

DEXALONE TABLET

Dexamethasone (0.5mg, 0.75mg)

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What Dexalone Tablet is used for

Dexamethasone can be used to:

- reduce inflammation
- treat a number of different diseases of the immune system

Please refer to the doctor for more information.

How Dexalone Tablet works

Dexalone Tablet contains dexamethasone. This belongs to a group of medicines called corticosteroids. Corticosteroids work by reducing inflammation.

Before you start to use Dexalone Tablet

- When you must not use it

Do not take this medicine:

- after the expiry date printed on the pack
- if the packaging is torn or shows signs of tampering.
- if you are allergic (hypersensitive) to dexamethasone or any other ingredients in this medicine. The signs of an allergic reaction include a rash, itching or shortness of breath
- if you have an infection
- if you have taken vaccination recently

If you are not sure whether you should start taking it, talk to your doctor or pharmacist.

Doctor will prepare a few test or examination for you e.g. blood test, urine test, stool test, eye examination, growth and development for children and adolescent.

Pregnancy and lactation

Do not take Dexalone Tablet if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take Dexalone Tablet if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

Dexamethasone may be found in breast milk and may cause unwanted effects.

- Before you start to use it

Tell your doctor if you have:

- Acquired Immunodeficiency Syndrome (AIDS) or Human Immunodeficiency Virus (HIV)
- Recent intestinal surgery
- Heart diseases
- High blood pressure
- Kidney or liver impairment
- Undergoing dialysis
- Recent exposure to Chickenpox or Measles
- Diabetes
- Systemic infection
- Glaucoma (Increased pressure within eyeball causing gradual loss of sight)
- Osteoporosis (Porous and fragile bone)
- Ocular herpes simplex (Eye viral infection)
- Hyperlipidemia (High fats in blood)
- Abnormal level of thyroid hormones

- Myasthenia gravis (Abnormal muscle weakness)
- Oral herpetic lesions (Virus infection causing painful sores on lips, gums, tongue, roof of mouth or inside cheeks).
- Tuberculosis (Bacterial infection that mainly affects the lungs)
- Systemic lupus erythmatosus (Condition where one's own immune system attacks healthy tissues)

- Taking other medicines

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

Other medicines can affect the way Dexamethasone works or Dexamethasone can affect the way they work. In particular:

- Oral contraceptives containing estrogen
- Medicines to treat epilepsy such as barbiturate, carbamazepine, phenytoin and primidone
- Antibiotics such as rifampicin
- Medicines to relieve pain and reduce inflammation such as Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)
- Medicines to treat blood problems including anticoagulant and thrombolytic agents
- Medicines to treat diabetes such as insulin
- Water tablets such as diuretic
- Medicines to treat heartburn, stomach irritation and indigestion such as antacids
- Anti-cancer medicine such as Aminoglutethimide

- Medicines used to relieve symptoms of blocked nose such as Ephedrine
- Medicines used to treat glaucoma such as Acetazolamide
- Supplements for potassium, sodium and folic acid.
- Pain relieving medicine such as Salicylates

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while taking Dexalone Tablet.

How to use Dexalone Tablet

- How much to use

Dosing range between 0.5mg to 9mg daily as a single dose or in divided doses.

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking Dexalone Tablet for as long as your doctor recommends.

- 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 many tablets may cause indigestion or mild gastrointestinal irritation and mental depression or psychoses.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Dexalone Tablet. Avoid taking alcohol.

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.

Do not take any new medicines without consulting your doctor or pharmacist.

Do not give Dexalone Tablet to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines.

If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

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

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Steroids including Dexamethasone can cause serious mental health problems.

Other side effects include increased appetite, indigestion, nervousness or restlessness, having problems sleeping, cataracts (clouding of lens of eye), diabetes, changes in skin colour (hypo pigmentation), dizziness, flushing, increased hair growth on face or body, generalised allergic reaction, sudden blindness, delirium (disturbed state of mind), feeling high or moods that go up and down, disorientation, hallucination (feeling, seeing or hearing things that do not exist), mental depression, paranoia, increased blood clot, osteoporosis, unusual bruising and impaired wound healing.

Dexamethasone may mask the symptoms of progression or reactivation of nonspecific ulcerative colitis (inflammation of large intestine), diverticulitis (inflammation of bulging sacs in the large intestine wall), esophagitis (inflammation of esophagus), gastritis (inflammation of stomach lining), or peptic ulcer (ulcer in stomach or intestine).

Thus internal bleeding and/or perforation may occur without warning.

Sudden withdrawal or reduction in dosage may precipitate adrenal insufficiency causing malaise, muscle weakness, muscle or joint pain, abdominal or back pain, dizziness, fainting, low-grade fever, prolonged loss of appetite, nausea, vomiting, shortness of breath, frequent or

continuing unexplained headaches, unusual tiredness or weakness, rapid weight loss, hypoglycemia (low blood sugar), hypotension (low blood pressure), and dehydration. Reappearance of disease may also occur.

Tell your doctor straight away if you notice any of these problems, talk to a doctor straight away.

If you have allergic reactions to Dexamethasone see a doctor straight away.

An allergic reaction may include:

- Any kind of skin rash or itching of the skin
- Difficulty in breathing or collapse

If any of the side effects gets serious, or if you notice any side effects not listed 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 visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Dexalone Tablet

- Storage

Keep out of reach and sight of children. Store in a dry place below 30°C.

- 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

Dexalone Tablet 0.5mg
A 6.5 mm diameter, round, flat, scored, white tablet.

Dexalone Tablet 0.75mg
An oval shape, scored, white tablet.

- Ingredients

- Active ingredient
Each tablet of Dexalone Tablet 0.5mg and 0.75mg contains dexamethasone 0.5mg and 0.75mg.

- Inactive ingredients

- Corn Starch
- Tween 80
- Lactose
- Isopropyl Alcohol
- Magnesium Stearate

- MAL numbers:

Dexalone Tablet 0.5mg:
MAL19870623AZ

Dexalone Tablet 0.75mg:
MAL19870636AZ

Manufacturer

Duopharma Manufacturing (Bangi) Sdn Bhd
Lot 2&4, Jalan P/7, Section 13, Bangi Industrial Estate, 43650 Bandar Baru Bangi, Selangor Darul Ehsan

Product Registration Holder

Duopharma Manufacturing (Bangi) Sdn Bhd
Lot No. 2, 4, 6, 8 & 10, Jalan P/7, Section 13, Bangi Industrial Estate, 43650 Bandar Baru Bangi, Selangor Darul Ehsan

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