PROPOSED PATIENT INFORMATION LEAFLET FOR DEXONA INJECTION 4 mg/1 ml

Please read this leaflet carefully before using DEXONA INJECTION 4 mg/1 ml

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- This medicine 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.

Scheduling Status: S4

Proprietary name, Strength and Pharmaceutical Form:

DEXONA INJECTION 4 mg/1 ml (Solution for IV/IM injection)

1. WHAT DEXONA INJECTION 4 mg/1 ml CONTAINS

The active ingredient is Dexamethasone sodium phosphate 4 mg/ml.

Inactive ingredients: Creatinine, sodium citrate, sodium metabisulfite (antioxidant 1mg/ml), methyl parabene, propyl parabene, disodium edetate, sodium hydroxide and water for injection.

2. WHAT DEXONA INJECTION 4 mg/1 ml IS USED FOR

DEXONA INJECTION 4 mg/1 ml is used to provide relief for inflammatory and allergic conditions of the body.

3. BEFORE YOU TAKE DEXONA INJECTION 4 mg/1 ml

Do not take DEXONA INJECTION 4 mg/1 ml:

- If you are hypersensitive (allergic) to dexamethasone.
- If you have or previously had tuberculosis.
- If you have a herpes simplex eye infection.
- If you suffer from glaucoma (increased eye pressure).
- If you suffer from a psychiatric disorder.
- If you currently have an infection of any kind.
- If you have a stomach ulcer.
- If you suffer from osteoporosis.
- If your immune system is weakened or suppressed.

Take special care with DEXONA INJECTION 4 mg/1 ml:

Your doctor should check your progress at regular visits. Also, your progress may have to be checked after you have stopped using this medicine, since some of the effects may continue.

If you will be using **corticosteroids** including **DEXONA INJECTION 4 mg/1 ml** for a long time:

- Your doctor may want you to have your eyes examined by an ophthalmologist (eye doctor) before, and also sometime later during treatment.
- Your doctor may want you to carry a medical identification card stating that you are using this medicine.

Tell the doctor in charge that you are using this medicine:

- Before having skin tests.
- Before having any kind of surgery (including dental surgery) or emergency treatment.
- If you get a serious infection or injury.

Avoid close contact with anyone who has chickenpox or measles. This is especially important for children. Tell your doctor right away if you think you have been exposed to chickenpox or measles.

While you are being treated with **DEXONA INJECTION 4 mg/1 ml**, and after you stop receiving it, *do not have any immunizations without your doctor's approval*. Also, other people living in your home should not receive the oral polio vaccine, since there is a chance they could pass the polio virus on to you. In addition, you should avoid close contact with other people at school or work who have recently taken the oral polio vaccine, or any other live attenuated virus vaccinations.
Consult your doctor before receiving any vaccinations.

For patients with diabetes:
DEXONA INJECTION 4 mg/1 ml may affect blood glucose (sugar) levels. If you notice a change in the results of your blood or urine sugar tests or if you have any questions, check with your doctor.

For patients having **DEXONA INJECTION 4 mg/1 ml** injected into their joints:

- If this medicine is injected into one of your joints, you should be careful not to put too much stress or strain on that joint for a while, even if it begins to feel better. Make sure your doctor has told you how much you are allowed to move this joint while it is healing.
- If redness or swelling occurs at the place of injection, and continues or gets worse, check with your doctor.

Taking DEXONA INJECTION 4 mg/1 ml with food and drink:

If you are receiving **DEXONA INJECTION 4 mg/1 ml** for a long time, your doctor may want you to:

- Follow a low-salt diet and/or a potassium-rich diet.
- Watch your calories to prevent weight gain.
- Add extra protein to your diet.

Make certain your health care professional knows if you are already on any special diet, such as a low-sodium or low-sugar diet.

Pregnancy and breast-feeding:

Safety in pregnancy and breast-feeding has not been established. You should not receive **DEXONA INJECTION 4 mg/1 ml** if you are pregnant or breastfeeding your baby.

