

METHYLPRED

methylprednisolone (as 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.

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

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

How your medicine works

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 Methylpred must not be used

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.

Some symptoms of an allergic reaction may include rash, itching or hives on the skin; shortness of breath, wheezing or difficulty in breathing; 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 METHYLPRED, check with your doctor,

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.

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

METHYLPRED must not be used with certain types of vaccines.

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

Do not administer this medicine to yourself.

METHYLPRED must be administered by intravenous or intramuscular injection.

It should not be administered in the spinal cord (intrathecal or epidural) or by local injection due to the risk of serious side effects.

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 METHYLPRED

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:

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

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 breast-feeding.

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.

Children

Long term treatment with corticosteroids may 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 METHYLPRED.

Some of the METHYLPRED products contain benzyl alcohol once reconstituted. Benzyl alcohol has been associated with rare but serious side effects in infants. Your doctor will decide if treatment is appropriate.

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.

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:

- non-steroidal anti-inflammatory medicines such as salicylates or aspirin, medicines used to relieve pain, swelling and other symptoms of inflammation including arthritis
- bronchodilators e.g. salbutamol
- medicines used to treat TB e.g. isoniazid

- neuromuscular blocking drugs, e.g. pancuronium, vecuronium
- some antibiotics e.g. erythromycin, rifampicin
- some antifungal agents e.g. ketoconazole, amphotericin B (amphotericin)
- medicines used to treat HIV e.g. indinavir, ritonavir
- blood pressure, heart disease or stroke medicines e.g. digoxin, diltiazem
- some diuretics e.g. furosemide (frusemide)
- medicine for nausea, e.g. aprepitant, fosaprepitant
- oral contraceptives
- anticonvulsants e.g. phenobarbital (phenobarbitone), phenytoin
- anticoagulants e.g. heparin, warfarin
- antidiabetic medicines e.g. insulin, glibenclamide, metformin
- immunosuppressants e.g. methotrexate, ciclosporin
- some immunisations, inoculations or vaccinations
- medicines to treat anxiety and psychiatric disorders
- medications for myasthenia gravis
- certain medicines to treat breast cancer
- grapefruit juice

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.

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

Immediately telephone your doctor or Poisons Information Centre on 13 11 26 for advice, or go to Accident and Emergency (Casualty) at your nearest hospital if you think your doctor may have been given too much METHYLPRED.

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.

While being treated with METHYLPRED

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 METHYLPRED.

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

Tell your doctor immediately if you become pregnant while taking METHYLPRED.

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

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 METHYLPRED.

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

Be careful when driving or operating machinery until you know how METHYLPRED affects you.

METHYLPRED 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.

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:

- 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
- fatigue or generally feeling unwell
- changes in your menstrual periods
- mood changes
- mental abnormalities such as memory loss, reduced perception and problem solving skills
- nausea and vomiting
- itchy or peeling skin
- loss of appetite or weight loss
- thin fragile skin or bruising
- facial redness or bands, stripes or lines on the skin
- acne
- excessive hair growth particularly in women

- lumps as a result of fat deposits in the tissues
- stomach pain or discomfort
- diarrhoea
- pain or redness at the injection site
- 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
- red, purple or brown patches on your skin
- yellowing of the skin or eyes, dark urine, loss of appetite
- loss of sensation or problems with your reflexes (slow or too fast)
- 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 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
- difficulty or pain when swallowing, heartburn or inflammation of food pipe
- 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
- vision changes such as blurred vision or loss of vision, distorted vision or a blind spot in your central vision, pressure in the eye
- passing large amounts of urine, increased thirst and appetite.
- pain and tenderness in the leg, pain on extending the foot, swelling of the lower leg, ankle and foot
- chest pain and breathlessness.

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 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
- increased number of white blood cells (leucocytosis)
- 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.

This is not a complete list of all possible side-effects. 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.

After using it

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.

Do not leave METHYLPRED in a car.

Disposal

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

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

Product description

What it looks like

METHYLPRED is available in four strengths:

- 40 mg
- 125 mg
- 500 mg
- 1000 mg

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

- 1000 mg: 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:

- dibasic sodium phosphate
- monobasic sodium phosphate dihydrate
- lactose monohydrate (40 mg only)

Sponsor

METHYLPRED is supplied in Australia by:

Alphapharm Pty Limited

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.mylan.com.au

Australian Registration Numbers:

40 mg: AUST R 145028

125 mg: AUST R 145102

500 mg: AUST R 145103

1000 mg: AUST R 161750.

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