

# Stadeltime Film-Coated Tablet 5mg

- What Stadeltime Film-Coated Tablet 5mg looks like**  
Stadeltime Film-Coated Tablet 5mg appears as white, caplet-shaped, film-coated tablet, biconvex, engraved with "5" on one side and plain on the other side.
- What Stadeltime Film-Coated Tablet 5mg contains**  
*Active substance:*  
Each tablet contains 5mg levocetirizine dihydrochloride.  
*Other ingredients:*  
Microcrystalline cellulose, lactose monohydrate, low-substituted hydroxypropyl cellulose, magnesium stearate, colloidal anhydrous silica, hypromellose, macrogol 6000, talc and titanium dioxide.
- What Stadeltime Film-Coated Tablet 5mg is**  
The active substance in Stadeltime Film-Coated Tablet 5mg is levocetirizine. Levocetirizine belongs to a group of antiallergic medicines called antihistamines.
- What Stadeltime Film-Coated Tablet 5mg is used for**  
Stadeltime Film-Coated Tablet 5mg is used to treat symptoms such as sneezing, a runny nose and watery eyes associated with allergic rhinitis (including persistent allergic rhinitis) and to relieve the rashes and itching of chronic urticaria.
- Before you take Stadeltime Film-Coated Tablet 5mg**

## Do not take Stadeltime Film-Coated Tablet 5mg

- if you are allergic (hypersensitivity) to levocetirizine, cetirizine, hydroxyzine, any piperazine derivatives (closely related active substances of other medicines) or any other ingredients of Stadeltime Film-Coated Tablet 5mg (listed in Section 2).
- if you have severe kidney disease (severe impairment of kidney function with creatinine clearance below 10ml/min).
- if you use other antiallergic medicines.

## Take special care with Stadeltime Film-Coated Tablet 5mg

Tell your doctor or pharmacist if you have any of the following conditions:

- if you have difficulty passing urine or you have conditions that make you more likely to be unable to empty your bladder, such as spinal cord injury or enlarged prostate.
- if you have kidney problems (your doctor may lower your dose of Stadeltime Film-Coated Tablet 5mg).
- if you have epilepsy or you are at the risk of convulsions (fits).
- if you are pregnant or breast-feeding.
- if you have an intolerance to some sugars. This tablet contains lactose.

**Stadeltime Film-Coated Tablet 5mg is not recommended for children under 6 years**, as this formulation does not allow for appropriate dose adaption.

## While you are taking Stadeltime Film-Coated Tablet 5mg

- Avoid alcohol while you are taking Stadeltime Film-Coated Tablet 5mg.
- Stadeltime Film-Coated Tablet 5mg may affect your allergy test result. If you are scheduled for allergy testing, ask your doctor if you should stop taking Stadeltime Film-Coated Tablet 5mg for several days before testing.
- Contact your doctor if you have high temperature (fever), shivering or chills, as you may require other type of treatment.

## Conditions you need to look out for

- Stadeltime Film-Coated Tablet 5mg can make some existing conditions worse or cause severe allergic reactions or urinary retention.
- Some people may have suicidal thoughts when taking Stadeltime Film-Coated Tablet 5mg.
- You must look out for certain symptoms while you are taking Stadeltime Film-Coated Tablet 5mg, to reduce the risk of any problems.

## Other medicines and Stadeltime Film-Coated Tablet 5mg

- Tell your doctor or pharmacist if you are taking any other medicines, if you have taken any recently, or if you start taking new ones. This includes medicines bought without a prescription.
- Some medicines may affect how Stadeltime Film-Coated Tablet 5mg works or make it more likely that you will have side effects. Stadeltime Film-Coated Tablet 5mg can also affect how some other medicines work. These include:
  - theophylline (used to treat respiratory disease such as asthma)
  - ritonavir (used to treat HIV/AIDS)
  - medicines acting on the brain, for example other antihistamines such as hydroxyzine, clemastine, medicines used to treat anxiety such as diazepam or sleeping pills such as zolpidem (concurrent administration of Stadeltime Film-Coated Tablet 5mg with other agents acting on the brain may cause additional reductions in alertness and impairment of performance).

## Food and drink with Stadeltime Film-Coated Tablet 5mg

Caution is advised if you take Stadeltime Film-Coated Tablet 5mg at the same times as alcohol. In sensitive patients, the concurrent administration of Stadeltime Film-Coated Tablet 5mg and alcohol may cause additional reductions in alertness and impairment of performance.

## Pregnancy and breast-feeding

- There is only limited information about the safety of Stadeltime Film-Coated Tablet 5mg in pregnant women.
- Stadeltime Film-Coated Tablet 5mg should therefore be avoided in pregnant women. It can only be administered if necessary and after medical advice.
- Tell your doctor if you are pregnant or planning to become pregnant.
- Tell your doctor if you do become pregnant during treatment with Stadeltime Film-Coated Tablet 5mg.
- The ingredients in Stadeltime Film-Coated Tablet 5mg can pass into breast milk. If you are breast-feeding, you must check with your doctor before you take Stadeltime Film-Coated Tablet 5mg.

## Driving and using machines

- Stadeltime Film-Coated Tablet 5mg at the recommended dose is unlikely to affect your ability to drive or use machines. However, some patients being treated with Stadeltime Film-Coated Tablet 5mg may feel drowsy, tired or weak.
- Do not drive or use machines unless you are sure you are not affected.

