Package leaflet: Information for the patient

Solu-Medrone® powder and solvent for solution for injection or concentrate for solution for infusion 40 mg/vial, 125 mg/vial, 500 mg/vial, 1000 mg/vial
methylprednisolone (as sodium succinate)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- **Solu-Medrone is a steroid medicine**, prescribed for many different conditions, including serious illnesses.
- **You need to take it regularly** to get the maximum benefit.
- **Don't stop taking this medicine** without talking to your doctor – you may need to reduce the dose gradually.
- **Solu-Medrone can cause side effects in some people** (read section 4. Possible side effects). Some problems such as mood changes (feeling depressed, or "high"), or stomach problems can happen straight away. If you feel unwell in any way, keep taking Solu-Medrone, but **see your doctor straight away.**
- **Some side effects only happen after weeks or months**. These include weakness of arms and legs, or developing a round face (read section 4. Possible side effects for more information).
- **If you take it for more than 3 weeks, you will get a blue "steroid card":** always keep it with you and show it to any doctor or nurse treating you.
- **Keep away from people who have chicken-pox or shingles,** if you have never had them. They could affect you severely. If you do come into contact with chicken-pox or shingles, **see your doctor straight away.**

Now read the rest of this leaflet. It includes other important information on the safe and effective use of this medicine that might be especially important for you.

- Keep this leaflet. You may need to read it again
- If you have any further questions please ask your doctor, pharmacist or nurse.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Solu-Medrone is and what it is used for

Solu-Medrone contains methylprednisolone sodium succinate.
Methylprednisolone belongs to a group of medicines called steroids. Their full name is corticosteroids. These corticosteroids occur naturally in the body and help maintain health and well-being.

Boosting your body with extra corticosteroid such as Solu-Medrone is an effective way to treat various illnesses involving inflammation of the body. Solu-Medrone

reduces this inflammation, which could otherwise go on making your condition worse. You must take this medicine regularly to get maximum benefit from it.
These include inflammatory or allergic conditions affecting the:

- **brain** caused by a tumour or meningitis
- **bowel** and **gut** e.g. 'Crohn's disease' and 'ulcerative colitis'
- **heart** inflammation (carditis) due to rheumatic fever
- **immune system,** e.g. to stop your body from rejecting tissue after transplantation
- **lungs** caused by asthma, severe allergy or hypersensitivity, tuberculosis or breathing in (aspirating) vomit or stomach contents
- **nervous system** due to multiple sclerosis or injury to the spinal cord
- **skin and/or joints** due to Stevens-Johnson Syndrome or lupus (also known as SLE or systemic lupus erythematosus).

Solu-Medrone may be prescribed to treat conditions other than those listed above, such as adrenal insufficiency or to stop you from feeling or being sick after cancer treatment.
Talk to your doctor if you are unsure why you have been given this medicine, if you do not feel better or if you feel worse.

2. What you need to know before you are given Solu-Medrone

Do not use Solu-Medrone if:

- You think you have ever suffered an **allergic reaction**, or any other type of reaction after being given Solu-Medrone, or any other medicine containing a corticosteroid or any of the other ingredients of this medicine (listed in section 6). An allergic reaction may cause a skin rash or reddening, swollen face or lips or shortness of breath.
- You have any **infection,** including **fungal infections** (such as thrush), which is not being treated.
- You have recently had, or are about to have any vaccination.

See your doctor immediately if any of the above applies to you.

This medicine should not be injected:

- into the spinal cord (intrathecal) or by the epidural route.

Warnings and precautions
Talk to your doctor or pharmacist before taking this medicine if you have any of the following conditions.

Your doctor may have to monitor your treatment more closely, alter your dose or give you another medicine.

- **Adrenal insufficiency** if you are being treated for this condition your doctor may also prescribe salt supplements for you to take while you are taking this medicine.
- **Chickenpox, 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.
- **Severe depression or manic depression** (bipolar disorder). This includes having depression before or while taking steroid medicines like Solu-Medrone, or **if any of your close family** has had these illnesses.
- **Cushing's disease** (a hormone disorder caused by high levels of cortisol in the blood).
- **Diabetes** (or if there is a family history of diabetes).
- **Epilepsy, fits or seizures**.

