PRELONE SYRUP

Prednisolone (3mg/5ml)

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What Prelone Syrup is used for

It is used for disease such as lack of cortisol hormone, severe allergies, asthma, skin problems, "auto-immune" diseases, cancer diseases, swelling states and gastrointestinal diseases.

How Prelone Syrup works

Prednisolone is known as corticosteroid or steroid. It helps by reducing inflammation effect in many diseases and disorders.

Before you use Prelone Syrup

- When you must not use it

Do not use Prelone Syrup if:-

- you have fungal infections.
- you have hypersensitivity to prednisolone or any ingredients listed at the end of this leaflet.

- Before you start to use it

You should check with your doctor if you have the following :-

- congestive heart failure
- diabetes
- long term kidney failure
- high blood pressure
- recent intestinal operation
- infectious diseases
- muscle weakness
- eye infection due to herpes simplex virus
- tuberculosis disease (bacterial infection that mainly affects the lungs)
- systemic sclerosis (an autoimmune disorder). Taking daily doses of 15 mg or more may increase the risk of a serious complication called scleroderma renal crisis which may cause your blood pressure to increase and reduce urination.

Some medicines may increase the effects of Prelone Syrup and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV such as cobicistat). Prolonged use of corticosteroids may produce cataracts (clouding of eye lens) and glaucoma (increased pressure in the eye) with possible damage to the optic nerves, and may increase the risk of secondary eye infections due to fungi or viruses.

Pregnancy and breastfeeding

You should check with your doctor if you are or think you may be pregnant, planning to become pregnant or if you are breastfeeding. It is not recommended for pregnant women and nursing mothers unless the expected benefit outweighs any potential risks. Corticosteroids appear in breast milk and can cause other unwanted effects.

- Taking other medicines

There are a few medicines which may interact with Prelone Syrup. It is important to tell your doctor or pharmacist about all the medicines that you are taking, including those obtained without doctor's prescription. You should talk to your doctor or pharmacist if you are taking:-

- Phenytoin and Phenobarbital, treatment for fits
- Ephedrine, medicine for asthma
- Rifampicin treatment for bacterial infections
- Barbiturates, treatment for anxiety and sleep disorders.
- Cobicistat, medicine for HIV.

How to use Prelone Syrup

- How much to use

You should take Prelone Syrup exactly as advised by your doctor or pharmacist. The amount you take each day will depend on your condition. Do not take more or less than what your doctor prescribes.

Oral administration

Dosage requirements are variable and must be individualized on the basis of the disease and the response of the individual. The initial dosage may vary from 5mg to 60mg daily in divided doses, as a single daily dose after breakfast or as a double dose on alternate days depending on the specific disease entity being treated.

- When to use it

Use Prelone Syrup when needed and according to doctor's prescription.

- How long to use it

It is important to take Prelone Syrup as long as your doctor prescribes.

If after long-term therapy the medicine is to be stopped, it is recommended that is be withdrawn gradually better than abruptly.

- 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.

Overdose signs such as elevation of blood pressure and increased potassium excretion.

While you are using it

- Things you must do

- Tell all the doctors, dentists and pharmacists treating you that you are taking Prelone 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 because too rapid withdrawal of corticosteroids may cause adrenal gland insufficiency and may be minimized by gradual reduction of dosage. Other may include fever, joint pain, muscle pain and feeling of discomfort.
- Do not take any new medicines without consulting your doctor.
- Do not give Prelone Syrup to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

If you experience any side effects, consult your doctor or pharmacist for advice.

Side effects

Like all medicines, Prelone Syrup can cause side effects, although not everybody gets them. Adverse reactions include fluid and electrolyte disturbance, muscle weakness, osteoporosis (brittle bone), acute pancreas inflammation, Cushing's syndrome (weight gain, rounded face, fatty tissue hump between shoulders), growth retardation. Growth and development of infants and children on prolonged corticosteroids therapy should be carefully observed.

Besides this, other side effects are menstrual irregularities, visual disturbances, manifestation of latent diabetes due to body's immune system attacks, stomach ulcer, delayed wound healing, increase pressure in brain tissue and also eye nerve swelling.

Any other effects not listed above may also occur in some people. Please refer to your doctor or pharmacist if you experience any other symptoms while taking this medication.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website <u>npra.gov.my</u> [Consumers \rightarrow Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and disposal of Prelone Syrup

- Storage

Store at or below 30 °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

<u>- What it looks like</u> Clear, red syrup with raspberry flavour.

- Ingredient(s)

- Active Ingredient
- Prednisolone
- Inactive Ingredients
- Spirit Chloroform
- Citric Acid
- Sodium Metabisulphite
- Raspberry Flavour 05174
- Raspberry Red 09679

- Propylene Glycol
- Deionised Water
- Syrup Simplex

<u>- MAL number</u> MAL 19870540A7

MAL19870540AZ

Manufacturer

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Product Registration Holder

Sunward Pharmaceutical Sdn. Bhd. No. 9,11 & 17, Jalan Kempas 4, Taman Perindustrian Tampoi Indah, 81200 Johor Bahru, Johor, Malaysia.

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