangerous, if you have any of these symptoms.**

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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 being treated with Methylprednisolone Alphapharm.**

All medicines can have side effects and Methylprednisolone Alphapharm may have unwanted side effects in a few people. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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

You may not experience any of them.

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

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

- weight gain as a result of fluid retention or increased appetite
- muscle weakness or loss of muscle mass
- loss of ability to feel pain in the joint and instability of the joint
- pain when putting weight or pressure on a joint
- increased sweating
- headache or dizziness
- light headedness
- changes in your menstrual periods

- mood changes and other mental disorders such as memory loss, reduced perception and problem solving abilities
- nausea
- vomiting
- itchy or peeling skin
- loss of appetite or weight loss
- thin fragile skin or bruising
- acne
- facial redness or bands, stripes or lines on the skin
- excessive hairiness, particularly in women
- benign tumour like lumps as a result of fat deposits in the tissues
- persistent hiccups
- stomach pain or discomfort
- diarrhoea
- fatigue or generally feeling unwell
- pain, redness at the injection site.

**If these effects do not go away, or they are worrying to you, tell your doctor.**

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

- bone weakness possibly leading to fractures
- wounds that will not heal
- red, purple or brown patches on your skin
- loss of sensation or problems with your reflexes (slow or too fast).

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

- signs of increased pressure in the skull, including drowsiness, vomiting, headache, weakness, numbness and/or eye problems such as double vision
- 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)
- swelling of hands, ankles or feet
- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing
- inflammation of the food pipe. You may experience difficulty or pain when swallowing or heartburn
- poor appetite, fever, chills, nausea and a persistent stomach ache that becomes worse with movement
- uncomfortable or severe stomach pains or belching after eating
- convulsions or fits
- blurred or loss of vision, distorted vision or a blind spot in your central vision, pressure in the eye.
- pain and tenderness in the leg, pain on extending the foot, swelling of the lower leg, ankle and foot
- chest pain and breathlessness.

Methylprednisolone Alphapharm can also cause: chemical imbalances in the blood and urine, 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 or increased number of white blood cells (leucocytosis).

Some of these side effects can only be found when your doctor does tests from time to time to check on your progress.

This is not a complete list of all possible side effects. Some people may get other side effects while being treated with Methylprednisolone Alphapharm.

**It is very important to tell your doctor if you notice any side effects during a course of treatment with Methylprednisolone Alphapharm.**

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## After treatment with Methylprednisolone Alphapharm

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### *Storage*

Normally your doctor will get Methylprednisolone Alphapharm from the hospital pharmacy or their consulting rooms. If you do take your Methylprednisolone Alphapharm from the pharmacy to your doctor, it is important to store it in a safe place away from heat (below 25°C).

**Do not leave Methylprednisolone Alphapharm in a car or on window sills.**

Heat can destroy some medicines.

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

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

### *Disposal*

If your doctor stops treating you with Methylprednisolone Alphapharm, your hospital pharmacist will dispose of any unused medicine.

The expiry date is printed on the labels. Methylprednisolone Alphapharm should not be used after this date has passed.

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## Product description

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### *What it looks like*

Methylprednisolone Alphapharm is a white powder, which has to be reconstituted with water for injection, before being injected into the vein.

Methylprednisolone Alphapharm 500 mg and 1 g are available in packs of 1 vial.

### *Ingredients*

Each vial of Methylprednisolone Alphapharm contains 500 mg and 1 g of methylprednisolone sodium succinate.

Methylprednisolone Alphapharm 500 mg and 1 g also contain the following inactive ingredients:

- sodium phosphate monobasic anhydrous
- sodium phosphate dibasic anhydrous
- sodium hydroxide

Methylprednisolone Alphapharm 500 mg and 1 g do not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

### *Supplier*

Methylprednisolone Alphapharm is supplied 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:

Methylprednisolone Alphapharm

500 mg - AUST R 166624

Methylprednisolone Alphapharm

1 g - AUST R 166625

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