- **Glaucoma** (increased pressure in the eye) or if there is a family history of glaucoma. Your doctor may wish to monitor the condition of your eyesight, particularly in children.
- Contact your doctor if you experience **blurred vision or other visual disturbances.**
- You have recently suffered a **heart attack**.
- You are suffering from a **traumatic brain injury.**
- **Heart problems**, including heart failure or infections.
- **Hypertension** (high blood pressure) or dyslipidaemia (abnormal lipid levels in the blood).
- **Hypothyroidism** (an under-active thyroid).
- **Joint infection.**
- **Pancreatitis** (Inflammation of the pancreas which causes severe pain in the abdomen and back).
- **Peritonitis** (Inflammation of the thin lining (peritoneum) around the gut and stomach).
- **Kaposi's sarcoma** (a type of skin cancer).
- **Kidney** or **liver** disease.
- **Scleroderma** (also known as systemic sclerosis, an autoimmune disorder), because the risk of a serious complication called scleroderma renal crisis may be increased.
- **Muscle problems** (pain or weakness) have happened while taking steroid medicines in the past.
- **Myasthenia gravis** (a condition causing tired and weak muscles).
- **Osteoporosis** (brittle bones – bones that break easily).
- **Pheochromocytoma** (a rare tumour of adrenal gland tissue. The adrenal glands are located above the kidneys).
- **Skin abscess**.
- **Stomach ulcer, diverticulitis** (inflammation of the bowel wall) or other serious stomach or intestinal problems.
- **Thrombophlebitis** - vein problems due to thrombosis (clots in the veins) resulting in phlebitis (red, swollen and tender veins).
- **Tuberculosis** (TB) or if you have suffered tuberculosis in the past.
- Unusual **stress.**
- **Acute pancreatitis** (inflammation of the pancreas).
- **Hyperthyroidism** (an over-active thyroid gland).

Tumour lysis syndrome can occur when corticosteroids are used during cancer treatment. Tell your doctor if you have cancer and have symptoms of tumour lysis syndrome such as muscle cramping, muscle weakness, confusion, irregular heartbeat, visual loss or visual disturbances and shortness of breath.

Hypertrophic cardiomyopathy (thickening of the heart muscle) may develop if Solu-Medrone is given to a prematurely born baby, monitoring of heart function and structure may be needed.

Solu-Medrone treatment may increase your susceptibility to different infections, may mask some signs of infections, make current infections worse, or cause old, hidden infections to return or get worse. New infections may also appear during Solu-Medrone use. Different infections may therefore occur more easily during the treatment. These infections may be mild or can be severe and at times lead to death. Your doctor will monitor you closely, for the development of infection and consider stopping treatment or reducing the dose as needed.

Contact your doctor promptly if you experience muscle weakness, muscle aches, cramps and stiffness while using methylprednisolone. These can be symptoms of a condition called Thyrotoxic Periodic Paralysis which may occur in patients with an over-active thyroid gland (hyperthyroidism) who are treated with methylprednisolone. You may need additional treatment to alleviate this condition.

Oral anticoagulants (medicines taken by mouth to prevent blood clotting) if used together with Solu-Medrone can increase your risk of bleeding. In some instances, the effect of the oral anticoagulants may also be reduced. Your doctor may need to frequently monitor your bleeding risk by running additional blood test, while you are treated with Solu-Medrone. They may also adjust your Solu-Medrone dose if needed.

Other medicines and Solu-Medrone
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines (including any you have obtained without a prescription) as taking Solu-Medrone with other medicines could be harmful, or affect the way Solu-Medrone or the other medicine works:

