Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Depo-Medrone

- KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.
- Do not store above 25°C. Protect from freezing.
- For single dose use only. Your doctor or pharmacist will discard the remaining contents after use.
- Do not take this medicine after the expiry date shown on the carton after EXP. The expiry date refers to the last day of that month.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Depo-Medrone contains

Each 1 ml vial contains 40 mg of methylprednisolone acetate as the active ingredient.
- It also contains macrogol 3550, sodium chloride, myristyl-gamma-picolinium chloride and water for injection. When necessary, pH was adjusted with sodium hydroxide and/or hydrochloric acid.

What Depo-Medrone looks like

Depo-Medrone is a white, sterile aqueous suspension for injection contained in a glass vial fitted with a rubber cap and metal seal.

Depo-Medrone is available in packs containing 1 vial, each containing 1 ml of suspension.

Manufacturer

This product is manufactured by Pfizer Manufacturing Belgium NV Rijswijk 12, B 2870 Puurs, Belgium.

Product Licence holder

Procured from within the EU and repackaged by the Product Licence holder: S&M Medical Ltd, Chemilines House, Alporton Lane, Wembley, HA0 1DX.

Leaflet revision date: 24 April 2017

Blind or partially sighted? Is this leaflet hard to see or read? Call 02087997607 to obtain the leaflet in large print, tape, CD or Braille.

Depo-Medrone is a trademark of Pharmacia Ltd., United Kingdom.
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 Depo-Medrone or the other medicine works:
- Acetazolamide - used to treat glaucoma and epilepsy.
- Aminoglutethimide and cyclophosphamide - used for cancer treatment.
- Antibacterials (such as isoniazid, erythromycin, clariptomycin 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 neostigmine and pyridostigmine.
- Antidiabetics - medicines used to treat high blood sugar.
- Antileptics (such as aprepitant and fosaprepitant).
- Antineoplastics - 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 psoriasis, severe psoriasis or following an organ or bone marrow transplant.
- Digoxin - used for heart failure and/or an irregular heart beat.
- Dilazep - used for heart problems or high blood pressure.
- Erythristoidal and norethindrone - oral contraceptives.
- Indinavir - used for treating cancer.
- Itraconazole - used to treat fungal infections.
- Pancuronium and vecuronium - used in some surgical procedures.
- Potassium depleting agents - such as diuretics (sometimes called water tablets), amphotericin B, xanthenes or beta2 antagonists (e.g. medicines used to treat glaucoma).
- 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 any recent vaccines, even if you think you don’t have ‘live’ vaccines while using this medicine. Other vaccines may be less effective.

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 medical-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.

5. 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 for which it not treated properly could become serious.
In certain medical conditions medicines like Depo-Medrone (medrone) should not be stopped abruptly. If you suffer from any of the following symptoms seek IMMEDIATE medical attention. Your doctor will decide whether you should continue taking your medicine.

- Allergic reactions, such as skin rash, swelling of the face or tongue, difficulty breathing. This type of side effect is rare, but can be serious.
- Pancreatitis, stomach pain spreading to your back, possibly fever, nausea, vomiting, loss of appetite, loss of consciousness.
- Ulcers or bleeding ulcers, symptoms of which are severe stomach pain which may go back to the head and could be associated with bleeding from the back passage, black or tarry blood and/or vomiting blood.
- Infections, this medicine can change or hide 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 may include a raised temperature and feeling unwell. Symptoms of a flare up of a previous TB infection could be coughing or breathlessness. This medicine may also make you more likely to develop a severe infection.
- Peritonitis, an infection (inflammation) 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, eye pain, watering and dizziness. This side effect usually occurs after several doses have been given. These symptoms may disappear if the dose is reduced.
- Thrombophlebitis (blood clots or thrombosis in a leg vein), symptoms of which include painful swelling, red and tender skin, and a swelling along the vein.
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Pharmaceutical precautions
Do not store above 25°C. Protect from freezing. Depo-Medrone should not be mixed with any other fluid. Discard any remaining suspension after use.

Package quantities
Depo-Medrone is available in packs containing 1 vial, containing 1 mg of methylprednisolone acetate.

Product Licence holder
Procured from within the EU and repackaged by the PL holder: S&M Medical Ltd, Chemilines House, Alperton Lane, Wembley, HA0 1DX.

Leaflet revision date: 28 April 2017

Use in Pregnancy and Lactation

Pregnancy
The ability of corticosteroids to cross the placenta varies between individual drugs, however, methylprednisolone does cross the placenta. One retrospective study found an increased incidence of low birth weights in infants born of mothers receiving corticosteroids.

Administration of corticosteroids to pregnant animals can cause abnormalities of fetal development including cleft palate, intra-uterine growth retardation and effects on brain growth and development. There is no evidence that corticosteroids result in an increased incidence of congenital abnormalities, such as cleft palate in man, however, when administered for long periods or repeatedly during pregnancy, corticosteroids may increase the risk of intra-uterine growth retardation.

