

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before being treated with DEPO-NISOLONE suspension for injection. This leaflet answers some common questions about DEPO-NISOLONE. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you being treated with DEPO-NISOLONE against the benefits this medicine is expected to have for you.

If you have any concerns about this medicine, ask your doctor or pharmacist.

Consider keeping this leaflet even after treatment with DEPO-NISOLONE is finished. You may need to read it again.

What DEPO-NISOLONE is used for

DEPO-NISOLONE is used to treat disorders of many organ systems such as skin, lung, eye, gastrointestinal tract, nervous system, joints and blood. DEPO-NISOLONE works by reducing inflammation and changing the body's natural ability to respond when the immune response is not working properly. It is also used in certain conditions where the adrenal gland doesn't function correctly.

Your doctor may have prescribed DEPO-NISOLONE for another reason.

Ask your doctor if you have any questions about why DEPO-NISOLONE has been prescribed for you.

This medicine is available only with a doctor's prescription.

Before treatment with DEPO-NISOLONE

Some information is provided below. However, always talk to your doctor if you have concerns or questions about your treatment.

When DEPO-NISOLONE must not be used

DEPO-NISOLONE must not be used:

- if you have an allergy to:**
 - methylprednisolone acetate
 - any of the other ingredients listed under Product Description at the end of this leaflet.Symptoms of an allergic reaction may include skin rash, itching or difficulty in breathing.
- if you have a severe fungal infection**
- it must not be injected into the spinal cord (intrathecal or epidural) or into a vein (intravenous)**
- it must not be given by any other unapproved route of administration**
- if you have been given a vaccine**
- if the packaging is torn or shows signs of tampering**
- after the expiry date (EXP) printed on the carton.**

If you use it after the expiry date, it may have no effect at all, or an entirely unexpected effect.

If you are not sure whether you should be treated with DEPO-NISOLONE, talk to your doctor.

Before treatment with DEPO-NISOLONE

Before treatment with DEPO-NISOLONE, tell your doctor if:

- you are pregnant or intend to become pregnant**

Your doctor will discuss the risks and benefits of using DEPO-NISOLONE during pregnancy.
- you are breastfeeding or plan to breastfeed**

Your doctor will discuss the risks and benefits of using DEPO-NISOLONE when breastfeeding.
- you have allergies to any other medicines or any other substances such as foods, preservatives or dyes**
- you have or have had any of the following:**
 - tuberculosis
 - underactive thyroid gland
 - kidney or liver disease
 - herpes in the eye
 - hypoprothrombinaemia (a blood clotting disorder)
 - disease of the bowel, e.g., ulcerative colitis or diverticulitis
 - stomach ulcers
 - diabetes
 - emotional problems or mental disorder
 - any pus-producing infection
 - problems with your heart, including high blood pressure or congestive heart failure
 - Cushing's disease (a hormone disorder)
 - seizure disorders e.g. epilepsy
 - myasthenia gravis (ongoing muscle weakness and chronic fatigue)
 - thin or weak bones, or bones that tend to break easily (osteoporosis)
 - recent head injuries
 - blood clots.

Children

Long term treatment with corticosteroids can affect growth and development in children. It can also increase the risk of high pressure in the brain. Your doctor will monitor your child closely if your child needs long term treatment with DEPO-NISOLONE.

Elderly

If you are over 65 years old, you may have an increased chance of side effects such as bone weakness possibly leading to fractures. You may also experience fluid retention which may lead to increased blood pressure.

If you have not told your doctor about any of the above, do so before you are treated with DEPO-NISOLONE.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines or food and DEPO-NISOLONE may interfere with each other. Some of these medicines and food include:

- cyclosporin, cyclophosphamide, tacrolimus (medicines used to suppress the immune system e.g. after a transplant)
- isoniazid (a medicine to treat tuberculosis)
- non-steroidal anti-inflammatory drugs [NSAID] such as salicylates or aspirin (medicines used to relieve pain, swelling and other symptoms of inflammation including arthritis)
- some antifungals, e.g. ketoconazole, itraconazole
- some antibiotics e.g. rifampicin, erythromycin, clarithromycin
- phenobarbitone, phenytoin, carbamazepine (medicines used to treat epilepsy, convulsions)
- anticoagulants, e.g. warfarin, heparin
- some immunisations, inoculations or vaccinations
- some diuretics e.g. frusemide, a medicine to help kidneys get rid of salt and water by increasing the amount of urine produced
- neuromuscular blocking drugs (medicines that block nerve and muscle action) e.g. pancuronium
- medicines used to treat myasthenia gravis (ongoing muscle weakness and chronic fatigue), glaucoma, Alzheimer's disease
- medicines used to treat psychiatric disorders
- medicines used to treat anxiety
- bronchodilators (a type of medicine that opens up the airways in the lungs) used to treat asthma, bronchitis, emphysema, and other lung diseases, e.g., salbutamol
- medicines used to treat diabetes e.g. insulin, glibenclamide and metformin
- anti-nausea medicines e.g. aprepitant, fosaprepitant
- medicines to treat HIV e.g. indinavir, ritonavir
- some medicines to treat blood pressure, heart conditions and stroke, e.g., digoxin and diltiazem
- oral contraceptives e.g. ethinylestradiol, norethisterone
- grapefruit juice
- medicines used to treat breast cancer and hormone disorders.

These medicines and food may be affected by DEPO-NISOLONE or may affect how well it works. You may need different amounts of your medicine or you may need to take different medicines.

Your doctor or pharmacist can tell you what to do if you are taking any of these medicines. They also have a more complete list of medicines to be careful with or avoid while being treated with DEPO-NISOLONE.

Ask your doctor or pharmacist if you are not sure if you are taking any of these medicines.