- **Acetazolamide** - used to treat glaucoma and epilepsy.
- **Aminoglutethimide** – used for treating cancer.
- **Oral anticoagulants** – medicines taken by mouth to prevent blood clotting
- **Anticholinergics** such as **Pancuronium** or **vercuronium** – or other medicines called neuromuscular blocking agents which are used in some surgical procedures.
- **Anticholinesterases** – used to treat myasthenia gravis (a muscle condition) such as **neostigmine**.
- **Antibiotics** such as erythromycin, clarithromycin or troleandomycin.
- **Antidiabetics** – medicines used to treat high blood sugar.
- **Aprepitant** and **Fosaprepitant** – used to prevent nausea and vomiting.
- **Aspirin** and non-steroidal anti-inflammatory medicines (also called **NSAIDs**) such as ibuprofen used to treat mild to moderate pain.
- **Carbamazepine and phenytoin** – used to treat epilepsy.
- **Ciclosporin** - used to treat conditions such as severe rheumatoid arthritis, severe psoriasis or following an organ or bone marrow transplant.
- **Digoxin** - used for heart failure and/or an irregular heartbeat.
- **Diltiazem** – used for heart problems or high blood pressure.
- **Ethinylestradiol and norethisterone** – an oral contraceptive.
- **Some medicines for HIV** - such as ritonavir, cobicistat, may increase the effects of Solu-Medrone and your doctor may wish to monitor you carefully if you are taking these medicines.
- **Isoniazid** - used to treat bacterial infections.
- **Ketoconazole** or **itraconazole** – used to treat fungal infections.
- Potassium depleting agents – such as **diuretics** (sometimes called water tablets), **amphotericin B, xanthenes or beta$_2$ agonists** (e.g. medicines used to treat asthma).
- **Rifampicin** – antibiotics used to treat tuberculosis (TB).
- **Tacrolimus and cyclophosphamide** – used following an organ transplant to prevent rejection of the organ.
- **Vaccines** - tell your doctor or nurse if you have recently had, or are about to have any vaccination. You **must not** receive any 'live' vaccines while using this medicine. Other vaccines may be less effective.
- **Grapefruit juice.**

If you are taking long term medication(s)
If you are being treated for diabetes, high blood pressure or water retention (oedema) tell your doctor as he/she may need to adjust the dose of the medicines used to treat these conditions.

Before you have any operation tell your doctor, dentist or anaesthetist that you are taking Solu-Medrone.

If you require a test to be carried out by your doctor or in hospital it is important that you tell the doctor or nurse that you are taking Solu-Medrone. This medicine can affect the results of some tests.

Solu-Medrone with drink
Do not drink grapefruit juice while taking this medicine.

Pregnancy and breast-feeding
If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine as it could slow the baby's growth. There is a risk associated with low birth weight of the baby.

Cataracts have been observed in infants born to mothers treated with long-term corticosteroids during pregnancy.

If you are breast-feeding, ask your doctor or pharmacist for advice, as small amounts of corticosteroid medicines may get into breast milk.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
Undesirable effects, such as dizziness, vertigo, visual disturbances and fatigue are possible after treatment with corticosteroids. If you are affected do not drive or operate machinery.

Solu-Medrone contains sodium
Solu Medrone 40 mg contains less than 1 mmol sodium (23 mg) in each vial, that is to say essentially 'sodium-free'.

Solu Medrone 125 mg contains less than 1 mmol sodium (23 mg) in each vial, that is to say essentially 'sodium-free'.

Solu-Medrone 500 mg contains 58.3 mg of sodium (main component of cooking/table salt) in each vial. This is equivalent to 2.92% of the recommended maximum daily dietary intake of sodium for an adult.

Solu-Medrone 1 g contains 116.8 mg of sodium (main component of cooking/table salt) in each vial. This is equivalent to 5.84% of the recommended maximum daily dietary intake of sodium for an adult.

3. How Solu-Medrone is given to you

Steroid Cards
Remember to always carry a Steroid Treatment Card. Make sure your doctor or pharmacist has filled out the details of your medicine, including the dose and how long you will require steroid treatment.

You should show your steroid card to **anyone** who gives you treatment (such as a doctor, nurse or dentist) while you are taking this medicine, and for 3 months after your last injection.

If you are admitted to hospital for any reason always tell your doctor or nurse that you are taking Solu-Medrone. You can also wear a medic-alert bracelet or pendant to let medical staff know that you are taking a steroid if you have an accident or become unconscious.

Dosage information
Your doctor will decide on the site of injection, how much of the medicine and how many injections you will receive depending on the condition being treated and its severity. Your doctor will inject you with the lowest dose for the shortest possible time to get effective relief of your symptoms.

Your doctor will decide when you should be switched to oral therapy.

Adults
Solu-Medrone will be given as an injection by your doctor or nurse, either into a vein (intravenous) or into a muscle (intramuscular). Usually the first dose is given into a vein, especially in an emergency.

