PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

MYLAN METHYLPREDNISOLONE 40 (vial with powder for solution for injection)

MYLAN METHYLPREDNISOLONE 120 (vial with powder for solution for injection)

MYLAN METHYLPREDNISOLONE 500 (vial with powder for solution for injection)

MYLAN METHYLPREDNISOLONE 1000 (vial with powder for solution for injection)

Methylprednisolone 40 mg, 120 mg, 500 mg, 1000 mg

MYLAN METHYLPREDNISOLONE 40 mg & 120 mg :

Contains: Dextrose monohydrate 27,50 mg

Read all of this leaflet carefully before receiving MYLAN METHYLPREDNISOLONE

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **MYLAN METHYLPREDNISOLONE** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours. (May be omitted if **MYLAN METHYLPREDNISOLONE** is not self-administered).

What is in this leaflet

1. What MYLAN METHYLPREDNISOLONE is and what it is used for

MYLAN METHYLPREDNISOLONE is used is used for its potent anti-inflammatory (reduces swelling) effect.

It lowers the immune response at high doses.

2. What you need to know before you receive MYLAN METHYLPREDNISOLONE

MYLAN METHYLPREDNISOLONE should not be administered to you :

- If you have **chicken pox**, **measles**, **shingles** or a **herpes** eye infection. If you think you have been in contact with someone with chickenpox, measles or shingles and you have not already had these illnesses, or if you are unsure if you have had them.
- If you have ever suffered an **allergic reaction,** or any type of reaction after being given **MYLAN METHYLPREDNISOLONE**, or any other medicine containing a corticosteroid or any of the ingredients in this medicine. An allergic reaction may cause a skin rash or reddening, swollen face or lips or shortness of breath.
- If you have any **fungal infection** (such as thrush), which is not being treated.

- If you have a **blood disorder** or are taking medicines to make the blood thinner.

Warnings and precautions

Tell your doctor or healthcare provider before being given the injection if:

Note! If you are an athlete you are warned that the active ingredient, methylprednisolone, in **MYLAN METHYLPREDNISOLONE** is on the list of banned substances.

Before you receive **MYLAN METHYLPREDNISOLONE,** tell your doctor:

- If you have **tuberculosis** (TB) or if you have suffered tuberculosis in the past.
- If you currently have an **infectious disease**.
- If you have **diverticulitis** (inflammation of the bowel wall).
- If you have **non-specific ulcerative colitis** if there is a risk of impending perforation, abscess or other infection.
- If you have a **stomach ulcer** or other serious stomach or intestinal problems.
- If you have **osteoporosis** (brittle bones).
- If you have **kidney function disorders**.
- If you have **high blood pressure**.
- If you are psychotic (suffering from **mental disorders**).
- If you have **diabetes**.
- If you have **HIV (AIDS).**
- If you are **elderly.**

Risk of bradycardia (slower than normal heart rate), possibly unrelated to the speed of infusion, has been reported during and after administration of **MYLAN METHYLPREDNISOLONE**.

Other medicines with MYLAN METHYLPREDNISOLONE

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following medicines:

- **Ciclosporin** – used to treat conditions such as severe rheumatoid arthritis, severe psoriasis or after an organ or bone marrow transplant.
- **Rifampicin** (antibiotic for treatment of tuberculosis)**, carbamazepine** (for treatment of epilepsy)**, phenytoin** (for treatment of epilepsy) – this could cause reduced efficacy of **MYLAN METHYLPREDNISOLONE**.
- **Erythromycin** (an antibiotic) and **ketoconazole** (for treatment of fungal infections) inhibit metabolism – and may cause an increase in **MYLAN METHYLPREDNISOLONE** side effects.
- **Vaccines** – tell your doctor or nurse if you have recently had, or are about to have any vaccination. You should not have 'live' vaccines while receiving this medicine.
- **Aspirin** – used for the treatment of mild to moderate pain.
- **Pancuronium** – or other medicines called neuromuscular blocking agents which are used in some surgical procedures.
- **Other immunosuppressant medicines** – medicines capable of suppressing immune response as this may increase the risk of infection.
- **Diuretics** – sometimes called water tablets.
- **Digoxin** - used for treatment of heart failure and/or an irregular heart beat.
- **Antidiabetic medicines** – used for the treatment of diabetes.
- **Anticoagulants** – used to 'thin' the blood.
- **Anticholinesterase agents** – used to treat myasthenia gravis (a muscle condition).
- **Carbonic anhydrase inhibitors** such as acetazolamide) – used for treatment of glaucoma and epilepsy.

