SCHEDULING STATUS

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

DYNA CEFPODOXIME 100 mg (film coated tablet)

DYNA CEFPODOXIME SUSPENSION (powder for oral suspension)

Please read this leaflet carefully before taking DYNA CEFPODOXIME 100 mg tablets or DYNA CEFPODOXIME SUSPENSION.

- 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.

1. WHAT DYNA CEFPODOXIME CONTAINS

DYNA CEFPODOXIME 100 mg:

Active ingredient:

Sugar free.

Each film coated tablet contains cefpodoxime proxetil equivalent to 100 mg cefpodoxime.

Inactive ingredients:

Carmellose calcium, lactose monohydrate, hydroxypropyl cellulose, sodium lauryl sulphate, magnesium stearate, Opadry White (as the colourant) 03A28718 and purified water.

DYNA CEFPODOXIME SUSPENSION:

Active ingredient:

Each 5 ml of suspension contains cefpodoxime proxetil equivalent to 40 mg cefpodoxime.

Inactive Ingredients:

Microcrystalline cellulose and carboxymethyl cellulose sodium, silica colloidal anhydrous, maize starch, hydroxypropyl cellulose, sodium benzoate, anhydrous citric acid, aspartame, artificial banana flavour spray dry, spectracol yellow iron oxide (colourant).

2. WHAT DYNA CEFPODOXIME IS USED FOR

DYNA CEFPODOXIME belongs to the antibiotic group of medicines known as the cephalosporins.

DYNA CEFPODOXIME is used for a variety of bacterial infections of the respiratory tract, including infections of the tonsils, throat, lungs and sinus cavities.

3. BEFORE YOU USE DYNA CEFPODOXIME

Do not use DYNA CEFPODOXIME:

- If you are allergic to any of the components of **DYNA CEFPODOXIME** or other cephalosporin antibiotics (see **WHAT DYNA CEFPODOXIME CONTAINS**).
- If you are pregnant or breast feeding (see *Pregnancy and breast feeding*).

Take special care with DYNA CEFPODOXIME:

- DYNA CEFPODOXIME should be taken with caution in patients who are generally allergic. Please tell your doctor about all allergic reactions you have had previously, especially to medicines.
- Take care if you are allergic to penicillin antibiotics, as you may have an increased chance of being allergic to cephalosporins (including **DYNA CEFPODOXIME**) as well.
- Take care if you develop diarrhoea while using DYNA CEFPODOXIME. This may be an
 indication of inflammation of the large intestine (colitis). Please consult your doctor
 immediately.
- Take care if you have a kidney disorder.

- **DYNA CEFPODOXIME** contains lactose. Take special care if you have lactose intolerance (inability to digest milk and milk products).

DYNA CEFPODOXIME may interfere with certain blood and urine tests. Please tell your doctor you are using **DYNA CEFPODOXIME** before having any laboratory tests done. Safety and efficacy in children under one year of age have not been established.

Pregnancy and breastfeeding:

Do not use **DYNA CEFPODOXIME** if you are pregnant, planning to become pregnant or breastfeeding.

Driving and using machines:

DYNA CEFPODOXIME is not expected to affect your ability to drive a car or operate machinery. Do take care until you know how **DYNA CEFPODOXIME** affects you.

Using other medicines with DYNA CEFPODOXIME:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **DYNA CEFPODOXIME** with these medicines may cause undesirable interactions. Consult your doctor or pharmacist if you are taking any other medicines, including any you have bought at your pharmacy, supermarket or health food shop.

Certain medicines may interact with **DYNA CEFPODOXIME**. In these cases, it may be necessary to change the dose or interrupt the treatment of one of the medicines.

Probenecid (used for the treatment of gout) may increase the blood levels of **DYNA CEFPODOXIME** and increase the chance of side effects.

Medicines that affect the kidneys such as certain diuretics (e.g. furosemide) and aminoglycoside antibiotics (e.g. gentamicin) may interact with **DYNA CEFPODOXIME** which may lead to kidney problems.

Not all the medicines that may interact with DYNA CEFPODOXIME are listed above.

4. HOW TO TAKE DYNA CEFPODOXIME

The dose of **DYNA CEFPODOXIME** will be different for each patient even if their symptoms are the same as yours.

The dose may depend on the following factors:

- what the medicine is being used for
- other medical conditions the you may have
- whether or not other medicines are also being taken

Adults:

Infection of the tonsils, throat and acute bronchitis:

The usual dose is one **DYNA CEFPODOXIME 100 mg** tablet every 12 hours (200 mg/day) with meals.

Infection of the sinus cavities, chronic bronchitis and pneumonia (lungs):

The usual dose is two **DYNA CEFPODOXIME 100 mg** tablets every 12 hours (400 mg/day) with meals.

If you have a kidney disorder, you will receive lower doses that the normal adult dose. Your doctor will determine the correct dose according to your condition.

In children:

The average dose is 8 mg/kg/day, given in two doses every 12 hours with meals. Your doctor will adjust the dose according to the child's weight. The use of **DYNA CEFPODOXIME SUSPENSION** in children under 1 year of age has not been established.

In the event of an overdosage

In the event of an overdosage, contact your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre as soon as possible. Take this leaflet

and any remaining tablets or suspension with you, so that the doctor knows what you have taken.

If you forget to take your DYNA CEFPODOXIME

If you forget to take a dose, take it as soon as you remember. **Do not take a double or larger dose** to make up for the forgotten individual doses. Continue to take the next dose at the usual time.

5. POSSIBLE SIDE EFFECTS

DYNA CEFPODOXIME may have side effects.

If you experience the following, please consult your doctor <u>immediately</u>, as you may have had a negative reaction to **DYNA CEFPODOXIME**:

- Allergic reactions (swelling of the hands, feet, ankles, face, lips, mouth, or throat which
 may cause difficulty in swallowing or breathing, severe skin rashes).
- Severe diarrhoea, abdominal pain, swelling, tenderness.

The above side effects are very serious but do not occur frequently.

Other frequent side effects that may occur:

- Nausea, vomiting, diarrhoea, abdominal pain
- Headache

Other less frequent side effects may include:

- Dizziness
- Itching and hives

Other side effects that have been reported:

- Ringing in the ears
- Tingling, pricking or numbness of the skin
- Weakness

PATIENT INFORMATION LEAFLET

DYNA CEFPODOXIME 100 mg / DYNA CEFPODOXIME SUSPENSION:

Not all side effects reported for DYNA CEFPODOXIME are included in this leaflet.

Should your general health worsen while using DYNA CEFPODOXIME, please consult your doctor for advice.

6. STORAGE AND DISPOSAL OF DYNA CEFPODOXIME

DYNA CEFPODOXIME 100 mg:

Store at or below 25 °C, protected from light and humidity. Keep blister strip in the carton until required for use

KEEP OUT OF REACH OF CHILDREN.

DYNA CEFPODOXIME SUSPENSION:

Before reconstitution:

Store at or below 25 °C, protect from light and humidity.

After reconstitution:

Use within 10 days. Store in a refrigerator $(2 - 8 ^{\circ}C)$.

Shake well before use.

Keep the bottle tightly closed. Discard any unused portion. Do not freeze.

KEEP OUT OF REACH OF CHILDREN.