## 6. How to take Stadeltime Film-Coated Tablet 5mg

### How much to take

- Always take Stadeltime Film-Coated Tablet 5mg exactly as your doctor or pharmacist have told you. You should check with your doctor or pharmacist if you are not sure.
- Do not take more than the recommended dose.
- Do not take Stadeltime Film-Coated Tablet 5mg for longer than 7 days, without advice of your doctor or pharmacist.
- Contact your doctor if your symptoms worsen or do not improve after 3 days.

The usual dose is:

- Adults and adolescents 12 years and above:** the daily recommended dose is 5mg (1 film-coated tablet), taken once a day.
- Children aged 6 to 12 years:** the daily recommended dose is 5mg (1 film-coated tablet), taken once a day.

## Special dosage instructions for specific populations:

- If you have impaired kidney function, you may be given a lower dose according to the severity of your kidney disease, and body weight will be taken into consideration in children. The dose will be determined by your doctor.

- If you have end-stage kidney disease or are undergoing dialysis you must not take Stadeltime Film-Coated Tablet 5mg.
- No dose adjustment is needed if you have liver impairment alone. However, if you have both liver and kidney impairment, please consult your doctor for dose adjustments.
- No dose adjustment is needed in the elderly, provided their kidney function is normal.

## How to take

Swallow the tablet whole, with some water.

Take Stadeltime Film-Coated Tablet 5mg once daily, with or without food.

It is best to take Stadeltime Film-Coated Tablet 5mg at bedtime as it can make you feel drowsy.

## If you forget to take Stadeltime Film-Coated Tablet 5mg

Do not take an extra dose to make up for a missed dose. Just take your next dose at the usual time.

## If you take too much Stadeltime Film-Coated Tablet 5mg

- If you take more Stadeltime Film-Coated Tablet 5mg than you should contact your doctor or pharmacist for advice.
- Symptoms of overdose in adults may include drowsiness. Children may initially show agitation and restlessness, followed by drowsiness.

## If you stop taking Stadeltime Film-Coated Tablet 5mg

Rarely pruritus (intense itching) may occur if you stop taking Stadeltime Film-Coated Tablet 5mg, even if those symptoms were not present before treatment initiation. The symptoms may resolve spontaneously. In some cases, the symptoms may be intense and may require treatment to be restarted. The symptoms resolve when the treatment is restarted.

## 7. Possible side effects

Like all medicines, Stadeltime Film-Coated Tablet 5mg can cause side effects, but not everybody gets them.

## Conditions you need to look out for

- Severe allergic reactions.** These have occurred in a small number of people, but their exact frequency is unknown. Signs include:
  - Raised and itchy rash (hives)
  - Swelling, sometimes of the face or mouth (angioedema), causing difficulty in swallowing or breathing
  - Collapse or loss of consciousness
- Suicidal thoughts.** Some people had suicidal thoughts when taking Stadeltime Film-Coated Tablet 5mg.

- Urinary retention.** Signs include pain when passing urine or inability to pass urine.

Contact your doctor immediately if you get any of these symptoms. Stop taking Stadeltime Film-Coated Tablet 5mg.

## Common side effects

These may affect up to 1 in 10 people:

- Headache, feeling drowsy
- Dry mouth
- Lack of energy
- Sleep disorders, diarrhoea, constipation (in children)

## Uncommon side effects

These may affect up to 1 in 100 people:

- Stomach pain
- Feeling weak
- Vomiting, headache (in children)

## Other side effects

Other side effects have occurred in a very small number of people but their exact frequency is unknown:

- Allergic reactions (hypersensitivity) including severe allergic reactions
- Increased weight, increased appetite
- Aggression, agitation, seeing or hearing things that are not really there, depression, difficulty in sleeping, nightmares, suicidal thoughts
- Fits (seizures), tingling or numbness of the hands or feet, dizziness, fainting, tremor, taste disturbance
- Visual disturbances, blurred vision, oculogyration (eyes having uncontrolled circular movements)
- Spinning sensation
- Fast or irregular heart beats, heart beating faster
- Shortness of breath.
- feeling sick (nausea), vomiting, diarrhoea
- Inflammation of the liver
- Small patches of swelling and redness of the skin, which may blister
- Itching, rash
- Itchy, bumpy rash (hives)
- Muscle and joint pain
- Pain when passing urine, inability to pass urine
- Swelling caused by fluid
- Intense itching (pruritus) upon discontinuation

Side effect that may show up in the blood test is abnormal liver function test (increased amounts of liver enzymes in the blood).

Tell your doctor or pharmacist if you have any of the side effects listed above or if you notice any side effects not listed in this leaflet.

## 8. How to store Stadeltime Film-Coated Tablet 5mg

- The expiry date of this pack is printed on the box. Do not use this pack after this date.
- Do not store above 30°C.
- Keep out of reach of children.
- Do not use Stadeltime Film-Coated Tablet 5mg if you notice any visible sign of deterioration.
- Medicines should not be disposed of using wastewater or household waste. Ask your pharmacist how to dispose of medicines which are no longer required. These measures will help to protect the environment.

## 9. Packaging

Blister of 10 film-coated tablets. Box of 5 blisters.

## 10. Name and address of product registrant

AUXILTO IMPEX PTE. LTD.

152 Beach Road

#26-02

Gateway East

Singapore 189721

## 11. Name, address of manufacturer

STELLAPHARM J.V. CO., LTD. – BRANCH 1

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