- **Amphotericin B** – used for treatment of fungal infections.
- **Antihypertensive medicines** – used to bring down blood pressure.

Pregnancy and breastfeeding and fertility

You should not receive **MYLAN METHYLPREDNISOLONE** during pregnancy and breastfeeding you baby.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taki**ng MYLAN METHYLPREDNISOLONE.**

Driving and using machinery

It is not always possible to predict to what extent **MYLAN METHYLPREDNISOLONE** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which **MYLAN METHYLPREDNISOLONE** affects them.

3. How to receive MYLAN METHYLPREDNISOLONE

Do not share medicines prescribed for you with any other person.

The usual dose is:

Your doctor will tell you how long your treatment with **MYLAN METHYLPREDNISOLONE** will last.

- The correct dose of **MYLAN METHYLPREDNISOLONE** will be decided by your doctor and depends on the type of infection, whether you are on any other antibiotics and your weight and age.
- If your condition does not improve your doctor will review your treatment.

- **MYLAN METHYLPREDNISOLONE** is usually administered as an intravenous infusion or intramuscular injection at your doctor's office, hospital or clinic.
- If the vials are cracked or damaged in any way, they must not be used.
- Keep the **MYLAN METHYLPREDNISOLONE** as well as syringes and needles, out of the reach of children. Do not reuse needles, syringes, or other materials, Dispose properly after use. Ask your doctor, pharmacist or health professional to explain local regulations for proper disposal.

If you have the impression that the effect of **MYLAN METHYLPREDNISOLONE** is too strong or too weak, tell your doctor or pharmacist.

If you receive more MYLAN METHYLPREDNISOLONE than you should:

Since a healthcare professional will administer **MYLAN METHYLPREDNISOLONE**, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to revceive a dose of MYLAN METHYLPREDNISOLONE

Do not take a double dose to make up for forgotten individual doses.

Since a healthcare professional will administer **MYLAN METHYLPREDNISOLONE**, it is unlikely that the dose will be missed.

4. Possible side effects

MYLAN METHYLPREDNISOLONE can have side effects.

Not all side effects reported for **MYLAN METHYLPREDNISOLONE** are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking **MYLAN METHYLPREDNISOLONE**, please consult your healthcare professional for advice.

If any of the following happens, stop taking MYLAN METHYLPREDNISOLONE and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Problems with the pumping of your heart (heart failure) symptoms of which are swollen ankles, difficulty in breathing and palpitations (awareness of heart beat) or irregular beating of the heart, irregular or very fast or slow pulse.
- High blood pressure, symptoms of which are headaches, or generally feeling unwell.
- Sudden welling of the face, lips, tongue or other parts of the body.
- Skin rashes and itching.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **MYLAN METHYLPREDNISOLONE**. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

The following side effects have been reported frequently:

- Feeling nervous or restless; having problems sleeping.
- Gastrointestinal irritation (feeling or being sick); increase in appetite; indigestion; weight gain.

The following side effects have been reported less frequently but serious:

Bradycardia (abnormally slow heart rate)

Other side effects reported are:

- **Diabetes** or worsening of existing diabetes.

