

# Avalair Chewable Tablets 4mg

Montelukast Sodium 4.16mg, equivalent to Montelukast 4mg

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## **What AVALAIR is used for**

The name of your medicine is Avalair Chewable Tablets 4mg (Called 'Avalair' in this leaflet). Avalair contains a medicine called montelukast sodium.

Avalair is used to prevent and treat chronic asthma in adults and pediatrics patients 12 months of age and older.

It is also used for the relief of daytime and nighttime symptoms of seasonal allergic rhinitis (hay fever) in adults and pediatrics patients 2 years of age and older.

## **How AVALAIR works:**

Avalair is a leukotriene receptor antagonist that blocks substances called leukotrienes. Leukotrienes cause narrowing and swelling of airways in your lungs. Blocking leukotrienes improves asthma symptoms and helps prevent asthma attacks. Leukotrienes also cause allergy symptoms. Blocking leukotrienes improves allergic rhinitis (seasonal and perennial, also known as outdoor and indoor nasal allergies).

## **Before you use AVALAIR**

*When you must not use it.*

Do not take this medicine and tell your doctor if you or your child:

- Are allergic to any of its components.
- If you have 'phenylketonurics' as this product contains Aspartame.

*Before you start to use it*

Check with your doctor or pharmacist before taking this medicine:

- If you have any medical problems or allergies you or your child has now or has had.
- If you are pregnant or planning to become pregnant.
- If you are breast feeding or plan to breastfeed.

## *Taking other medicines*

In general, Avalair does not interfere with other medicines that you or your child may be taking. However, some medicines may affect how Avalair works, or Avalair may affect how your other medicines work. They include:

- Gemfibrozil
- Prednisone
- Repaglinide
- Phenytoin
- Phenobarbital
- Rifampicin

It is important to tell your doctor or pharmacist about all drugs that you or your child is using or plan to use, including those obtained without a prescription.

## **How to use Avalair**

Your doctor or pharmacist will advise you how much to take and how long to use Avalair. Read the direction labels carefully.

## *How much to use?:*

The dose is one 4mg chewable tablet taken once daily, in the evening.

The dosage for pediatric patients 2 to 5 years of age is one 4mg chewable tablet once daily.

Chew the chewable tables thoroughly and swallow.

The dosage for pediatric patients 12 months to 2 years of age is by using one packet of Avalair 4mg oral granules, once daily.

## *When to use it?:*

Avalair can be taken with or without food in the evening

## *How long to use it?:*

It is important to continue taking Avalair for as long as your doctor prescribes it in order to maintain

control of your or your child's asthma.

Avalair can treat you or your child's asthma only if you or your child continue to take it.

## *If you forget to use it:*

Try to take Avalair as prescribed. However, if your child misses a dose, just resume the usual schedule of one tablet once daily. Do not double up the dose.

## *If you take too much (overdose):*

Contact your doctor immediately or go to the nearest hospital emergency room right away.

## **While you are using Avalair**

*Things you must do.*

It is important that you or your child continue taking Avalair daily as prescribed by your doctor, even when you or your child has no symptoms or if you or your child has an asthma attack.

If your or your child's asthma symptoms get worse, you should contact your doctor immediately.

Avalair is not for the treatment of acute asthma attacks. If an attack occurs, you or your child should follow the instructions your doctor has given you for that situation.

Behavior and mood-related changes have been reported in patients taking Avalair. If you or your child experience these changes while taking Avalair (see "Side effects"), tell your doctor.

## *Things you must not do*

- Do not stop your medication without consulting your doctor and never give it to anyone else.
- Do not give Avalair 4mg chewable tablet to children less than 2 years of age as the safety and efficacy has not been established.

## *Things to be careful of:*

- Do not use Avalair during acute asthma attack. If an attack occurs, you or your child should follow

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the instructions your doctor has given you for that situation.

- If you are allergic to aspirin or non-steroidal anti-inflammatory agents, your symptoms become worst

## Side effects

Any medicines may give you undesirable side effects. Avalair is generally well-tolerated and the side effects usually were mild, did not require discontinuation of therapy.

Tell your healthcare provider right away if you notice any other the following behavior and mood-related changes:

- Obsessive-compulsive symptoms

## Cardiovascular effect:

- Heart throb
- Churg-Strauss syndrome: disorder marked by blood inflammation.

## Skin and subcutaneous tissue disorder:

- Bruising, eczema, rash, urticaria.

## Gastrointestinal Effects:

- abdominal pain, dental pain, diarrhea, gastroenteritis (irritation and inflammation of stomach and intestines), indigestion, infection of tooth, nausea, pancreatitis, tonsillitis, vomiting

## Hematologic Effects:

- Blood coagulation disorder (increased bleeding tendency)

## Hepatic Effects:

- Liver enzymes increase.
- Hepatitis (liver inflammation).

## Immunologic Effects:

- Allergic reactions.

## Neurologic Effects:

- Body weakness, dizziness, headache, hyperactive behavior, insomnia, seizure, sinus headache,

drowsiness, and tremor

## Ophthalmic Effects:

- Conjunctivitis, short sightedness

## Otic Effects:

- Otalgia (ear ache), Otitis media (ear infection)

## Psychiatric Effects:

- Aggressive behavior, agitation, altered behavior, anxiety, depression, dream disorder, feeling nervous, hallucinations, irritability, nightmares, restlessness, sleep disorder, suicidal thinking and behavior (including suicide)

## Renal Effects:

- Pus in the urine

## Respiratory Effects:

- Bronchitis, cough, nasal congestion, nasal discharge, sore throat, respiratory tract infection, upper respiratory infection, wheezing.

## Musculoskeletal and connective tissue disorders:

- Joint pain and muscle pain

## Other:

- Tiredness fever, traumatic injury

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website [npra.gov.my](http://npra.gov.my) [(Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI))

## Storage and disposal of Avalair

### Storage:

- Keep out of the reach and sight of children.
- Do not use Avalair after the expiry date refers to the last day on the carton. The expiry date refers to the last day of that month.
- Store below 30°C in the original pack in a dry place. Protect from light and moisture.

- Do not use Avalair if the tablets are chipped or there are other visible signs of deterioration.

## 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?:* Avalair chewable tablet 4mg is a pink, oval, bi-convex-shaped chewable tablets, engraved with "CCP D79" on one side.

## Ingredients in Avalair

Active ingredients: Montelukast Sodium

Inactive ingredients: Mannitol oral, Lactose, Red ferric oxide, Croscarmellose sodium, Colloidal silicon dioxide, hydroxypropyl cellulose, magnesium stearate, aspartame, flavor orange.

*MAL number:* MAL18116130ACZ

## Manufacturer

China Chemical & Pharmaceutical Co. Ltd. (CCPC Ltd)  
182-1, Keng Tze Kou, Hsinfong, Hsinchu, Taiwan R.O.C.

## Product Registration Holder:

Nano Medic Care Sdn Bhd  
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