It will be given slowly over at least 5 minutes. For larger doses this may take 30 minutes or more. Large doses should normally be used for only two to three days.

The medicine is first dissolved in Sterile Water for Injections. If the medicine is to be given by infusion (using a pump or drip) it is then mixed with another suitable fluid. No other medicines should be mixed with it.

Elderly
Treatment will normally be the same as for younger adults. However your doctor may want to see you more regularly to check how you are getting on with this medicine.

Children and adolescents
Corticosteroids can affect growth in children so your doctor will prescribe the lowest dose that will be effective for your child.

Do not drink grapefruit juice while being treated with Solu-Medrone.

If you are given more Solu-Medrone than you should
If you think you have been given too many injections of Solu-Medrone please speak to your doctor immediately.

Stopping/reducing the dose of your Solu-Medrone
Your doctor will decide when it is time to stop your treatment.
You will need to come off this treatment slowly if you:

- have had repeated doses of corticosteroids for more than 3 weeks
- have been given high doses of Solu-Medrone, over 32 mg daily, even if it was only for 3 weeks or less
- have already had a course of corticosteroid tablets or injections in the last year
- already had problems with your adrenal glands (adrenocortical insufficiency) before you started this treatment.

You will need to come off this medicine slowly to avoid **withdrawal symptoms**. These symptoms may include itchy skin, fever, muscle and joint pains, runny nose, sticky eyes, sweating and weight loss.

If your symptoms seem to return or get worse as your dose of this medicine is reduced tell your doctor immediately.

Mental problems while taking Solu-Medrone
Mental health problems can happen while taking steroids like Solu-Medrone (see also section 4, Possible side effects).

- These illnesses can be serious.
- Usually they start within a few days or weeks of starting the medicine.

- They are more likely to happen at high doses.
- Most of these problems go away if the dose is lowered or the medicine is stopped. However, if problems do happen they might need treatment.

Talk to a doctor if you (or someone **taking** this medicine) show any signs of mental problems. This is particularly important if you are depressed, or might be **thinking** about suicide. In a few cases mental problems have happened when doses are being lowered or stopped.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines this medicine can cause side effects, although not everybody gets them. Your doctor will have given you this medicine for a condition which if not treated properly could become serious.

In certain medical conditions medicines like Solu-Medrone (steroids) should not be stopped abruptly. If you suffer from any of the following symptoms seek immediate medical attention. Your doctor will then decide whether you should continue taking your medicine.

- **Allergic reactions** such as skin rash, swelling of the face or wheezing and difficulty breathing. This type of side effect is rare, but can be serious.
- **Pancreatitis** stomach pain spreading to your back, possibly accompanied by vomiting, shock and loss of consciousness.
- **Peritonitis** inflammation of the lining of the stomach.
- **Burst or bleeding ulcers** symptoms of which are stomach pain (especially if it seems to spread to your back), bleeding from the back passage, black or bloodstained stools and/or vomiting blood.
- **Infections** This medicine can hide or change the signs and symptoms of some infections, or reduce your resistance to the infection, so that they are hard to diagnose at an early stage. Symptoms might include a raised temperature and feeling unwell. Symptoms of a flare up of a previous TB infection could be coughing blood or pain in the chest. Solu-Medrone may also make you more likely to develop a severe infection.
- **Pulmonary embolus** (blood clots in the lung), symptoms include sudden sharp chest pain, breathlessness and coughing up blood.
- **Raised pressure within the skull** of children (pseudotumour cerebri) symptoms of which are headaches with vomiting, lack of energy and drowsiness. This side-effect usually occurs after treatment is stopped.
- **Thrombophlebitis** (blood clots or thrombosis in a leg vein), symptoms of which include painful swollen, red and tender veins.
- **Pheochromocytoma crisis** - a serious condition which can occur in patients with an adrenal gland tumour. Symptoms include very high blood pressure, heart attack, fast or irregular heartbeat, headache, abdominal pain or chest pain.

If you experience any of the following side effects, or notice any other unusual effects not mentioned in this leaflet, tell your doctor straight away.

The side effects may occur with certain frequencies, which are defined as follows:
- *not known*: frequency cannot be estimated from the available data.

