

# ZORALONE FORTE SYRUP SUGAR FREE

Prednisolone Sodium Phosphate (5mg/ml)

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This leaflet answers some common questions about Zoralone Forte. It does not contain all the information that is known about Zoralone Forte.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor or pharmacist has weighed the risks of you taking Zoralone Forte against the benefits they expect it will have for you.

**Keep this leaflet with the medicine.** You may need to read it again.

## What Zoralone Forte is used for

Zoralone Forte is used in the treatment of many conditions:

- asthma
- Allergic disorders
- Fever due to inflammation that may develop after a bacteria infection
- Rheumatoid arthritis (joint pain and inflammation)
- Inflammatory skin disease

Zoralone Forte is also used to reduce the symptoms of skin

inflammation (such as swelling, redness, pain, tenderness or itching).

## How Zoralone Forte works

It works by entering inflammatory cells and blocking the inflammatory reaction.

## Ask your doctor if you have any questions about why Zoralone Forte has been prescribed for you.

Your doctor may have prescribed it for another reason. There is no evidence that it is addictive.

## Before you use Zoralone Forte

### -When you must not use it

#### Do not take Zoralone Forte if:

- You are allergic to Prednisolone or glucocorticoids or to any of the ingredients listed at the end of this leaflet.
- You have a current serious or uncontrolled infection, including fungal infections.
- You have stomach ulcer, osteoporosis (brittle bone), psychoses (mental disorder), severe psychoneurosis (mental disorder), acute bacterial infection, certain viral infections example varicella and herpes genitalis and glaucoma (increased pressure in the eye).

**Do not take Zoralone Forte to treat any other complaints unless your doctor has instructed you to do so.**

### -Before you start to use it

**Tell your pharmacist or doctor if you are allergic to other medicines foods, dyes or preservatives.**

#### Please inform doctor if you have:

- tuberculosis (bacteria infections that mainly affect the lungs)

- high blood pressure
- sugar in the urine
- low potassium blood level
- gastric discomfort
- mental changes

**Your doctor may stop gradually, increase dosage or restart the glucocorticoid therapy according to your conditions. Your doctor may arrange some tests before prescribing prednisolone because glucocorticoid may mask some signs of infections and new infections may appear.**

**While on glucocorticoid therapy, you should not be vaccinated with live vaccine. If you are pregnant, trying to become pregnant or breastfeeding, you must tell your doctor before you start the treatment.**

### -Taking other medicines

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

Zoralone Forte should only be given under your doctor's supervision. Please inform your doctor if you are taking:

- barbiturates-a type of sedative medicine
- phenylbutazone-analgesic (pain relief)
- phenytoin-treat seizures
- rifampicin-antibiotic for bacteria infection
- anticoagulant-prevent blood clots
- diuretics-promotes the secretion of water from the body

-Use in children

If possible, children should not be exposed to common childhood illnesses such as chickenpox or measles while they are taking this medicine. They may suffer from more serious attacks of these illnesses if such exposure occurs.

Children should not be vaccinated with 'live' vaccines against common childhood illnesses while they are taking it, as this may result in severe attacks of these illnesses.

Potentially serious side effects can occur in children and growing teenagers who are taking corticosteroids. Some of these include slowed growth, osteoporosis (bone become brittle) and changes to the adrenal glands (hormone imbalance).

**How to use Zoralone Forte**

-How much to use

The dose will depend on the condition being treated and your response to the treatment. Your initial dose will be maintained or adjusted until a satisfactory response is noted.

For children with normal hormone secretion, recommended 0.5 to 2mg per kg daily of prednisolone in 3 or 4 divided doses after meals.

Your doctor will tell you how much Zoralone Forte to take.

-When to use it

Zoralone Forte is best taken immediately after food.

How often Zoralone Forte can be taken may vary depending on what condition is being treated. If you are taking **Zoralone Forte**:

Once a day: It is better to be taken at the same time each day as instructed by your doctor.

Several times a day: It is better if you can have the doses evenly spaced throughout the day.

**Do not miss any doses and do not stop taking the medicine even if you feel better.**

-How long to use it

**Continue taking Zoralone Forte for as long as your doctor or pharmacist tells you.**

This will depend on your condition and on your response to treatment. Some people will need this medicine for only short periods of time whilst others may require long term therapy.

-If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take the medicine at your next regularly scheduled time.

**Do not try to make up for missed doses by taking more than one dose at a time.**

-If you use too much (overdose)

**Immediately telephone your doctor for advice or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Zoralone Forte. Do this even if there are no signs of discomfort or poisoning. Bring any remaining medicine with you.**

**While you are using Zoralone Forte**

-Things you must do

**Take Zoralone Forte exactly as your doctor has prescribed.**

**Tell your doctor if your condition returns or becomes worse after your dose of Zoralone Forte has been reduced or treatment has been stopped.**

**Tell your doctor immediately if you become pregnant while taking Zoralone Forte.**

**Tell any other doctors, dentists and pharmacists who are treating you that you are taking Zoralone Forte, especially if you are being started on any new medicines.**

**Tell your doctor, surgeon or dentist that you are taking Zoralone Forte if you are about to undergo surgery or an operation.**

The trauma of the operation or surgery may mean that your dose of Zoralone Forte may need to be increased to cover the stressful period.

**Tell your doctor straight away if you are a diabetic, and you notice a change in the results of your blood or urine sugar tests.**

This medicine may affect your blood sugar levels as it can affect the body's ability to handle glucose. For diabetics, this means that your diabetes may become more severe. For others, diabetes may develop for the first time while taking corticosteroids such as Zoralone Forte.

**Ask your doctor when and how you should stop taking Zoralone Forte.**

-Things you must not do

**Do not give this medicine to anyone else, even if they have the same condition as you.**

**Do not stop taking Zoralone Forte suddenly unless advised by your doctor.**

**Do not have any immunisations (particularly with 'live' vaccines such as measles, oral polio or yellow fever) without your doctor's approval while you are being treated with Zoralone Forte.**

-Things to be careful of

**Avoid close contact with anyone who has a contagious disease such as measles or chickenpox.**

Exposure to such diseases while you are taking Zoralone Forte, particularly if large doses are being taken, can put you at greater risk of developing these diseases if you have not had them before.

**Tell your doctor straight away if you think you have been exposed to chickenpox or measles.**

As with any new medicine, you should take care when driving, operating machinery or drinking alcohol until you know how Zoralone Forte affects you.

The signs and symptoms of infections such as fever or inflammation may be hidden by the anti-inflammatory action of Zoralone Forte. You should see your doctor for medical advice for any but the most minor infections.

**Side effects**

**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Zoralone Forte.**

Zoralone Forte helps most people who take it but it may have unwanted side effects in some people. All medicines have side effects. Sometimes they are serious, most of the time they are not.

Some side effects can only be detected by your doctor. So, when Zoralone Forte is taken for long

periods of time it is important to visit your doctor regularly for check-ups.

Some side effects are as below:

- Disturbance of Electrolyte Balance - Sodium and water retention with swelling and high blood pressure increased removal of potassium with possibility of low blood potassium level.
- Metabolic Effects – Movement of calcium and phosphorous with osteoporosis (fragile bone) & spontaneous fractures, nitrogen depletion due to protein breakdown, high blood sugar level, increased requirement for insulin or other oral hypoglycemic agents in diabetes.
- Gastrointestinal - Stomach ulcer with possible perforation and haemorrhage, pancreas inflammation.
- Neurological - high blood pressure inside the skull and headache.
- Tissue Repair – Delayed wound healing which able to increased liability to infection.
- Endocrine - Suppression of growth in children.
- Musculoskeletal – Muscle weakness, aseptic necrosis of the bone (death of bone tissue due to poor blood supply).
- Ophthalmic such as posterior subcapsular cataracts (clouding of eye lens), increased pressure in the eye.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

If you get any side effects, even those not mentioned in this leaflet, tell your doctor or pharmacist.

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

[portal.bpfk.gov.my](http://portal.bpfk.gov.my) (Consumers → Reporting)

**Storage and Disposal of Zoralone Forte**

-Storage

Store below temperature 30 °C.  
Keep in a cool dry place, protected from light.  
Keep out of reach of children.

-Disposal

Dispose the medicine after the expiry date.  
Consult your pharmacist on how to dispose of any medicines no longer required.

**Product description**

-What it looks like

A clear light brown sugar-free liquid with blackcurrant and ice cream soda flavour.

Zoralone Forte is packed in 60ml PET amber bottle.

-Ingredients

Active ingredient:  
Each ml contains 5mg of prednisolone.

Inactive ingredients:  
Methylparaben, Propylparaben, Disodium Hydrogen Phosphate Dihydrate, Sodium Dihydrogen Phosphate Dihydrate, Glycerin, Disodium Edetate, Blackcurrant Flavour, Ice Cream Soda Flavour and Purified Water.

MAL number: MAL11075002A

**Manufacturer:**

HOE Pharmaceuticals Sdn. Bhd.  
Lot 10, Jalan Sultan Mohd. 6,  
Bandar Sultan Suleiman,  
42000 Port Klang, Selangor,  
Malaysia.

**Product Registration Holder:**

HOE Pharmaceuticals Sdn. Bhd.  
Lot 10, Jalan Sultan Mohd. 6,  
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Malaysia.

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