

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

NEOFORDEX 40 mg (tablet)

Dexamethasone, 40 mg

Read all of this leaflet carefully before you start taking NEOFORDEX

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- NEOFORDEX has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What NEOFORDEX is and what it is used for.
2. What you need to know before you take NEOFORDEX.
3. How to take NEOFORDEX.
4. Possible side effects.
5. How to store NEOFORDEX.
6. Contents of the pack and other information.

1. What NEOFORDEX 40 mg is and what it is used for



- NEOFORDEX is a medicine that contains the active substance dexamethasone.
- Dexamethasone is a type of hormone called a glucocorticoid, sometimes called a corticoid or corticosteroid, with various actions including effects on white blood cells, which form part of the immune system (the body's natural defences).
- Dexamethasone is similar to glucocorticoids which are naturally produced in the body.
- NEOFORDEX is used to treat adult patients with multiple myeloma, a cancer of the blood affecting the white blood cells that produce antibodies.
- NEOFORDEX will be given with other medicines for multiple myeloma. They act together by killing cancerous white blood cells.

2. What you need to know before you take NEOFORDEX 40 mg

Do not take NEOFORDEX 40 mg:

- if you are allergic (hypersensitive) to dexamethasone or one of the other ingredients of this medicine (listed in *section 6 'Contents of the pack and other information'*),
- if you have a viral infection, especially viral hepatitis, herpes, chickenpox or shingles,
- if you have an untreated psychiatric illness,
- if you are pregnant or breastfeeding your baby (*see section 'Pregnancy and breastfeeding and fertility'*),
- Do not use with live, weakened vaccines,
- Do not use if you have active tuberculosis,
- Do not use with a medicine called ciclosporin (for the treatment of psoriasis, atopic dermatitis, rheumatoid arthritis or nephrotic syndrome, and to suppress immune reactions after an organ or bone marrow transplantation).

Warnings and precautions

Take special care with NEOFORDEX 40 mg:



- if you notice signs of infection. Treatment with a high-dose corticosteroid may reduce your body's ability to fight infection. This can sometimes lead to infections caused by germs that rarely cause infection under normal circumstances (called opportunistic infections);
- if you notice signs of pneumonia such as cough, fever, shortness of breath and chest pain;
- if you previously had tuberculosis. Your healthcare professional may decide to treat you with anti-TB medicines if you receive a prolonged course of treatment with NEOFORDEX;
- if you stayed in regions where roundworm infections are common;
- if you require vaccinations (particularly with 'live virus' vaccines. See "*Do not take NEOFORDEX*");
- if you have an allergy test, a suppression test (test for hormone levels) or a test for an infection, you should inform the person performing the test that you are taking NEOFORDEX as it may interfere with the results.
- it is important that while you are taking NEOFORDEX you avoid contact with anyone who is suffering from chickenpox, measles or shingles;
- if you or a member of your immediate family have suffered, or currently suffer from severe depression or manic attacks. This is especially important if you feel depressed or might be thinking about suicide;
- if you have symptoms of tumour lysis syndrome such as muscle cramping, muscle weakness, confusion, visual loss or disturbances and shortness of breath;
- if you had or have a gastric or duodenal ulcer (sores in your stomach);
- treatment with NEOFORDEX may cause central serous chorioretinopathy, an eye disease that leads to blurred or distorted vision. This happens usually in one of the eyes.



If you notice blurring or distorted vision that lasts for several days, please contact your doctor;

- if you have glaucoma (raised eye pressure) or there is a family history of glaucoma;
- if you notice inflammation of a tendon with symptoms such as painful, stiff or swollen joints or tendons. Treatment with NEOFORDEX may cause tendon inflammation. In extremely rare cases, a tendon may rupture. This risk is increased by treatment with certain antibiotics and by kidney problems;
- if you have or are suspected of having pheochromocytoma (a tumor of the adrenal glands);
- during treatment with NEOFORDEX it is important to maintain a balanced diet;
- your doctor will advise on an appropriate diet, and may prescribe potassium, calcium or vitamin D supplements;
- if you are elderly with osteoporosis (thinning of the bones); hypertension (high blood pressure), diabetes and prone to infection and thinning of skin;
- if you have liver or kidney disease;
- if you have heart disease or you have recently had a heart attack;
- if you have high blood pressure;
- if you have diabetes or if there is a history of diabetes in your family;
- if you have osteoporosis, especially if you are a woman who has been through the menopause;
- if you have myasthenia gravis (a disease affecting the muscles);
- if you have inflammation of the colon (diverticulitis) or have recently had surgery on the intestine;
- if you have had blood clots in the past you should inform your doctor before taking NEOFORDEX. The combination of NEOFORDEX with thalidomide, lenalidomide or pomalidomide (medicines to treat multiple myeloma) increases the risk of blood clots in



the veins and arteries. You must tell your doctor immediately if you experience shortness of breath, chest pain or swelling in the arms or legs;

- the combination of NEOFORDEX with lenalidomide or pomalidomide may cause a decrease in normal white blood cells (blood cells that help fight infection) and/or blood platelets (which help prevent bleeding). Your doctor will arrange appropriate blood tests before and during treatment.