Blood, heart and circulation
not known
- High blood pressure, symptoms of which are headaches, or generally feeling unwell.

- Problems with the pumping of your heart (heart failure) symptoms of which are swollen ankles, difficulty in breathing and palpitations (awareness of heartbeat) or irregular beating of the heart, irregular or very fast or slow pulse.
- Low blood pressure.
- Increase of white blood cells (leukocytosis).
- Dyslipidaemia – abnormal level of lipid in the blood.
- Increased clotting of the blood.
- Warmth and reddening of the skin (Flushing).

Body water and salts
not known
- Swelling and high blood pressure, caused by increased levels of water and salt content.
- Cramps and spasms, due to the loss of potassium from your body. In rare cases this can lead to congestive heart failure (when the heart cannot pump properly).

Digestive system
not known
- Ulcers.
- Nausea (feeling sick) or vomiting (being sick).
- Diarrhoea.
- Thrush or inflammation (oesophagitis) in the gullet causing discomfort on swallowing.
- Indigestion.
- Bloated stomach.
- Abdominal pain, with or without fever.
- Hiccups.

Ears
not known
- A feeling of dizziness or spinning (vertigo).

Eyes
not known
- Damage to the optic nerve or cataracts (indicated by failing eyesight). Children may be more prone to develop cataracts compared to adults, with prolonged use of the medicine.
- Glaucoma (raised pressure within the eye, causing pain in the eyes and headaches).
- Swollen optic nerve (causing a condition called papilloedema, and which may cause sight disturbance).
- 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 (exophthalmos).
- Disease of the retina and choroid membrane.
- Blurred vision.

General disorders
not known
- Feeling tired or unwell.
- Accumulation of fluid in tissues causing swelling.
- Skin reactions at the site of injection.

Hormones and metabolic system
not known
- Slowing of normal growth in infants, children and adolescents which may be permanent.

- Round or moon-shaped face (Cushingoid facies).
- Hypopituitarism (a condition in which the pituitary gland does not produce normal amounts of some or all of its hormones).
- Irregular or no periods in women.
- Increased hair on the body and face in women (hirsutism).
- Increased appetite and weight gain.
- Diabetes or worsening of existing diabetes.
- Prolonged therapy can lead to lower levels of some hormones which in turn can cause low blood pressure and dizziness. This effect may persist for months.
- Production of excessive acid in the body.
- The amount of certain chemicals (enzymes) called alanine transaminase, aspartate transaminase and alkaline phosphatase that help the body digest drugs and other substances in your body may be raised after treatment with a corticosteroid. The change is usually small and the enzyme levels return to normal after your medicine has cleared naturally from your system. You will not notice any symptoms if this happen, but it will show up if you have a blood test.
- Accumulation of fat tissue on localized parts of the body.

Immune system
not known
- Increased susceptibility to infections.
- Suppression of reactions to skin tests, such as that for tuberculosis.

Muscles and bones
not known
- Brittle bones (bones that break easily).
- Muscle weakness.
- Muscle pain or wasting.
- Joint pain or loss of sensation in joint.
- Broken bones or fractures.
- Breakdown of bone due to poor circulation of blood, this causes pain in the hip.
- Torn muscle tendons causing pain and/or swelling.
- Muscle cramps or spasms.

Nerves and mood issues
Steroids, including Solu-Medrone, can cause serious mental health problems.
These are common in both adults and children. They can affect about 5 in every 100 people taking medicines like Solu-Medrone.
- Feeling depressed.
- Feeling high (mania) or moods that go up and down.
- Feeling anxious, having problems sleeping, difficulty in thinking or being confused and losing your memory.
- Feeling, seeing or hearing things which do not exist. Having strange and frightening thoughts, changing how you act or having feelings of being alone.

If you notice any of these problems **talk to a doctor straight away.**

not known
- Other nervous system side effects may include convulsions (seizures), dizziness and headaches.

Skin
not known
- Bruising.

- Acne.
- Thinning of the skin.
- Poor wound healing.
- Stretch marks.
- Small purple/red patches on the skin.
- Pale or darker patches on your skin, or raised patches which are an unusual colour.
- Excessive growth of bodily and facial hair.
- Rash, itching, hives.
- Increased sweating.
- Inflammation of the fatty tissue under the skin which can make the skin feel hard and possibly develop painful red lumps or patches (panniculitis). Panniculitis has been reported following dose reduction or discontinuation of long term, high dose treatment and most cases resolve spontaneously.

