Package leaflet: Information for the patient

PFIZER

Solu-Medrone® 40 mg, 125 mg, 500 mg, 1 gram for injection
methylprednisolone

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- 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**
2. **What you need to know before you are given Solu-Medrone**
3. **How Solu-Medrone is given to you**
4. **Possible side effects**
5. **How to store Solu-Medrone**
6. **Contents of the pack and other information**

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 corticosteroids (steroids). Corticosteroids are produced naturally in your body and are important for many body functions.

Boosting your body with extra corticosteroid such as Solu-Medrone can help following surgery (e.g. organ transplants), flare-ups of the symptoms of multiple sclerosis or other stressful conditions.

These include inflammatory or allergic conditions affecting the:

- **brain** caused by a tumour or tuberculosis meningitis
- **bowel** and **gut** e.g. 'Crohn's disease' and 'ulcerative colitis'
- **lungs** caused by asthma, severe allergy or hypersensitivity, tuberculosis or breathing in (aspirating) vomit or stomach contents
- **skin** e.g. Stevens-Johnson Syndrome.

Solu-Medrone may be prescribed to treat conditions other than those listed above.
Talk to your doctor if you are unsure why you have been given this medicine.

You must talk to a doctor 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 are allergic to Solu-Medrone or any medicine containing 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.
- If you have a widespread **fungal infection** (such as thrush) which is not being treated.
- If you have recently had, or are about to have any **vaccination**.
- If you are suffering from, or receiving treatment for, swelling of the brain, due to **malaria.**
- If you are suffering from a **traumatic brain injury** or **stroke**.

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

Warnings and precautions

Talk to your doctor or pharmacist before using Solu-Medrone 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.

- **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.
- **Worm infestation** (e.g. threadworm).
- Severe **depression** or **manic depression** (bipolar disorder). This includes having had depression before while taking steroid medicines like Solu-Medrone, or having a family history of these illnesses.
- **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.
- Contact your doctor if you experience **blurred vision or other visual disturbances.**
- You have recently suffered a **heart attack**.
- **Heart problems**, including heart failure or infections.
- **Hypertension** (high blood pressure).
- **Hypothyroidism** (an under-active thyroid).
- **Joint infection**.
- **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).
- **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**.
- **Cushing's disease** (condition caused by an excess of cortisol hormone in your body).
- **Acute pancreatitis** (inflammation of the pancreas).

Solu-Medrone should not be used in the treatment of septic shock.

This medicine is not recommended for injection via the spinal cord (intrathecal or epidural). Serious side effects have been reported with this use on occasions.

If methylprednisolone is given to a prematurely born baby, monitoring of heart function and structure may be needed.

Tumour lysis syndrome can occur after treatment of a fast-growing cancer, especially certain leukemias and lymphomas (cancers of the blood) or solid tumours. As the tumour cells die, they break apart and release their contents into the blood. This causes a change in certain chemicals in the blood, which may cause damage to organs, including the kidneys, heart and liver that may lead to muscle cramping, muscle weakness, confusion, irregular heartbeat, visual loss or visual disturbances, and shortness of breath. Your doctor will monitor you closely, especially if you are at high risk of developing tumour lysis syndrome.

Other medicines and Solu-Medrone

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
This could be harmful or affect the way Solu-Medrone or the other medicine works:

- **Acetazolamide** - used to treat glaucoma and epilepsy
- **Aminoglutethimide** or **Cyclophosphamide** – used for treating cancer
- **Anticoagulants** - used to 'thin' the blood such as acenocoumarol, phenindione and warfarin
- **Anticholinesterases** - used to treat myasthenia gravis (a muscle condition) such as distigmine and neostigmine
- **Antibiotics** (such as erythromycin, clarithromycin or troleandomycin)
- **Antidiabetics** – medicines used to treat high blood sugar
- **Antihypertensives** – medicines used to lower blood pressure
- **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
- **Barbiturates, carbamazepine, phenytoin** and **primidone** – used to treat epilepsy
- **Carbenoxolone** and **cimetidine** - used for heartburn and acid indigestion
- **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** or **mibefradil** – used for heart problems or high blood pressure
- **Ethinylestradiol and norethisterone** – an oral contraceptive
- **Antivirals** (such as ritonavir, indinavir) and **pharmacokinetic enhancers** (such as cobicistat) used to treat HIV infections
- **Isoniazid** - used to treat bacterial infections
- **Ketoconazole** or **itraconazole** – used to treat fungal infections
- **Mifepristone** – used for the medical termination of a pregnancy
- **Pancuronium** or **vercuronium** – or other medicines called neuromuscular blocking agents which are used in some surgical procedures
- Potassium depleting agents – such as **diuretics** (sometimes called water tablets), **amphotericin B, xanthenes or beta2 agonists** (e.g. medicines used to treat asthma)
- **Rifampicin** and **rifabutin** – antibiotics used to treat tuberculosis (TB)
- **Tacrolimus** – 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 **should not** have 'live' vaccines while using this medicine. Other vaccines may be less effective.

