

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.

You **must** tell your doctor before you take this medicine if you have any of the conditions listed above.

Other medicines and Depo-Medrone

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

You should tell your doctor if you are taking any of the following medicines which can affect the way Depo-Medrone or the other medicine works:

- Acetazolamide** - used to treat glaucoma and epilepsy.
- Aminogluthimide** and **cyclophosphamide** - used for treating cancer.
- Antibacterials** (such as isoniazid, erythromycin, clarithromycin and troleandomycin).
- 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.
- Antidiabetics** – medicines used to treat high blood sugar.
- Antiemetics** (such as aprepitant and fosaprepitant).
- Antivirals** (such as ritonavir, indinavir) and **pharmacokinetic enhancers** (such as cobicistat) used to treat HIV infections.
- 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** - 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 heart beat.
- Diltiazem** – used for heart problems or high blood pressure.
- Ethinylestradiol** and **norethidrone** – oral contraceptives.
- Ketoconazole** or **itraconazole** – used to treat fungal infections.
- Pancuronium** and **vecuronium** – 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 **must 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 this medicine.

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 Depo-Medrone. This medicine can affect the results of some tests.

Depo-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 this medicine could slow the baby's growth. There is a risk associated with low birth weight of the baby; this risk can be reduced by administering a lower out dose of the medicine.

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 before taking this medicine, as small amounts of corticosteroid medicines may get into breast milk.

If you continue breast-feeding while you are having treatment, your baby will need extra checks to make sure he or she is not being affected by your 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.

Depo-Medrone contains sodium

This medicinal product contains less than 1 mmol sodium (23 mg) per vial, that is to say essentially 'sodium-free'.

3. How Depo-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 this medicine. 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.

Adults

Your doctor/nurse will tell you how many injections you will require for the condition you are being treated for, and when you will get them.

Joints - the normal dose for the injections into joint will depend on the size of the joint. Large joints (e.g. knee, ankle and shoulder) may require 20 – 80 mg (0.5 – 2 ml), medium sized joints (e.g. elbow or wrist) 10 – 40 mg (0.25 – 1 ml) and small joints (e.g. finger or toe joints) may require a 4 – 10 mg (0.1 – 0.25 ml) dose.

Joint injections may be given weekly over a period of several weeks, depending on how quickly you respond to treatment.

Bursitis and epicondylitis (tennis elbow) – the usual dose is between 4 – 30 mg (0.1 – 0.75 ml). In most cases repeat injections will not be needed for bursitis and epicondylitis. Repeat injections may be necessary to treat long standing conditions.

Skin conditions – the usual dose is between 20 – 60 mg (0.5 – 1.5 ml) injected into the affected part or parts of the skin.

For other more general conditions 40 – 120 mg (1 – 3 ml) of this medicine may be injected into a large muscle.

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

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 Depo-Medrone than you should

If you think you have been given too many injections of this medicine please speak to your doctor immediately.

Stopping/reducing the dose of your Depo-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 been given Depo-Medrone for more than 3 weeks
- have been given high doses of Depo-Medrone, over 32 mg (0.8 ml) 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 have 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 Depo-Medrone

Mental health problems can happen while taking steroids like Depo-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 the problems do happen they might need treatment.

Talk to a doctor if you (or someone using 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 Depo-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 or dizziness. 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.
- Ulcers or bleeding ulcers**, symptoms of which are severe stomach pain which may go through to the back and could be associated with 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. This medicine may also make you more likely to develop a severe infection.
- Peritonitis**, an inflammation (irritation) of the peritoneum, the thin tissue that lines the inner wall of the abdomen and covers most of the abdominal organs. Symptoms are, the stomach (abdomen) being very painful or tender, the pain may become worse when the stomach is touched or when you move.
- Pulmonary embolus** (blood clot 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 immediately.

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 heart beat) 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).
- Increase of white blood cells (leukocytosis).
- Increased clotting of the blood.
- Warmth and reddening of the skin (Flushing).
- Post injection pain flare (a temporary increase in pain at the injection site).

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).
- Thrush in the gullet (discomfort on swallowing).
- Indigestion.
- Diarrhoea.
- Bloated stomach.
- Abdominal pain.
- Persistent hiccups, especially when high doses are taken.

Ears

not known

- A feeling of dizziness or spinning (vertigo).

Eyes

not known

- Cataracts (indicated by failing eyesight).
- 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).
- Increased intra-ocular pressure, with possible damage to the optic nerve (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 (exophthalmos).
- Blurred or distorted vision (due to disease of the retina and choroid membrane).

General disorders

not known

- Poor wound healing.
- Irritability in children.
- Feeling tired or unwell.
- Skin reactions at the site of injection.
- Irritability in adults.

Hepatobiliary disorders

not known

- Methylprednisolone can damage your liver, hepatitis and increase of liver enzymes have been reported.

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).

S1373 Leaflet Depo-Medrone 20240503

Depo-Medrone® 40 mg/ml Injection (methylprednisolone acetate)

The following information is intended for healthcare professionals only:

FOR FURTHER INFORMATION PLEASE REFER TO THE SUMMARY OF PRODUCT CHARACTERISTICS.