Hepatobiliary disorder
not known
- Inflammation of the liver.
- Methylprednisolone can damage your liver; hepatitis and increase of liver enzymes have been reported.

If you experience any of the side effects listed above tell your doctor straight away.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance. Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Solu-Medrone

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

125 mg
Do not store above 25°C. Do not freeze.

40 mg, 500 mg and 1000 mg
This medicinal product does not require any special storage conditions.

After reconstitution with solvent:
Chemical and physical in-use stability of the reconstituted solution has been demonstrated for 48 hours at 2-8°C. It should be used immediately if stored below 25°C.

After reconstitution with solvent and further dilution with other solutions for infusion:
Chemical and physical in-use stability of the reconstituted and further diluted solution has been demonstrated for 24 hours at 2-8°C. It should be used within 3 hours if stored at 20-25°C.

From a microbiological point of view, unless the method of opening/ reconstitution/ dilution precludes the risk of microbial contamination, the product should be used immediately.
If not used immediately, in-use storage times and conditions are the responsibility of the user.

Refer to 'The following information is intended for healthcare professionals only:' for more storage information of reconstituted and diluted solutions.

Your doctor will check that the solution contains no particles and is not discoloured before using it.

6. Contents of the pack and other information

What Solu-Medrone contains
This medicine contains the following amounts of methylprednisolone sodium succinate as the active ingredient:

40 mg Act-o-Vial: 53 mg methylprednisolone sodium succinate (equivalent to 40 mg methylprednisolone)
125 mg Act-o-Vial: 165.8 mg methylprednisolone sodium succinate (equivalent to 125 mg methylprednisolone)
500 mg vial: 663 mg methylprednisolone sodium succinate (equivalent to 500 mg methylprednisolone)
1000 mg vial: 1.328 g methylprednisolone sodium succinate (equivalent to 1 g methylprednisolone).

The 40 mg Act-o-Vial also contains the inactive ingredients sucrose, monobasic sodium phosphate monohydrate and dibasic sodium phosphate anhydrous (see section 2 "Solu-Medrone contains sodium"). The separate solvent compartment also contains Sterile Water for Injections.

The 125 mg Act-o-Vial also contains the inactive ingredients sodium hydroxide, sodium biphosphate and sodium phosphate (see section 2 "Solu-Medrone contains sodium"). The separate solvent compartment also contains Sterile Water for Injections.

The 500 mg and 1000 mg vials also contain the inactive ingredients sodium hydroxide, sodium biphosphate and sodium phosphate (see section 2 "Solu-Medrone contains sodium"). Each pack also contains a vial containing Sterile Water for Injections.

What Solu-Medrone looks like and contents of the pack
Solu-Medrone 40 mg and Solu-Medrone 125 mg is an off-white powder which comes in an Act-o-Vial two compartment vial. A separate compartment of the Act-o-Vial contains a clear solution. The two compartments are separated by a rubber seal.

Solu-Medrone 40 mg is available in packs containing a 1 ml Act-o-Vial.
Solu-Medrone 125 mg is available in packs containing a 2 ml Act-o-Vial.

Solu-Medrone 500 mg and Solu-Medrone 1000 mg is an off-white powder which comes in a clear glass vial fitted with a rubber stopper. Each pack also contains a vial of Sterile Water for Injections.

Solu-Medrone 500 mg and Solu-Medrone 1000 mg are available in packs containing 1 vial of powder and 1 vial of Sterile Water for Injections.

Marketing Authorisation Holder
Pfizer Healthcare Ireland Unlimited Company
The Watermarque Building
Ringsend Road,
Dublin 4,
D04 K7N3,
Ireland

Manufacturer
Pfizer Manufacturing Belgium NV

Rijksweg 12
2870
Puurs-Sint-Amands
Belgium.