Other medicines and NEOFORDEX 40 mg:

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following medicines:

- acetylsalicylic acid (aspirin), a substance present in many medicines used to relieve pain and lower fever, and other medicines to treat pain, inflammation and fever: ibuprofen, naproxen, diclofenac, meloxicam and others;
- vaccinations (particularly with 'live virus' vaccines);
- medicines that reduce blood potassium levels such as laxatives and diuretics (medicines used to increase the production of urine);
- tetracosactide (used to test for adrenal function);
- amphotericin B (an antibiotic);
- digitalis (medicines for heart disease);
- oestrogen hormones including the contraceptive pill and hormone replacement therapy (HRT);
- erythropoietin (EPO, a medicine used to treat anaemia);
- medicines used for treatment of diabetes;
- medicines used for treatment of hypertension (high blood pressure);



- methotrexate (a medicine used to treat rheumatism or psoriasis and cancer);
- fluoroquinolones (antibiotics);
- aminogluthetimide (a medicine used to treat Cushing's syndrome or breast cancer);
- rifampicin (medicines used to treat tuberculosis);
- carbamazepine, fosphenytoin, phenobarbital, phenytoin, primidone (medicines used to treat seizures);
- colestyramine (a medicine used for high cholesterol);
- antacids and activated carbon (medicines used for too much acid ion the stomach);
- ephedrine (a medicine used to treat asthma attacks or relieve nasal congestion);
- aprepitant or fosaprepitant (for the treatment of nausea and vomiting after surgery or caused by chemotherapy [cancer treatment]);
- antibiotics e.g.clarithromycin, erythromycin, telithromycin;
- antifungals (to treat fungal infections) e.g. itraconazole, ketoconazole, posaconazole, voriconazole;
- anti-HIV medicines e.g. nelfinavir, ritonavir, indanavir;
- anticoagulant medicines (which thin the blood);
- certain medicines to treat cancer e.g. docetaxel, cyclophosphamide, lapatinib;
- ciclosporin (for the treatment of psoriasis, atopic dermatitis, rheumatoid arthritis or nephrotic syndrome, and to suppress immune reactions after an organ or bone marrow transplantation);
- midazolam (a medicine used as a sleeping pill and for the treatment of epilepsy);
- ivermectin (a medicine used to treat many types of parasite infestations e.g. head lice, scabies, river blindness);
- rifabutin (an antibiotic used to treat tuberculosis) and isoniazid;
- praziquantel (a medicine used to treat a number of types of parasitic worm infections).



Pregnancy and breastfeeding and fertility

You should not take NEOFORDEX if you are pregnant or breastfeeding your baby. If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking NEOFORDEX.

You must avoid getting pregnant during treatment with NEOFORDEX.

You and your partner must use appropriate contraception.

Inform your doctor immediately if you are pregnant or if you become pregnant during treatment.

Driving and using machinery

NEOFORDEX 40 mg may cause confusional state, hallucinations, dizziness, somnolence, fatigue, syncope and blurred vision and affect mental and/or physical abilities to perform or execute tasks or activities requiring mental alertness, judgment and/or sound coordination and vision e.g. driving, riding, flying, sailing, operating machines/equipment (see section 4 '*Possible side effects*'))

NEOFORDEX 40 mg contains lactose

NEOFORDEX contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance should not take NEOFORDEX 40 mg.

3. How to take NEOFORDEX 40 mg:

Do not share medicines prescribed for you with any other person.



Always take NEOFORDEX exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will decide the dose and tell you on which days you should take it. The recommended dose is one tablet each time. If you are over 65 years old and/or frail, your doctor may prescribe another product containing a lower dose. Do not exceed or take less than the prescribed dose. You must take this medicine on the appropriate days, exactly as your doctor prescribed.

Your doctor may change the dose and frequency of administration based on certain parameters including your blood analyses, your general condition, other medicines prescribed to you and your response to the treatment.

The usual dose is:

Swallow the prescribed dose of one tablet (40 mg) in the morning with a glass of water.

If you have the impression that the effect of NEOFORDEX 40 mg is too strong or too weak, tell your doctor or pharmacist.

If you take more NEOFORDEX 40 mg than you should

In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you missed a dose of NEOFORDEX 40 mg

Do not take a double dose to make up for forgotten individual doses.



4. Possible side effects

NEOFORDEX can have side effects.

Not all side effects reported for NEOFORDEX are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking NEOFORDEX, please consult your healthcare professional for advice.