- **Round or moon-shaped face** (Cushingoid facies); slowing of normal growth in infants, children and adolescents which may be permanent; irregular or no periods in women.
- **Cramps and spasms**, due to the loss of potassium from your body.
- **Difficulty in thinking** or being confused; feeling high or moods that go up and down; feeling depressed; feeling, seeing or hearing things which do not exist. Have strange and frightening thoughts, changing how you act or having feelings of being alone.
- **Seizures**.
- **Eyes**: Glaucoma (raised pressure within the eye, causing pain in the eyes and headaches); swollen optic nerve (indicated by sight disturbance); damage to the optic nerve or cataracts (indicated by failing eyesight); thinning of the clear part at the front of the eye (cornea) or of the white part of the eye (sclera); worsening of viral or fungal eye infections; protruding of the eyeballs; blurred or double vision.
- **Congestive heart failure** in susceptible individuals.
- **Acne**; poor wound healing; thinning of skin with stretch marks; thinning of hair; bruising; small purple/red patches on the skin; pale or darker patches on your skin, or raised patches which are an unusual colour.
- **Muscle weakness**; brittle bones (bones that break easily); broken bones and fractures; torn muscle tendons causing pain and/or swelling.
- **Burning**, numbness, pain or tingling at or near injection site. Local allergic reaction or infection at injection site (redness, swelling, pain or other signs of infection or allergic reaction); scarring at injection site.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/. By reporting side effects, you can help provide more information on the safety of **MYLAN METHYLPREDNISOLONE**.

5. How to store MYLAN METHYLPREDNISOLONE

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Store in the original package / container.
- Do not store in a bathroom
- Do not use after the expiry date stated on the label / carton / bottle
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

Before reconstitution, keep the vials in the carton to protect the contents against light until required for use.

The **reconstituted solution** can be stored for up to 24 hours if stored in a refrigerator at 2 – 8 °C or must be used immediately if not used stored in a refrigerator. Discard any remaining solution.

6. Contents of the pack and other information

What MYLAN METHYLPREDNISOLONE contains:

MYLAN METHYLPREDNISOLONE 40:

- Each vial of the active substance contains methylprednisolone hydrogen succinate equivalent to 40 mg methylprednisolone.

- The other ingredients are: Sodium dihydrogen phosphate dihydrate, disodium hydrogen phosphate dodecahydrate, sodium hydroxide.

  Contains: Lactose monohydrate 26,32 mg/vial.

MYLAN METHYLPREDNISOLONE 120:

- Each vial of the active substance contains methylprednisolone hydrogen succinate equivalent to 120 mg methylprednisolone.
- The other ingredients are: Sodium dihydrogen phosphate dihydrate, disodium hydrogen phosphate dodecahydrate, sodium hydroxide.

  Contains: Lactose monohydrate26,32 mg/vial.

MYLAN METHYLPREDNISOLONE 500:

- Each vial of the active substance contains methylprednisolone hydrogen succinate equivalent to 500 mg methylprednisolone.
- The other ingredients are: Sodium dihydrogen phosphate dihydrate, disodium hydrogen phosphate dodecahydrate, sodium hydroxide.

  Sugar free.

MYLAN METHYLPREDNISOLONE 1000:

- Each vial of the active substance contains methylprednisolone hydrogen succinate equivalent to 1000 mg methylprednisolone.
- The other ingredients are: Sodium dihydrogen phosphate dihydrate, disodium hydrogen phosphate dodecahydrate, sodium hydroxide.

  Sugar free.

What MYLAN METHYLPREDNISOLONE looks like and contents of the pack

What MYLAN METHYLPREDNISOLONE looks like:

MYLAN METHYLPREDNISOLONE 40: 1 x Type I clear, colourless glass vials of 3,0 ml or 3,5 ml, sealed by a red chlorobutyl rubber stopper and a violet, aluminium, flip off cap in an outer carton.

MYLAN METHYLPREDNISOLONE 120: 1 x Type I clear, colourless glass vials of 3,0 or 3,5 ml, sealed by a red chlorobutyl rubber stopper and an orange, aluminium, flip off cap in an outer carton.

MYLAN METHYLPREDNISOLONE 500: 1 x Type I clear, colourless glass vials, sealed by a red halobutyl rubber stopper and a green, aluminium, flip off cap in an outer carton.

MYLAN METHYLPREDNISOLONE 1000: 1 x Type I clear, colourless glass vials, sealed by a red chlorobutyl rubber stopper and a black, aluminium, flip off cap in an outer carton.

Contents of the pack:

Before reconstitution: White lyophilized (freeze-dried) powder, free from visible particles.

After reconstitution: Clear, colourless or slightly yellowish solution, free from visible particles.

Holder of Certificate of Registration and Manufacturer

Xixia Pharmaceuticals (Pty) Ltd

4 Brewery Street

Isando

Gauteng

Republic of South Africa

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Access to the corresponding Professional Information

Can be obtained on the SAHPRA website