Company contact address
For further information on your medicine contact Medical Information at the following address:

Pfizer Healthcare Ireland Unlimited Company, The Watermarque Building, Ringsend Road, Dublin 4, D04 K7N3, Ireland.
Telephone 1800 633 363

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Solu-Medrone®
powder and solvent for solution for injection or concentrate for solution for infusion
40 mg/vial, 125 mg/vial, 500 mg/vial and 1000 mg/vial
methylprednisolone (as sodium succinate)

PFIZER

The following information is intended for healthcare professionals only:

For further information, consult the SmPC (Summary of Product Characteristics).

Pharmaceutical form
Powder and solvent for solution for injection or concentrate for solution for infusion.

Posology and method of administration
Solu-Medrone may be administered intravenously (injection or infusion) or intramuscularly, the preferred method for emergency use being intravenous injection given over a suitable time interval. When administering Solu-Medrone intravenously in high doses, it should be given over a period of at least 30 minutes.

Doses up to 250 mg should be given intravenously over a period of at least five minutes.

Dosage requirements are variable and must be individualized on the basis of the disease under treatment, its severity and the response of the patient over the entire duration of treatment. A risk/benefit decision must be made in each individual case on an ongoing basis.

The lowest possible dose of corticosteroid should be used to control the condition under treatment for the minimum period. The proper maintenance dosage should be determined by decreasing the initial drug dosage in small decrements at appropriate time intervals until the lowest dosage, which will maintain an adequate clinical response, is reached.

If after long-term therapy the drug is to be stopped, it needs to be withdrawn gradually rather than abruptly (see section 4.4 of the SmPC).

Following the initial emergency period, consideration should be given to employing a longer acting injectable preparation or an oral preparation.

As adjunctive therapy in life-threatening conditions, administer 30 mg/kg IV over a period of at least 30 minutes. The dose may be repeated every 4 to 6 hours for up to 48 hours.

Methylprednisolone IV pulses, consisting of administration of 250 mg/day or above for a few days (usually ≤ 5 days) may be suitable during exacerbation episodes or conditions unresponsive to standard therapy, such as: systemic lupus erythematosus. In multiple sclerosis unresponsive to standard therapy (or during exacerbation episodes), administer pulses of 500 or 1000 mg/day for 3 or 5 days over 30 minutes.

As adjunctive therapy in other conditions, the initial dose will vary from 10 to 500 mg IV, depending on the clinical condition. Larger doses may be required for short-term management of severe, acute conditions. Initial doses up to 250 mg should be administered IV over a period of at least 5 minutes, while larger doses should be administered over at least 30 minutes. Subsequent doses may be administered IV or IM at intervals dictated by the patient's response and clinical condition.

For intravenous infusion the initially reconstituted solution may be diluted with 5% dextrose in water, isotonic saline solution, or 5% dextrose in isotonic saline solution. To avoid compatibility and stability problems with other drugs Solu-Medrone should be administered separately from other drugs whenever possible either as an IV push through and IV medication chamber, as an IV “piggy-back” solution, or via an infusion pump only in the diluents mentioned above.

Solu-Medrone 40 mg and 125 mg are each supplied in an Act-o-Vial two compartment vial consisting of adjoining compartments of lyophilised powder and solvent (Sterile Water for Injections).
The following instructions for the use of the Act-o-Vial should be observed:-

1. Press down on plastic activator to force solvent into the lower compartment.
2. Gently agitate to effect dissolution. Use solution immediately.
3. Remove plastic tab covering centre of stopper.
4. Sterilise top of stopper with a suitable germicide.
5. Insert needle squarely through centre of plunger-stopper until tip is just visible. Invert vial and withdraw dose.

Solu-Medrone 500 mg and 1000 mg are supplied in vials with solvent (Sterile Water for Injections).

Parenteral drug products should, wherever possible, be visually inspected for particulate matter and discoloration prior to administration.

Undesirable effects may be minimised by using the lowest effective dose for the minimum period (see section 4.4 of the SmPC).

Adult
Dosage should be varied according to the severity of the condition, initial dosage will vary from 10 to 500 mg. In the treatment of graft rejection reactions following transplantation, a dose of up to 1000 mg/day may be required. Although doses and protocols have varied in studies using Solu-Medrone in the treatment of graft rejection reactions, the published literature supports the use of doses of this level, with 500 mg to 1000 mg most commonly used for acute rejection. Treatment at these doses should be limited to a 48- 72 hour period until the patient’s condition has stabilised, as prolonged high dose corticosteroid therapy can cause serious corticosteroid induced side-effects (see sections 4.8 and 4.4 of the SmPC).