If any of the following happens, stop taking NEOFORDEX 40 mg and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to NEOFORDEX. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Neofordex may cause serious mental health problems.

- feeling depressed (including thinking about suicide)
- feeling high (mania), very happy (euphoria) or moods that go up and down,
- feeling anxious, having difficulty in concentrating and memory loss,
- feeling, seeing or hearing things that do not exist or believing in things that are not real, having gloomy thoughts, changing how you act.

These are all serious side effects. You may need urgent medical attention.



Tell your doctor if you notice any of the following:

The following side effects have been reported frequently:

- increased blood sugar levels, constipation;
- having trouble sleeping;
- muscle cramps, muscle weakness;
- tiredness, weakness;
- bacterial, viral or fungal infections, including pneumonia, shingles, infections of the nose, mouth, tonsils or throat, bronchitis, herpes, bladder infection;
- reduction in the number of red or white blood cells and/or platelets, or increased number of white blood cells, decreased levels of potassium or of albumin (a protein) in the blood, increased levels of uric acid in the blood, changes in liver function tests;
- Cushing's syndrome, i.e. weight gain of the trunk and face, excessive sweating, stretch marks, visible swollen capillaries (small blood vessels) and dryness of the skin, growth of extra facial hair (especially in women) and thinning of the hair;
- development of diabetes, loss or increase of appetite, weight gain or weight loss, water retention;
- aggression, confusion, irritability, nervousness, restlessness, altered mood;
- sensitivity, numbness, tingling or burning sensation of the skin, or pain in the hands or feet due to nerve damage, dizziness, trembling, headache, loss of or change in the sense of taste;
- cataract, blurred vision;
- fast or irregular heart rhythm, too high or too low blood pressure, formation of blood clots that may clog blood vessels (for example in legs or lungs), swelling of arms or legs, reddening of the skin of the face or body;



- cough, breathing difficulties, difficulties speaking, sore throat or mouth, hoarseness, dry mouth, hiccough, inflammation of the mucous membranes;
- vomiting, nausea, diarrhoea, indigestion, bloating, swollen and/or painful stomach;
- muscle wasting, pain of the muscles, joints, bones or limbs;
- frequent urination;
- pain, fever, chills, fainting, vertigo, exhaustion, drowsiness, impaired sense of balance.

The following side effects have been reported less frequently:

- fever due to a lack of certain white blood cells, lack of all types of blood cells, diminished blood clotting, decreased magnesium or calcium levels in the blood;
- failure of the thyroid gland to produce normal amounts of hormones (hypothyroidism);
- lack of body water (dehydration) with thirst or headache;
- stroke, difficulties in coordination or movement, fainting;
- inflammation of the eye and/or eyelids, increased tearing;
- heart attack, abnormally slow heartbeat;
- hives;
- failure of the kidneys.

The following side effects have been reported but the frequency is unknown:

- infection, inflammation of the whole body due to infection (sepsis);
- inability of the body to respond normally to severe stress such as accidents, surgery or illness due to insufficient function of the adrenal glands, severe unusual headache with visual disturbances linked to the withdrawal of treatment, irregularity of menstrual cycles in women;
- increased need for diabetes medicine, salt imbalance, potassium loss due to low carbon dioxide levels (a condition called metabolic alkalosis);



- epileptic fits;
- increased pressure in the eye including glaucoma, choroid and retinal disorders (chorioretinopathy);
- inability of the heart to pump enough blood round the body (heart failure);
- ulcers, perforations and/or bleeding in the oesophagus (gullet), stomach or intestine, inflamed pancreas (which may show as pain in the back and abdomen);
- slow wound healing, acne, thinning of the skin, bruising, red or purple discolorations on the skin (purpura);
- thinning of the bones with increased risk of fracture, bone disease, ruptured tendon.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA *via* the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who- umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of NEOFORDEX.

5. How to store NEOFORDEX 40 mg

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Store in the original package / container.
- Do not store in a bathroom
- Do not use after the expiry date stated on the label / carton / bottle



- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What NEOFORDEX 40 mg contains:

- The active substance is:

Each tablet contains dexamethasone acetate equivalent to 40 mg dexamethasone as the active ingredient.

- The other ingredients are:

Colloidal anhydrous silica, lactose monohydrate, magnesium stearate, microcrystalline cellulose

Contains sugar: Lactose monohydrate 98,1 mg.

What NEOFORDEX 40 mg looks like and contents of the pack

White, oblong tablet with “40 mg” engraved on one side.

10 x 1 tablets in OPA/Aluminium /PVC-Aluminium perforated unit dose blister. 10 tablets are packed in an outer carton.

Holder of Certificate of Registration and Manufacturer

Key Oncologics (Pty) Ltd

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Access to the corresponding Professional Information

Can be obtained on the SAHPRA website www.sahpra.org.za

A handwritten signature in black ink, consisting of a stylized 'S' followed by a vertical line and a small flourish.