

NISOLON TABLET

Prednisolone (5mg)

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What NISOLON TABLET is used for

NISOLON TABLET is used in the treatment of many different conditions. Some of these conditions include: severe allergies, severe or chronic asthma, skin problems, arthritis, inflammatory diseases of the bowel, cancer and “auto-immune” diseases.

It is also used to prevent or reduce the symptoms of inflammation (such as swelling, redness, pain, tenderness or itching) in any part of the body.

These symptoms can occur in response to injury or can be caused by many different conditions.

Ask your doctor if you have any questions about why NISOLON TABLET has been prescribed for you. Your doctor may have prescribed it for another purpose.

How NISOLON TABLET works

NISOLON TABLET contains prednisolone as the active

ingredient. Prednisolone belongs to a group of medicines called corticosteroids which are a synthetic version of a naturally occurring body hormone called cortisol.

NISOLON TABLET works by entering inflammatory cells and blocking the inflammatory reaction. This medicine is only able to prevent or reduce symptoms of your condition, it does not cure it.

Before you use NISOLON TABLET

- When you must not use it

Do not use NISOLON TABLET if you are allergic to prednisolone or any of the other ingredients listed at the end of the leaflet.

Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty in breathing; swelling of the face, lips, tongue or any other parts of the body; rash, itching or hives on the skin.

Do not take it if you have

- Osteoporosis (softening of the bone)
- Stomach ulcer
- Fungal infection
- Mental disorder

Do not take NISOLON TABLET after the expiry date (EXP) printed on the pack.

It may have no effect at all or an entirely unexpected effect if you take it after the expiry date.

Do not take it if the bottle shows signs of having been tampered with.

Do not take this medicine to treat

any other complaints unless your doctor has instructed you to do so.

- Before you start to use it

Before taking NISOLON TABLET, you must tell your doctor or pharmacist if you, or have had, any of the following conditions:

- Recent surgery or serious injury
- Infectious disease including tuberculosis
- Underactive thyroid
- Diabetes
- Other stomach or intestinal problems
- Kidney or heart disease
- Muscle weakness
- High blood pressure
- Viral eye infection

Talk to your doctor or pharmacist before taking NISOLON TABLET, if you have:

- have pheochromocytoma (a tumour of the adrenal gland)
- 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.

If you are not sure if you have, or have had, any of these conditions, you should raise those concerns with your doctor or pharmacist.

Pregnancy

Ask for your doctor's advice if you are pregnant, or likely to become pregnant during your course of medication.

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Breastfeeding

Ask for your doctor's advice if you are breastfeeding, or likely to breastfeed during your course of medication.

NISOLON TABLET is expected to enter the breast milk.

It is not recommended that NISOLON TABLET be taken by women who are breastfeeding.

Some medicines may increase the effects of NISOLON TABLET and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV such as cobicistat).

- Taking other medicines

Inform your doctor or pharmacist before taking NISOLON TABLET.

Some medicines may interfere with NISOLON TABLET. These include:

- Medicines for diabetes
- Some medicines for heart burn (Antacids)
- Some medicines for heart disease
- Aspirin (used to treat pain, fever or inflammation)
- Anticoagulants (used to prevent blood clots)
- Methylprednisolone (medication used to suppress immune system and reduce inflammation)
- Cyclosporin (used to prevent rejection in people who have received organ or heart transplant)
- Some medicines for epilepsy (barbiturates, phenytoin and rifampicin, phenobarbital)

- Some types of antibiotics (troleandomycin) or antifungal (ketoconazole)
- Potassium supplements or salt containing medications
- Immunisations or vaccines.
- Medicines for removal of fluid (diuretics)

These medicines may be affected by NISOLON TABLET or may affect how well it works. You may need to take different amounts of your medicine or you may need to take different medicines. Your doctor or pharmacist has a more complete list of medicines to be careful with or avoid while taking NISOLON TABLET.

Use in children

Take special care when giving NISOLON TABLET to children. It should only be given under your doctor's supervision. If possible, children should not be exposed to common childhood illnesses such as chicken pox or measles while they are taking NISOLON TABLET. 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 including slow growth.

How to use NISOLON TABLET

- How much to use

Follow the instructions carefully. If you do not understand the instructions on the label, ask your

doctor, or pharmacist for help.

The usual dose:

Adults and adolescent dose:

5 to 60 mg a day as a single dose or in divided doses. It can be up to 250mg a day.

Children:

- Adrenal glands insufficiency – 0.14 mg per kg of body weight a day in 3 divided doses.
- Other indications – 0.5 mg to 2 mg per kg of body weight a day in 3 or 4 divided doses.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking NISOLON TABLET as your doctor recommended. If symptoms persist, consult your doctor.

Sudden withdrawal of the hormone treatment using NISOLON TABLET may trigger acute adrenal insufficiency with muscle weakness, low blood pressure, low blood glucose level, headache, nausea, vomiting, restlessness and muscle and joint pain.

- 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.

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- 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.

While you are using NISOLON TABLET

- Things you must do

Tell all the doctors, dentists and pharmacists treating you that you are taking NISOLON TABLET.

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 NISOLON TABLET 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 NISOLON TABLET affects you.

Side effects

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

If side effects persist, do not take the medicine and refer to the doctor.

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

- Accumulation of body fluid and sodium level.
- Heart failure
- Potassium loss
- High blood pressure
- Elevated pH of body tissue due to low potassium level
- Muscle weakness
- Loss of muscle mass
- Osteoporosis (softening of bone)
- Ulcer in the stomach or small intestine
- Inflammation of pancreas
- Increase in liver enzyme
- Impaired skin healing
- Thin and fragile skin
- Purple/red/brown spots on skin
- Increase sweating
- Negative nitrogen balance
- Increased pressure around the brain
- Seizure
- Spinning sensation
- Headache
- Menstrual irregularities
- Growth suppression
- Decreased carbohydrate tolerance/ increase blood sugar/ increased needs for insulin or diabetes medication
- Increased pressure in the eyes
- Bugling of eyes
- Clouding of eye lens
- Hives
- Allergic reactions such as rashes

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse

Drug Reaction Monitoring by visiting the website <http://www.npra.gov.my> (Consumer → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage and disposal of NISOLON TABLET

- Storage

Store below 30°C. Protect from light. Keep 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. These measures will help to protect the environment.

Product Description

- What it looks like

A white, 7 mm diameter round tablet, with marking 'd' and scored on another side.

- Ingredients

- Active ingredient:

- Prednisolone

- Inactive ingredient:

- Aerosil
- Cornstarch
- Magnesium stearate
- Promigel
- Lactose

- MAL number

MAL19890024AZ

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**Manufacturer and Product
Registration Holder:**

Duopharma (M) Sdn. Bhd.
Lot. 2599, Jalan Seruling 59,
Kawasan 3, Taman Klang Jaya,
41200 Klang, Selangor Darul
Ehsan, Malaysia.

Date of Revision

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