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 food, drink and alcohol

Do not drink grapefruit juice while taking this medicine.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, 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 of low birth weight of a baby; this risk can be minimised by taking the lowest effective dose of the corticosteroids.

Cataracts have been observed in infants born to mothers undergoing long-term treatment with 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.

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 and 125 mg contain 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 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 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.

Use in children and adolescents

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

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 section 4).

- 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 the problems do happen they might need treatment.

Talk to a doctor if you (or someone using this medicine) shows 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 or pharmacist.

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.
- **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. Symptoms of a previous malaria infection could involve chills and fever. 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.

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:

- rare: may affect up to 1 in 1,000 people.
- 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 symptoms may include dizziness, fainting, lightheadedness, blurred vision, a rapid, or irregular heartbeat (palpitations), general weakness.
- Increased numbers of white blood cells (leukocytosis).

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 in the gullet (discomfort on swallowing).
- Indigestion.
- Bloated stomach.
- Abdominal pain.
- Hiccups.

Ears
not known

- A feeling of dizziness or spinning (vertigo).

Eyes
rare

- Blurred vision.

not known

- Cataracts (indicated by failing eyesight).
- Glaucoma (raised pressure within the eye, causing pain in the eyes and headaches).
- Swollen optic nerve (papilledema, indicated by 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).
- Blurred vision (chorioretinopathy).

General disorders
not known

- Poor wound healing.
- Feeling tired or unwell.
- 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).
- Irregular or no periods in women.
- 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.
- 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 happens, but it will show up if you have a blood test.

- Accumulation of fat tissue on localised parts of the body, manifesting as different presentations for example back pain or weakness (due to epidural lipomatosis).

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 wasting.
- 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
not known
Steroids including methylprednisolone can cause serious mental health problems.
- Feeling depressed, including thinking about suicide.
- 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.
- Fits.

Skin
not known
- Acne.
- Bruising.
- Thinning of skin (skin atrophy).
- Stretch marks (skin striae).
- 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.

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

Vascular disorders
not known
- Increased clotting of the blood.
- Warmth and reddening of the skin (Flushing).

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 the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. 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.

This medicinal product does not require any special storage conditions.

Once the medicine has been mixed with Sterile Water for Injections the solution should be used straight away. Any unused liquid should be disposed of safely. Refer to 'The following information is intended for healthcare professionals only:' for more storage information of reconstituted and diluted solutions of the 40 mg vial.

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 vial: 53 mg methylprednisolone sodium succinate (equivalent to 40 mg methylprednisolone)
125 mg 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)
1 g vial: 1.326 g methylprednisolone sodium succinate (equivalent to 1 g methylprednisolone)

Solu-Medrone also contains the inactive ingredients monobasic sodium phosphate monohydrate and dibasic sodium phosphate anhydrous (see section 2 “Solu-Medrone contains sodium”).

The 40 mg vial also contains sucrose.

What Solu-Medrone looks like and contents of the pack

Solu-Medrone is a powder which comes in a clear glass vial fitted with a rubber stopper. Each pack also contains a vial of Sterile Water for Injections.

Marketing Authorisation Holder

Pfizer Limited, Ramsgate Road, Sandwich, Kent CT13 9NJ, UK.

Manufacturer

Pharmacia NV/SA, Rijksweg 12, B-2870, Puurs, Belgium.

Company Contact Address

For further information on your medicine contact Medical Information at Pfizer Limited, Walton Oaks, Dorking Road Tadworth, Surrey, KT20 7NS.

Tel: 01304 616161.

This leaflet was last revised in 03/2024.

Ref: SM 35_0

The following information is intended for healthcare professionals only:

Solu-Medrone® 40 mg, 125 mg, 500 mg, 1 gram for injection
methylprednisolone

PFIZER

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

Posology and method of administration

Posology:
Solu-Medrone may be administered intravenously or intramuscularly, the preferred method for emergency use being intravenous injection given over a suitable time interval. When administering Solu-Medrone in high doses intravenously, 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 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 SPC).

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

For intravenous infusion the initially prepared solution may be diluted with 5% dextrose in water, isotonic saline solution, or 5% dextrose in isotonic saline solution. To avoid compatibility problems with other drugs, Solu-Medrone should be administered separately, only in the solutions mentioned.