Hydropthalmia may, in theory, occur in the neonate following prenatal exposure to corticosteroids but usually resolves spontaneously following birth and is rarely clinically important. Although neonatal adrenal insufficiency appears to be rare in infants who were exposed in utero to corticosteroids, those exposed to substantial doses of corticosteroids must be carefully observed and evaluated for signs of adrenal insufficiency. As with all drugs, corticosteroids should only be prescribed when the benefit to the mother and child outweigh the risks. When corticosteroids are essential, however, patients with normal pregnancies may be treated as though they were in the non-pregnant state.

Cafergot has been observed in infants born to mothers treated with low-dose corticosteroids during pregnancy.

Breast feeding
Corticosteroids are excreted in small amounts in breast milk, however, doses of up to 40 mg daily of methylprednisolone are unlikely to cause systemic effects in the infant. Infants of months taking higher doses than this may have a degree of adrenal suppression, but the benefits of breast feeding are likely to outweigh any theoretical risk. Corticosteroids distributed into breast milk may suppress growth and interfere with endogenous glucocorticoid production in nursing infants. Since adequate reproductive studies have not been performed in humans with glucocorticoids, these drugs should be administered to nursing mothers only if the benefits of therapy are judged to outweigh the potential risks to the infant.

Overdosage
Following overdosage the possibility of adrenal suppression should be guarded against by gradual diminution of dose levels over a period of time. In such event the patient may require to be supported during any further traumatic episode.

Reports of acute toxicity and/or death following overdosage of corticosteroids are rare. In the event of overdosage, no specific antidote is available. Treatment is supportive and symptomatic.

Methylprednisolone is dialyzable.

Incompatibilities (major)
None stated.
Effects on ability to drive and to use machines

The effect of corticosteroids on the ability to drive a motor vehicle or to use machinery has not been systematically evaluated. Undesirable effects, such as dizziness, vertigo, visual disturbances, and fatigue are more frequent after treatment with corticosteroids. If affected, patients should not drive or operate machinery.

Other undesirable effects (frequency and seriousness)

Side effects: The incidence of predictable undesirable side effects associated with the use of corticosteroids depends on the dose, route of administration, and duration of treatment (see Special warnings and precautions and Metabolism and Nutrition).

Methone (VIS) System

Class Known

Frequency

Infected and inflations

Infection (including susceptibility and severity of infections with suppression of the immune system and signs of opportunistic infection).- Injection site: Pernicious: Recurrence of dormant tuberculosis

Immunosystem disorder

Drug hypersensitivity, Anaphylactic reaction

Investigations

Impaired healing; Oedema (periorificial or in children); Injection site reaction: Abscess; Fatigue; Malaise; Irritability (in ad

Corticosteroid disorders

Blood potassium decreased; Alkaline aminotransferase increased; Aspartate aminotransferase increased; Blood alanine increased; Carbohydrate tolerance decreased; Urine calcium increased; Suppression of reactions to skin tests [not a Medra DT]; Blood viscosity increased; Nitrogen balance negative (due to creatine metabolism)

Investigations

Tendon rupture (particularly of the Achilles tendon); Tophous compression fracture; Systemic corticosteroids should be used as a treatment of traumatic brain injury

CERTAIN SIDE EFFECTS REPORTED WITH SOME CONTRAINDICATIONS AND NON RECOMMENDED ROUTINES OF ADMINISTRATION AND NON

Intramuscular Injection: Usually systemic corticosteroid adverse reactions, headache, menorrhagia, amenorrhea, paraesthesias, mental fluid abnormalities, nausea, vomiting, sweating, arthralgias, functional gastrointestinal disorders/bladder dysfunction, convulsions, sensory disturbances. The frequency of these adverse reactions is not known.

Extravasal: Wound dehiscence, loss of splanchnic control. The incidence of predictable undesirable side effects associated with the use of corticosteroids depends on the dose, route of administration, and duration of treatment (see Special warnings and precautions and Metabolism and Nutrition).

Metabolism and Nutrition

Sodium tolerance; blood glucose retention; insufficiency of osteoporosis; intolerance of acute adrenal insufficiency; hypertensive crisis; idiopathic hypothyroidism; increased requirements for insulin (or oral hypoglycaemic agents in Table [not a Medra DP]; Alkalosis hypokalaemia; Dyslipidaemia, hypercholesterolaemia; appendicitis; the majority of patients. In the following patient groups, gradual withdrawal of systemic corticosteroid therapy should be considered:

Patients who may have reasons for adrenocortical insufficiency (especially in the following situations):

• Patients who may have had repeated courses of systemic corticosteroids, particularly if taken for greater than 3 weeks.

• Patients who may have been treated with corticosteroids for at least 3 months with no evidence of improvement, but who are likely to require corticosteroid therapy in the long term.

• Patients with a history of drug allergy.

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