

SIMTEC TABLET

Cetirizine hydrochloride (10mg)

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What Simtec is used for

Simtec relieves symptoms associated with seasonal rhinitis (hay fever) and perennial rhinitis (occurs throughout the year) such as sneezing, irritated, runny and blocked up nose, itchy, red and watering eyes.

Simtec is also used to relieve symptoms associated with a skin condition called urticaria; these symptoms include swelling, redness and itchiness of the skin.

How Simtec works

Simtec belongs to a class of medicines known as antihistamines. Antihistamines help reduce allergic symptoms by preventing the effects of a substance called histamine, which is produced by the body during an allergic reaction.

Your doctor may have prescribed Simtec for another reason. Ask your doctor if you have any questions about why Simtec has been prescribed for you.

Before you use Simtec

- When you must not use it

Do not take Simtec if you are allergic to cetirizine hydrochloride or any of the tablet ingredients listed at the end of this leaflet.

Pregnancy and breastfeeding

The safe use of cetirizine during pregnancy has not been established. As a precaution, Simtec should not be used during the first 3 months of pregnancy. Do not use Simtec if you are breastfeeding.

Do not use Simtec in children less than 3 years old.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

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

- Before you start to use it

Tell your doctor or pharmacist if you:

- are allergic to any other medicines, especially antihistamines, or to any other substances such as foods, preservatives or dyes
- have kidney or liver impairment
- If you are pregnant, planning to become pregnant or are breast-feeding, ask your doctor or pharmacist for advice before taking this medicine. Simtec are not recommended in pregnancy or breastfeeding.

- Taking other medicines

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

Simtec should be used with caution if sedative (a substance that induces sedation by reducing irritability or excitement) is also being taken.

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

How to use Simtec

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 pack, ask your doctor or pharmacist for help.

- How much to use

Your doctor or pharmacist will tell you how much Simtec you will need to take each day. This depends on your condition and whether or not you are taking any other medicines.

- Adults: 10mg once daily.
- Children \geq 6 years: 10mg daily, either 5mg twice daily or 10mg once daily.
- Children between 3 and 6 years: 5mg daily, either 2.5mg twice daily or 5mg once daily.
- For kidney impairment, dosage should be reduced to 5mg once daily.
- For liver impairment, a dose of 5mg once a day is recommended.

- When to use it

It is advisable to take the medicine with a little liquid during the evening meal since the symptoms for which the product is given usually appear during the night. If you are affected by side effects, the dose may be taken as 5mg in the morning and 5mg in the evening.

If you are not sure what to do, ask your doctor or pharmacist.

- How long to use it

Continue taking Simtec for as long as your doctor recommends.

- If you forget to take it

If you forget to take a dose, take it as soon as you remember it.

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 of Simtec to make up for the dose that you missed.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

- *If you take too much(overdose)*

If you (or someone else) swallow a lot of tablets at the same time, or you think a child may have swallowed any, contact your doctor or pharmacist immediately. Take the container and any remaining tablets with you to show the doctor.

Taking too much of this medicine may cause drowsiness.

While you are using it

- *Things you must do*

You should only take the dose of Simtec that is directed by the doctor or pharmacist.

Tell your doctor if, for any reason, you have not taken your medicine exactly as directed.

Tell any other doctors, dentists and pharmacists who are treating you that you are taking Simtec.

If you are about to be started on any new medicines, tell your doctor, dentist or pharmacist that you are taking Simtec.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking Simtec.

- *Things you must not do*

Do not give Simtec to anyone else, even if they have the same condition as you.

Do not take Simtec to treat any other complaints unless your doctor or pharmacist tells you to.

- *Things to be careful of*

Somnolens effects (drowsiness) has been reported in some patients taking Cetirizine. Do not drive or participate in any activity such as operating machinery until you are sure this medication does not affect you.

Make sure you know how you react to Simtec before you drive a car, operate machinery, or do anything else that could be dangerous if you are feeling drowsy. If this occurs do not drive.

Be careful when drinking alcohol while taking Simtec. Your doctor may suggest you to avoid alcohol while you are being treated with Simtec.

Side effects

Like all medicines, Simtec can cause side effects, although not everybody gets them. Stop taking Simtec and contact your doctor at once if you notice signs of:

- Somnolence (sleepy), dry mouth, headache, dizziness.

Tell your doctor if you notice any of the above side effects or notice any other effects not listed.

Other side effects not listed above may occur in some people. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

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 [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and disposal of Simtec

- *Storage*

Keep Simtec tablets in a cool dry place where the temperature stays below 30°C. Protect from light and excessive moisture

Keep your Simtec in the pack until it is time to take them. If you take the tablets out of the pack, they may not keep well.

Do not store Simtec or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on window sills. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

- *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*

A white to off white oval shape film-coated tablet with a break line on one side and embossed with 'UP' on the other side.

- *Ingredients*

Active Ingredient:

Each tablet of Simtec Tablet contains 10mg of Cetirizine hydrochloride.

Inactive Ingredients

- Opadry II OYL 28900 White
- Dicalcium Phosphate
- Magnesium Stearate
- Crospovidone
- Lactose Monohydrate

- *MAL Number*

MAL05051105ACZ

Manufacturer

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

Product Registration Holder

Duopharma Marketing Sdn. Bhd.
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