Children and adolescents
In the treatment of high dose indications, such as haematological, rheumatic, renal and dermatological conditions, a dosage of 30 mg/kg/day to a maximum of 1000 mg/day is recommended. This dosage may be repeated for three pulses either daily or on alternate days. In the treatment of graft rejection reactions following transplantation, a dosage of 10 to 20 mg/kg/day for up to 3 days, to a maximum of 1000 mg/day, is recommended. In the treatment of status asthmaticus, a dosage of 1 to 4

mg/kg/day for 1-3 days is recommended. The dosages may be reduced for infants and children but should be selected based on the severity of the condition and the response of the patient rather than on the average age or weight of the patient. The paediatric dosage should not be less than 0.5 mg/kg every 24 hours.

Elderly patients
Solu-Medrone is primarily used in acute short-term conditions. There is no information to suggest that a change in dosage is warranted in the elderly. However, treatment of elderly patients should be planned bearing in mind the more serious consequences of the common side-effects of corticosteroids in old age and close clinical supervision is required (see section 4.4 of the SmPC).

The following table contains suggested dosing schedules for Solu-Medrone for a range of indications:

Indication	Dosage
Rheumatic disorders unresponsive to standard therapy (or during exacerbation episodes)	Administer either regimen as IV pulse dosing over at least 30 minutes. The regimen may be repeated if improvement has not occurred within a week after therapy, or as the patient's condition dictates. 1 g/day for 1 to 4 days, or 1 g/month for six months.
Edematous states, such as glomerulonephritis or lupus nephritis, unresponsive to standard therapy (or during exacerbation episodes)	Administer either regimen as IV pulse dosing over at least 30 minutes. The regimen may be repeated if improvement has not occurred within 1 week after therapy, or as the patient's condition dictates. 30 mg/kg every other day for 4 days, or 1 g/day for 3, 5 or 7 days.
Terminal cancer (to improve quality of life)	Administer 125 mg /day IV for up to 8 weeks.
Pneumocystis jiroveci pneumonia in patients with AIDS	**Therapy should begin within 72 hours of initial anti-pneumocystis treatment.** One possible regimen is to administer 40 mg IV every 6 to 12 hours with gradual tapering over a maximum of 21 days or until the end of pneumocystis therapy. Due to the increased rate of reactivation of tuberculosis in AIDS patients, consideration should be given to the administration of antimycobacterial therapy if corticosteroids are used in this high risk group. The patient should also be observed for activation of other latent infections.
Exacerbation of chronic obstructive pulmonary disease (COPD)	Two dose regimens have been studied: 0.5 mg/kg IV every 6 hours for 72 hours, **or** 125 mg IV every 6 hours for 72 hours, switch to an oral corticosteroid and taper dose. Total treatment period should be at least 2 weeks.
Hepatobiliary	Drug-induced liver injury such as acute hepatitis can result from cyclical pulsed IV methylprednisolone (usually at doses of 1 gm/day). The time to onset of acute hepatitis can be several weeks or longer.

Shelf life
Solu-Medrone 40 mg and 125 mg Act-o-Vials and Solu-Medrone 500 mg and 1000 mg: after reconstitution with solvent (Sterile Water for Injections) use immediately, discard any remainder.

Storage of the product
125 mg
Do not store above 25ºC. Do not freeze.

40 mg, 500 mg and 1000 mg
This medicinal product does not require any special storage conditions.

After reconstitution with solvent:
Chemical and physical in-use stability of the reconstituted solution has been demonstrated for 48 hours at 2-8°C. It should be used immediately if stored below 25°C.

After reconstitution with solvent and further dilution with other solutions for infusion:
Chemical and physical in-use stability of the reconstituted and further diluted solution has been demonstrated for 24 hours at 2-8°C. It should be used within 3 hours if stored at 20-25°C.

From a microbiological point of view, unless the method of opening/ reconstitution/ dilution precludes the risk of microbial contamination, the product should be used immediately.
If not used immediately, in-use storage times and conditions are the responsibility of the user.

Refer to Posology and Method of Administration section. No diluents other than those referred to are recommended. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration.