

ZORALONE SYRUP

Prednisolone (3mg/5ml)

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

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 Syrup 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 Syrup is used for

Zoralone Syrup 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 Syrup is also used to reduce the symptoms of skin inflammation (such as swelling, redness, pain, tenderness or itching).

How Zoralone Syrup works

Zoralone Syrup contains Prednisolone as active ingredient.

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

Ask your pharmacist or doctor if you have any questions about this medicine.

Before you use Zoralone Syrup

-When you must not use it

Do not take Zoralone Syrup if:

- You are allergic to Prednisolone or glucocorticoids or to any of the ingredients listed at the end of this leaflet.
- 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).

-Before you start to use it

Growth and development of infants and children on prolonged glucocorticoid therapy should be carefully observed.

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.

-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 especially:

- barbiturates-a type of sedative
- phenylbutazone-analgesic (relieves pain)
- phenytoin-anticonvulsant
- rifampicin-antibiotic for bacteria infections
- anticoagulants-blood thinning agent
- diuretics-promotes the water removal from the body

How to use Zoralone Syrup

-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.

-When to use it

Zoralone Syrup is best taken immediately after food.

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

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 Syrup 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 Syrup.

While you are using it

-Things you must do

If you are about to start taking on any other new medicine, tell your pharmacist or doctor that you are taking Zoralone Syrup.

-Things you must not do

Do not take any new medication without discussion with your doctor or pharmacist.

-Things to be careful of

Special attention is required during use Zoralone Syrup.

Side effects

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

Zoralone Syrup 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 Syrup 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 intraocular pressure in the eye.

Some people may get other side effects while using Zoralone Syrup.

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 (Consumers → Reporting)

Storage and Disposal of Zoralone Syrup

-Storage

Store below 30°C.
Keep container well closed.
Protect from light.
Keep out of reach of children.

-Disposal

Dispose the medicine after the expiry date.

Consult your pharmacist on how to safely dispose of any medicines no longer required.

Product description

-What it looks like

An off straw colour syrup with aroma of raspberry and sweet minty taste followed by bitter after-taste.

Zoralone Syrup is packed in 60ml, 90ml PET bottle and 120ml, 3600ml PE bottle.

-Ingredients

Active ingredients:

Each 5ml contains 3mg of prednisolone.

Inactive ingredients:

Sodium Benzoate, Citric Acid, Chloroform Spirit, Aniseed Oil, Raspberry flavour, Banana Flavour 103, Menthol, Sucrose, Saccharin Sodium, Peppermint Oil and Purified Water.

-MAL number: MAL19870539AZ

Manufacturer and Product Registration Holder

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