

DYNALEXIN DRY SYRUP

Consumer Medication Information Leaflet (RiMUP)

Cephalexin Monohydrate (125mg/5ml, 250mg/5ml)

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What Dynalexin Dry Syrup is used for

Cephalexin is a semi-synthetic cephalosporin antibiotic for oral administration.

It is indicated in the treatment of the following infections due to susceptible microorganisms:

- Respiratory tract infections
- Otitis media (ear infection)
- Skin and soft tissue infections
- Bone and joint infections
- Urinary tract infections, including acute prostatitis
- Dental infections

How Dynalexin Dry Syrup works

Cephalexin is bactericidal that works by inhibiting synthesis of cell wall.

Before you use Dynalexin Dry Syrup

- When you must not use it

Do not use Dynalexin Dry Syrup in patients with known allergy to the Cephalosporin group of antibiotics

Pregnancy and lactation

Do not take Dynalexin Dry Syrup if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take Dynalexin Dry Syrup if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start use it

Tell your doctor if:

- Previously you have hypersensitivity reactions to

Cephalosporins, Penicillin or other drugs.

- You have impaired renal function.

- Taking other medicines

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

How to use Dynalexin Dry Syrup

- How much to use

Directions for Mixing

1. Shake well to loosen powder.
2. Add approximately half the final volume (30 ml or 50 ml) freshly boiled and cooled water and shake.
3. Add more water until the final volume mark (60 ml or 100 ml) is reached and shake well.

To be used within 7 days of mixing.

Adults: The adult dosage ranges from 1-4g daily in divided doses; most infections will respond to a dosage of 500mg every 8 hours. For skin and soft tissue infections, sore throat, and mild, urinary tract infections, the usual dosage is 250mg every 6 hours or 500 mg every 12 hours.

For more severe infections or those caused by less susceptible organisms, larger doses may be needed. If daily doses of Cephalexin greater than 4g are required, cephalosporin injection, in appropriate doses, should be considered.

The elderly and individuals with impaired renal function: As for adults. Reduce dosage if renal function is markedly impaired.

Children: The usual recommended daily dosage for children is 25-50mg/kg (10-20mg/lb) in divided doses. For skin and soft tissue infections, sore throat, and mild, uncomplicated urinary tract infections, the total daily dose may be divided and administered every 12 hours. For most infections the following schedule is suggested:

Children under 5 years: 125mg every 8 hours.

Children 5 years and over: 250mg every 8 hours.

In severe infections, the dosage may be doubled. In the therapy of ear infection, clinical studies have shown that a dosage of 75 to 100mg/kg/day in 4 divided doses is required.

In the treatment of beta-haemolytic streptococcal infections (Bacterial infection that causes complete destruction of red blood cells (haemolysis)), a therapeutic dose should be administered for at least 10 days.

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking Dynalexin Dry Syrup for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too much syrup may cause nausea, vomiting, epigastric distress (pain or discomfort in the upper part of the abdomen), diarrhoea and hematuria (the presence of blood in urine).

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While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Dynalexin Dry Syrup.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Dynalexin Dry Syrup to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Reduced dosage is recommended in patients with severe renal impairment.

Side effects

Like all medicines, Dynalexin Dry Syrup can cause side effects, although not everybody gets them.

Side effects of Dynalexin Dry Syrup include:

Gastrointestinal: Nausea and vomiting have been reported rarely. The most frequent side-effect has been diarrhoea. Dyspepsia (indigestion) and abdominal pain have also occurred.

Hypersensitivity: Allergic reactions have been observed in the form of rash, urticarial (skin rash with red, raised, itchy bumps), angioedema (swelling below the surface of the skin), and rarely erythema multiforme, Stevens-Johnson syndrome, and toxic epidermal necrolysis. Anaphylaxis has also been reported.

Blood disorders: Eosinophilia (an abnormally high number of eosinophils, disease-fighting white blood cell in the blood), neutropenia (abnormally low level of white blood cell), thrombocytopenia (low blood platelet count), and haemolytic anaemia have been reported.

Other: These have included genital and anal pruritus, genital candidiasis (overgrowth of the normal yeast in the vagina), vaginitis (inflammation of the

vagina) and vaginal discharge, dizziness, fatigue, headache, agitation, confusion, hallucinations, arthralgia, arthritis, and joint disorder. Reversible interstitial nephritis (a condition that affects the kidneys' ability to filter waste and extra fluid from the body properly) has been reported rarely.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public → Reporting Medicinal Problems/ Side Effects/ AEFI/ Vaccine Safety).

Storage and Disposal of Dynalexin Dry Syrup

- Storage

Keep out of reach of children.
Keep container tightly closed.
Store in a dry place below 25°C.
Protect from light.

- Disposal

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.

Product Description

Dynalexin Dry Syrup 125mg/5ml

- What it looks like

White coloured powder.
Light green in colour suspension, opaque and smooth with vanilla flavour on adding water.

- Ingredients

- Active ingredient
Cephalexin Monohydrate
- Inactive ingredients
Aerosil 200, Sodium Benzoate, Sugar, Sodium Metabisulphite, Green S, Sodium Lauryl Sulfate, Sodium Saccharin, Vanilla Flavour, Brilliant Blue, Xanthan Gum(Rhodigel)

Dynalexin Dry Syrup 250mg/5ml

- What it looks like

White coloured powder.
Light green in colour suspension, opaque and smooth with vanilla flavour on adding water.

- Ingredients

- Active ingredient
Cephalexin Monohydrate
- Inactive ingredients
Aerosil 200, Sodium Benzoate, Sugar, Sodium Metabisulphite, Green S, Sodium Lauryl Sulfate, Sodium Saccharin, Vanilla Flavour, Brilliant Blue, Xanthan Gum(Rhodigel)

- MAL number(s):

Dynalexin Dry Syrup 125mg/5ml
MAL07031083AZ

Dynalexin Dry Syrup 250mg/5ml
MAL07031092AZ

Manufacturer & Product

Registration Holder

DYNAPHARM (M) SDN. BHD.
2497, Mk. 1, Lorong Perusahaan Baru 5, Kawasan Perusahaan Perai 3, 13600 Perai, Pulau Pinang, MALAYSIA

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