Posology and method of administration

Depo-Medrone should not be mixed with any other suspending agent or solution. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever suspension and container permit. Depo-Medrone may be used by any of the following routes: intramuscular, intra-articular, periarticular, intrabursal, intralesional and into the tendon sheath. It must not be used by the intrathecal or intravenous routes.

Undesirable effects may be minimized by using the lowest effective dose for the minimum period (see special warnings and precautions).

Depo-Medrone vials are intended for single dose use only.

Adults

Intramuscular – for sustained systemic effect: Allergic conditions (asthma, drug reactions), 80 – 120 mg (2 – 3 ml).

Dermatological conditions, 40 – 120 mg (1 – 3 ml).

Rheumatic disorders and collagen diseases (rheumatoid arthritis, SLE), 40 – 120 mg (1 – 3 ml) per week.

Dosage must be individualised and depends on the condition being treated and its severity.

The frequency of intramuscular injections should be determined by the duration of the clinical response.

On average the effect of a single 2 ml (80 mg) injection may be expected to last approximately two weeks.

Intra-articular: Rheumatoid arthritis, osteo-arthritis. The dose of Depo-Medrone depends upon the size of the joint and the severity of the condition. Repeated injections, if needed, may be given at intervals of one to five or more weeks depending upon the degree of relief obtained from the initial injection. A suggested dosage guide is: large joint (knee, ankle, shoulder), 20 – 80 mg (0.5 – 2 ml); medium joint (elbow, wrist), 10 – 40 mg (0.25 – 1 ml); small joint (metacarpophalangeal, interphalangeal, sternoclavicular, acromioclavicular), 4 – 10 mg (0.1 – 0.25 ml).

Intrabursal: Subdeltoid bursitis, prepatellar bursitis, olecranon bursitis. For administration directly into bursae, 4 – 30 mg (0.1 – 0.75 ml). In most cases, repeat injections are not needed.

Intralesional: Keloids, localized lichen planus, localized lichen simplex, granuloma annulare, alopecia areata, and discoid lupus erythematosus. For administration directly into the lesion for local effect in dermatological conditions, 20 – 60 mg (0.5 – 1.5 ml). For large lesions, the dose may be distributed by repeated local injections of 20 – 40 mg (0.5 – 1 ml). One to four injections are usually employed. Care should be taken to avoid injection of sufficient material to cause blanching, since this may be followed by a small slough.

Periarticular: Epicondylitis. Infiltrate 4 – 30 mg (0.1 – 0.75 ml) into the affected area.

Into the tendon sheath: Tenosynovitis, epicondylitis. For administration directly into the tendon sheath, 4 – 30 mg (0.1 – 0.75 ml). In recurrent or chronic conditions, repeat injections may be necessary.

Special precautions should be observed when administering Depo-Medrone. Intramuscular injections should be made deeply into the gluteal muscles. The usual technique of aspirating prior to injection should be employed to avoid intravascular administration. Doses recommended for intramuscular injection must not be administered superficially or subcutaneously.

Intra-articular injections should be made using precise, anatomical localisation into the synovial space of the joint involved. The injection site for each joint is determined by that location where the synovial cavity is most superficial and most free of large vessels and nerves. Suitable sites for intra-articular injection are the knee, ankle, wrist, elbow, shoulder, phalangeal and hip joints. The spinal joints, unstable joints and those devoid of synovial space are not suitable. Treatment failures are most frequently the result of failure to enter the joint space.

Intra-articular injections should be made with care as follows: ensure correct positioning of the needle into the synovial space and aspirate a few drops of joint fluid. The aspirating syringe should then be replaced by another containing Depo-Medrone. To ensure position of the needle, synovial fluid should be aspirated and the injection made. After injection the joint is moved slightly to aid mixing of the synovial fluid and the suspension. Subsequent to therapy care should be taken for the patient not to overuse the joint in which benefit has been obtained. Negligence in this matter may permit an increase in joint deterioration that will more than offset the beneficial effects of the steroid.

Intrabursal injections should be made as follows: the area around the injection site is prepared in a sterile way and a wheal at the site made with 1 percent procaine hydrochloride solution. A 20-24 gauge needle attached to a dry syringe is inserted into the bursa and the fluid aspirated. The needle is left in place and the aspirating syringe changed for a small syringe containing the desired dose. After injection, the needle is withdrawn and a small dressing applied. In the treatment of tenosynovitis care should be taken to inject Depo-Medrone into the tendon sheath rather than into the substance of the tendon. Due to the absence of a true tendon sheath, the Achilles tendon should not be injected with Depo-Medrone.

The usual sterile precautions should be observed with each injection.

Paediatric population

Dosage may be reduced for infants and children but should be governed more by the severity of the condition and response of the patient, than by age or size.

Elderly patients

When used according to instructions, there is no information to suggest that a change in dosage is warranted in the elderly. However, treatment of elderly patients, particularly if long-term, 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.

Incompatibilities

None stated.

Special precautions for disposal and other handling

Do not freeze. Store this medicine at 15-30 °C. Depo-Medrone should not be mixed with any other fluid.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Product Licence holder

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