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

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

Adults: 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 1 g/day may be required. Although doses and protocols have varied in studies using methylprednisolone sodium succinate in the treatment of graft rejection reactions, the published literature supports the use of doses of this level, with 500 mg to 1 g 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 4.4 and 4.8 of the SPC).

Children and adolescents: 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 1 g/day, is recommended. In the treatment of status asthmaticus, a dosage of 1 to 4 mg/kg/day for 1-3 days is recommended.

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 SPC).

This medicine is not recommended for intrathecal or epidural use.

Method of administration:
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: rheumatic disorders, systemic lupus erythematosus, edematous states, such as glomerulonephritis or lupus nephritis. 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.

In anaphylactic reactions adrenaline or noradrenaline should be administered first for an immediate haemodynamic effect, followed by intravenous injection of Solu-Medrone (methylprednisolone sodium succinate) with other accepted procedures. There is evidence that corticosteroids through their prolonged haemodynamic effect are of value in preventing recurrent attacks of acute anaphylactic reactions.

In sensitivity reactions Solu-Medrone is capable of providing relief within one half to two hours. In patients with status asthmaticus, Solu-Medrone may be given at a dose of 40 mg intravenously, repeated as dictated by patient response. In some asthmatic patients it may be advantageous to administer by slow intravenous drip over a period of hours.

In graft rejection reactions following transplantation doses of up to 1 g per day have been used to suppress rejection crises, with doses of 500 mg to 1 g most commonly used for acute rejection. Treatment should be continued only until the patient's condition has stabilised; usually not beyond 48-72 hours.

In cerebral oedema corticosteroids are used to reduce or prevent the cerebral oedema associated with brain tumours (primary or metastatic).

In patients with oedema due to tumour, tapering the dose of corticosteroid appears to be important in order to avoid a rebound increase in intracranial pressure. If brain swelling does occur as the dose is reduced (intracranial bleeding having been ruled out), restart larger and more frequent doses parenterally. Patients with certain malignancies may need to remain on oral corticosteroid therapy for months or even life. Similar or higher doses may be helpful to control oedema during radiation therapy.

The following are suggested dosage schedules for oedemas due to brain tumour.

Schedule A (1)	**Dose (mg)**	**Route**	**Interval in hours**	**Duration**
Pre-operative:	20	IM	3-6	
During Surgery:	20 to 40	IV	hourly	
Post-operative:	20	IM	3	24 hours
	16	IM	3	24 hours
	12	IM	3	24 hours
	8	IM	3	24 hours
	4	IM	3	24 hours

	4	IM	6	24 hours
	4	IM	12	24 hours

Schedule B (2)	**Dose (mg)**	**Route**	**Interval in hours**	**Days Duration**
Pre-operative:	40	IM	6	2-3
Post-operative:	40	IM	6	3-5
	20	Oral	6	1
	12	Oral	6	1
	8	Oral	8	1
	4	Oral	12	1
	4	Oral		1

Aim to discontinue therapy after a total of 10 days.

In the treatment of acute exacerbations of multiple sclerosis in adults, the recommended dose is 500 mg/day or 1 g daily for 3 days. Solu-Medrone should be given as an intravenous infusion over at least 30 minutes.

In hepatobiliary effects drug induced liver injury including acute hepatitis or liver enzyme increase can result from cyclical pulsed IV methylprednisolone (usually at initial dose ≥ 1 g/day). Rare cases of hepatotoxicity have been reported. The time to onset can be several weeks or longer. In the majority of case reports resolution of the adverse events has been observed after treatment was discontinued. Therefore, appropriate monitoring is required.

In other indications, initial dosage will vary from 10 to 500 mg depending on the clinical problem being treated. Larger doses may be required for short-term management of severe, acute conditions. The initial dose, up to 250 mg, should be given intravenously over a period of at least 5 minutes, doses exceeding 250 mg should be given intravenously over a period of at least 30 minutes. Subsequent doses may be given intravenously or intramuscularly at intervals dictated by the patient's response and clinical condition. Corticosteroid therapy is an adjunct to, and not replacement for, conventional therapy.

Shelf life

The shelf-life is printed on labels and cartons. Do not use Solu-Medrone after this date. After reconstitution with Sterile Water for Injections, use immediately, discard any remainder. Refer to 'Storage of the product' for more storage information of reconstituted and diluted solutions of the 40 mg vial.

Storage of the product

This medicinal product does not require any special storage conditions.

40 mg

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 above. No diluents other than those referred to are recommended. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration.

This leaflet was last revised in 03/2024.

Ref: SM 28_0