Treatment with DEPO-NISOLONE

This medicine will be administered under medical supervision.

It may be given into a muscle (intramuscularly) or into a joint (intra-articularly) or into a lesion (intralesional). Due to the risk of serious side effects, it must not be injected into the spinal cord (intrathecally or epidural) or into a vein (intravenously).

How and where DEPO-NISOLONE is injected and the dose given will depend on the nature and the severity of your condition. You will be given a different dosage depending on your condition and how you react to the medicine.

If you are given too much (overdose)

Overdose is unlikely with DEPO-NISOLONE. However, repeated frequent doses over a long period of time, may cause an increase in side effects.

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency (Casualty) at your nearest hospital if you think that you or anyone else may have been given too much DEPO-NISOLONE. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Keep the telephone numbers for these services handy. Have the DEPO-NISOLONE box or this leaflet available to give details if needed.

While you are being treated with it

Things you must do

If you become pregnant while you are being treated with DEPO-NISOLONE, tell your doctor.

If you are about to start taking any new medicines, tell your doctor and pharmacist that you are being treated with DEPO-NISOLONE.

Tell all doctors, dentists and pharmacists who are treating you that you are being treated with DEPO-NISOLONE.

Tell your doctor that you are being treated with DEPO-NISOLONE:

- before having any skin tests
- before having any kind of surgery
- if you get a serious injury or infection.

Medicines such as DEPO-NISOLONE can increase the risk of infection and mask symptoms of infection.

Tell your doctor if you notice any of the following:

- fever
- tiredness
- sore or swollen joints.

Your doctor may request you follow a low-salt diet and/or take potassium supplements.

If you are a diabetic, your need for insulin or glucose lowering medicines may increase while being treated with DEPO-NISOLONE.

For patients having this medicine injected into their joints:

- be careful not to put too much stress onto that joint for a while
- ask your doctor how much you can move this joint while it is healing.

Your doctor may reduce the dose of DEPO-NISOLONE gradually if you have been on long-term treatment.

Side effects

Check with your doctor as soon as possible if you have any concerns while being treated with DEPO-NISOLONE, even if you do not think the concerns are connected with the medicine or are not listed in this leaflet.

Like other medicines, DEPO-NISOLONE can cause side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and it worries you:

- nausea
- vomiting
- headache or dizziness
- lightheadedness
- forgetfulness
- sleeplessness
- mood changes, e.g. over-excitement, depression, suicidal thoughts, hallucinations, anxiety
- changes to menstrual periods
- fluid retention
- muscle weakness, pain or loss of muscle mass
- problems with your joints, including pain
- problems with your growth
- thin fragile skin or bruising
- itchy or peeling skin
- increased sweating
- facial redness
- changes to skin at the injection site
- rashes, acne, hives
- diarrhoea or constipation
- heartburn
- increased appetite
- loss of appetite or weight loss
- persistent hiccups
- tiredness.

Tell your doctor immediately if you experience any of the following:

- bone weakness (can lead to fractures)
- wounds that will not heal
- loss in the control of your diabetes
- red, purple or brown patches on your skin
- problems with your back, including pain or weakness
- loss of sensation or problems with your reflexes (slow or too fast)
- bouts of anxiety and headaches, sweating, palpitations, dizziness, a feeling of weakness, nausea, vomiting, diarrhoea, dilated pupils and blurring vision, stomach pains, and raised blood pressure. These could be symptoms of a rare tumour of the adrenal gland, which sits near the kidney.

Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital if you notice any of the following symptoms:

- signs of increased pressure in the skull, including drowsiness, vomiting, headache, weakness, numbness and /or eye problems such as double vision

- allergic type reactions e.g. skin rash, itching and difficulty breathing, wheezing or coughing, chest pain (anaphylactic reaction)
- signs of infection such as fever, severe chills, sore throat or mouth ulcers
- severe stomach pains
- blurred or distorted vision or loss of vision, eye infections
- breathlessness, fatigue and swelling (heart failure)
- convulsions or fits
- passing large amounts of urine, increased thirst and appetite
- pain and tenderness in the leg, pain on extending the foot, swelling of the lower leg, ankle and foot
- chest pain and breathlessness.

DEPO-NISOLONE can also cause chemical imbalances in the blood, swelling of the pancreas (pancreatitis), masking of infections, increased risk of infection, hormone changes, metabolic changes and changes in liver enzymes, increased blood pressure, increased number of white blood cells (leucocytosis), or cataracts. Some of these side effects can only be found when your doctor does tests to check your progress.

This is not a complete list of all possible side effects. Some people may get other side effects while being treated with DEPO-NISOLONE.

It is very important to tell your doctor if you notice any side effects while being treated with DEPO-NISOLONE.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After treatment with DEPO-NISOLONE

Storage

DEPO-NISOLONE will normally be stored in a hospital or doctor's surgery. It should be stored in its original packaging in a cool, dry place where the temperature stays below 30°C. It must not be frozen.

Product Description

What it looks like

DEPO-NISOLONE is a suspension for injection packaged in a glass vial. It is supplied in cartons of 5 x 1 mL or 1 x 1 mL vials.

Ingredients

The active ingredient in DEPO-NISOLONE is methylprednisolone acetate. Each vial contains 40 mg of methylprednisolone acetate.

DEPO-NISOLONE also contains macrogol 3350, sodium chloride and miripirium chloride.

Identification

DEPO-NISOLONE can be identified by the Australian Register Number, AUST R 59388, which is found on the carton label.

Supplier

DEPO-NISOLONE is supplied in Australia by:

KENRAL

A Division of Pfizer Australia Pty Ltd
ABN 50 008 422 348
38-42 Wharf Road

West Ryde NSW 2114
Australia

Toll free number: 1800 675 229

This leaflet was revised in May 2016.

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