Using other medicines with DEXONA INJECTION 4 mg/1 ml:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **DEXONA INJECTION 4 mg/1 ml** with these medicines may cause undesirable interactions. Tell your doctor or pharmacist if you are taking any other medicines, including any you have bought at your pharmacy, supermarket or health food shop. Please consult your doctor, pharmacist or other healthcare professional for advice.

DEXONA INJECTION 4 mg/1 ml may interact with the following products:

- Aminoglutethimide (breast cancer treatment)
- Antibiotics namely macrolide (e.g. erythromycin) and amphotericin B (parenteral)
- Oral antidiabetic agents or insulin
- Digitalis glycosides (heart medication)
- Ketoconazole (anti-fungal agent)

- Somatrem or somatropin
- Water tablets, e.g. thiazides or furosemide
- Barbiturates (anxiety treatment), carbamazepine and phenytoin (anti-epileptic agents), primidone and rifampicin

4. HOW TO USE DEXONA INJECTION 4 mg/1 ml

DEXONA INJECTION 4 mg/1 ml is for intravenous use only. Your doctor will decide on the suitable dose and area of injection.

5. POSSIBLE SIDE EFFECTS

DEXONA INJECTION 4 mg/1 ml can have side effects. Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

If any of the following happen, immediately inform your doctor:

- Hives; shortness of breath; swelling of face and eyelids; tightness in chest and wheezing
- Fits
- If you develop an infection

These are all very serious side-effects and occur less frequently. You may need urgent medical attention or hospitalisation.

The following side-effects occur less frequently and indicate the need for medical attention:

- Diabetes mellitus (symptoms of decreased or blurred vision, frequent urination, increased thirst)
- Burning, numbness, pain or tingling at or near injection site

- Psychic disturbances such as confusion, excitement, restlessness, disorientation, false sense of well-being, hallucinations, and depression
- Irregular or fast heart beat

Long term use of **DEXONA INJECTION** can lead to the following less-frequent occurring effects:

- Acne; hip or shoulder pain; gradual blurring or loss of vision; thin and shiny skin; unusual bruising; growth suppression; impaired wound healing; scarring at injection site; tendon rupture.
- Cushing's syndrome (filling or rounding out of the face; unusual increase in hair growth; menstrual irregularities and muscle weakness)
- Fluid retention (rapid weight gain, swelling of feet or lower legs)
- Osteoporosis (pain in back, ribs, arms and legs due to weakened bone structure)
- Blurred vision or other changes in vision, eye pain, and sensitivity of eyes to light.

Frequent occurring side-effects are the following:

- Nausea and vomiting
- Increase appetite
- Indigestion
- Nervousness or restlessness
- Trouble in sleeping

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

6. STORING AND DISPOSING OF DEXONA INJECTION 4 mg/1 ml

- Store below 25ºC. Protect from light.

- KEEP ALL MEDICINES OUT OF SIGHT AND REACH OF CHILDREN
- Do not use **DEXONA INJECTION 4 mg/1 ml** after the expiry date printed on the carton and vial.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

7. PRESENTATION OF DEXONA INJECTION 4 mg/1 ml

1 ml amber, USP type-1 glass ampoule (OPC with blue dot).

2 ml 13 mm flint USP type-1 tubular vials with 13 mm grey butyl rubber stoppers packed into non-toxic PCV film (amber) / printed aluminium foil blister.

8. IDENTIFICATION OF DEXONA INJECTION 4 mg/1 ml

Clear, colourless to light yellow solution free from visible particulate matter and fibres, filled in 1 ml amber, USP type-1 glass ampoule (OPC with blue dot).

Clear, colourless to light yellow solution free from visible particulate matter and fibres, filled in 2 ml USP type-1 glass vial

9. REGISTRATION NUMBER

41/21.5.1/0225

10. NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Zydus Healthcare S.A. (Pty) Ltd

Southdowns Office Park,

Building B, Ground Floor,

22 Karee Street, Centurion,

Pretoria, 0157

11. DATE OF PUBLICATION

March 2009