

# REXOLONE SYRUP

Prednisolone (3mg/5ml)

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## What Rexolone is used for

For the treatment of adrenal insufficiency, immunosuppressant, anti-inflammatory and suppressive treatment of allergic reaction.

## How Rexolone works

Rexolone contains Prednisolone as active ingredient. It works by entering inflammatory cells and blocking the inflammatory reaction.

## Before you use Rexolone

### - When you must not use it

Do not use:

- in individuals with gastric ulceration, psychoses (mental health) and severe psychoneurosis (mental health), osteoporosis (brittle bone), acute infections, and vaccination with live vaccines.
- in the presence of congestive heart failure or high blood pressure, diabetes, epilepsy (seizures), increased eye pressure, infectious diseases, eye herpes simplex (eye infection), chronic kidney failure and uremia (excess of waste products in the blood) in elderly persons.
- if you have tuberculosis (bacterial infections that mainly affects the lungs)
- if you have hypersensitivity to any of the ingredient of Rexolone.

### -Before you start to use it

#### *Use in children*

Long term use of corticosteroids may suppress growth and development of the children or adolescent and should be undertaken with caution. Growth retardation may be irreversible, so prolonged or continuous treatment rarely given. Children may be at increased risk of developing osteoporosis (brittle bone), death of thigh bone tissue, damage to

eye's optic nerve or clouding of the eye's natural lens during prolonged therapy.

#### *Pregnancy and lactation*

Talk to your doctor before taking this medicine if you are pregnant, might become pregnant or are breastfeeding.

Corticosteroids crosses placenta. Weigh benefits against potential hazards to the mother and fetus.

Corticosteroids appear in breast milk and could suppress growth, interfere with internal corticosteroids production or cause unwanted effects in the nursing infant.

#### *Withdrawal*

Withdrawal must always be gradual, tapered off over weeks or months depending on dosage and duration of therapy. Too rapid reduction of dosage, following a prolonged course (7 days or more), can lead to acute adrenal insufficiency, low blood pressure or death.

#### -Taking other medicines

Inform your doctor or pharmacist before taking this medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Rexolone may interfere with each other. They may be affected by Rexolone or may affect how well it works especially:

- Barbiturates, carbamazepine, phenytoin, primidone and rifampicin (medicine for seizures)
- Potassium-depleting diuresis, such as thiazides or furosemide (medicine for high blood pressure)
- Nonsteroidal Antiinflammatory Drugs (NSAIDs) (reduce inflammation, pain and fever)
- Antidiabetics (stabilize and control blood glucose levels amongst people with diabetes)
- Antihypertensive (treat high blood pressure)
- Anticoagulants (prevent blood clots)
- Salicylates (reduce pain and fever).
- Antimuscarinics (treatment of digestive system)

## How to use Rexolone

### -How much to use

Always use Rexolone exactly as your doctor has prescribed. You should check with your doctor or pharmacist if in doubt.

### -The usual dose:

#### **Adult**

Initially: 10-20mg (16.7-33.3ml) daily, once or in divided doses (severe disease, up to 60mg daily in divided doses).

Maintenance: 2.5-15mg (4.17-25ml) daily, once or in divided doses.

#### **Children**

Initially: 0.2-2mg/kg (0.33-3.33ml/kg) body weight daily in divided doses.

Tapering: Gradually reduce by 2.5mg (4.17ml) to maintenance.

### -When to use it

Use as directed by your doctor or pharmacist.

### -How long to use it

Continue taking Rexolone as your doctor recommended.

### -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 Rexolone may cause:

- Acute adrenal insufficiency due to too rapid corticosteroid withdrawal after long term use resulting in fever, muscle pain, joint pain, reduce appetite, nausea, skin peeling, postural low blood pressure, dizziness, fainting, difficult breathing and low blood glucose level.

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- Cushingoid changes from continued use of large doses resulting in round, moon-shaped face, central obesity, stretch mark, excess body hair, acne, ecchymosis (discoloration of the skin resulting from bleeding underneath), high blood pressure, osteoporosis (brittle bone), myopathy (muscle disease), sexual dysfunction, diabetes, hyperlipidemia (high cholesterol), peptic ulcer (ulcer in the stomach and small intestine), increased susceptibility to infection and electrolyte and fluid imbalance.

## While you are using Rexolone

### -Things you must do

- Tell all the doctors, dentists and pharmacists treating you that you are taking Rexolone.
- Tell your doctor immediately if you become pregnant while taking this medication.

### -Things you must not do

- Do not take more than the recommended dose unless your pharmacist or doctor tells you.
- Do not take any new medicines without consulting your doctor or pharmacist.
- Do not give Rexolone to anyone else, even if they have the same symptoms or condition as you.

### -Things to be careful of

- Be careful driving or operating machinery until you know how Rexolone affects you.

## Side effects

Like all medicines, Rexolone can cause side effects, although not everybody gets them.

If symptoms persist, refer to the doctor.

**Tell your doctor** if you notice any of the following side effects or notice any other effects not listed:

- Metabolic effects leading to osteoporosis (brittle bone), nitrogen depletion and high blood glucose level.
- Increase appetite, delayed wound healing and increased susceptibility to all kinds of infection.
- Cushing's syndrome, growth retardation in children and acute adrenal insufficiency (hormonal disorder that occurs when the adrenal

glands do not produce enough of certain hormone).

- Amenorrhoea (absence of menstrual periods in a woman), abnormally increased sweating, skin thinning, metal and neurological (brain, spine and nerve) disturbances.
- High blood pressure in the skull, acute inflammation of the pancreas, bone death, increasing clotting of blood leading to thromboembolism (formation of a blood clot inside a blood vessel), peptic ulceration and less frequently electrolyte disturbances (altered potassium, magnesium, chloride, sodium, or calcium levels).

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](http://npra.moh.gov.my) (Public → Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

## Storage and disposal of Rexolone

### -Storage

Keep container tightly closed. Store below 30°C. Protect from heat and light. Keep medicine out of reach of children.

### -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

### -What it looks like

Light pink liquid with raspberry flavour.

### -Ingredients

-Active ingredient  
Each 5ml contains  
3 mg Prednisolone

### -Inactive ingredients

Raspberry Flavour, Carmoisine Supra, Propylene Glycol, Citric Acid Anhydrous, Liquid Glucose, Sodium Benzoate, Sugar Syrup, Purified water.

### -MAL number:

MAL20013122AZ

## Manufacturer and Product Registration Holder

KCK Pharmaceutical Industries Sdn. Bhd.  
Plot 61, Bayan Lepas Industrial Park  
Phase 4, 11900 Penang,  
Malaysia.

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