# Module 1.3.2: Patient Information Leaflet

## Information for the Patient about

## CICLOVENT 80 / 160 (pressurised inhalation solution)

**SCHEDULING STATUS:**

S3

**PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM**:

**CICLOVENT 80** containing **ciclesonide** 80 µg (Pressurised inhalation solution)

**CICLOVENT 160** containing **ciclesonide** 160 µg (Pressurised inhalation solution)

**Read all of this leaflet carefully before you start using CICLOVENT.**

- **Keep this leaflet, you may need to read it again.**
- **If you have further questions please ask your doctor or your pharmacist.**
- **CICLOVENT has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.**

**WHAT CICLOVENT CONTAINS:**

The active substance is ciclesonide.

**CICLOVENT 80:** 1 puff delivers 80 µg ciclesonide.

**CICLOVENT 160:** 1 puff delivers 160 µg ciclesonide.

Inactive ingredients are anhydrous ethanol, lecithin and tetrafluoroethane (HFA-134a propellant).

## WHAT CICLOVENT IS USED FOR:

- **CICLOVENT** belongs to a class of medicines called corticosteroids.
- **CICLOVENT** is used to prevent asthma in adults, teenagers and children 6 years of age and older.

## BEFORE YOU USE CICLOVENT:

**Do not use / give CICLOVENT if:**

- You / your child are hypersensitive or allergic to ciclesonide or any component of **CICLOVENT**.
- Your child is younger than 6 years of age, as safety and efficacy have not been established.

**Take special care with CICLOVENT:**

Tell your doctor if you have any of the following as you may then require a lower dose or special precaution:

- Impairment of liver function.
- Pulmonary tuberculosis.
- Cataract or glaucoma.
- Growth retardation if you are a teenager.
- Adrenal suppression (reduced function of your adrenal glands).
- If you are being treated with ketoconazole or other antifungals, ritonavir or nelfinavir (see **"Using other medicines with CICLOVENT"**).

Treatment with **CICLOVENT** is NOT indicated in people with status asthmaticus (difficult-to-control asthma of long-standing duration) or in people that require

intensive measures to treat acute episodes of asthma. **CICLOVENT** is not intended to relieve symptoms of acute asthma; an inhaled short-acting bronchodilator (medication that opens up the airways) is necessary to relieve such symptoms. You should always have your rescue medication available.

If you suffer from severe asthma or are at risk of acute attacks, you should go for regular assessments with your treating doctor. If you have to use your short-acting bronchodilator “reliever” more frequently to relieve your asthma symptoms, it may indicate that your asthma is not well-controlled.

If you find your short-acting bronchodilator treatment less effective, or if you need more inhalations than usual, you must consult your treating doctor. He/she may decide to increase your **CICLOVENT** dosage or to add additional corticosteroids in the form of tablets.

If your doctor switches you from oral corticosteroids to **CICLOVENT** your doctor will give you both the oral tablets and the **CICLOVENT** inhaler for a period of time. It is essential that you follow your doctor’s instructions carefully. You may have to take additional corticosteroids if your body is going through periods of stress, including medical or surgical emergencies. Consult your doctor.

Paradoxical (unexpected and contradictory) constriction of your airways after dosing, with an immediate increase in wheezing or other symptoms of a tight chest should be treated with an inhaled short-acting bronchodilator “reliever” that usually causes rapid relief. You should consult your treating doctor immediately.

You should not stop using **CICLOVENT** without consulting your treating doctor. You should also not stop treatment with **CICLOVENT** abruptly.

**Pregnancy and breastfeeding:**

The safety of **CICLOVENT** in pregnancy and breastfeeding has not been established. Thus, use in pregnancy and breastfeeding is not recommended.

**If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before using CICLOVENT.**

**Driving and using machinery:**

**CICLOVENT** has no or an insignificant effect on your ability to drive and use machines.

**Using other medicines with CICLOVENT:**

**Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)**

If you are currently taking an antifungal medicine, such as ketoconazole or itraconazole, or antiviral medicines to treat Human Immunodeficiency Virus (HIV) infection, e.g. ritonavir or nelfinavir, please discuss the use of **CICLOVENT** with your doctor (see **"Take special care with CICLOVENT"**).

**HOW TO USE CICLOVENT:**

**CICLOVENT** is for inhalation use only.

**Do not share medicines prescribed for you with any other person.**

**Always use CICLOVENT exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.**

**Adults and teenagers:**

The usual daily dose of **CICLOVENT** ranges from 80 µg to 320 µg, depending on the severity of your condition. Your doctor may have advised you to use this as a single inhalation in the morning or evening, or in two divided doses, one in the morning and one in the evening.

**Children 6 years and older:**

The usual daily dose of **CICLOVENT** ranges from 80 µg to 160 µg, depending on the severity of your child's condition. Your child's doctor may have advised you to give this as a single inhalation in the morning or evening, or in two divided doses, one in the morning and one in the evening.

Please consult your doctor before abruptly stopping the use of **CICLOVENT** as your doctor will advise you on the tapered dose to minimise the risk of discontinuation symptoms.

**Use in children under 6 years of age:**

Safety and efficacy of **CICLOVENT** in children below 6 years of age has not been established and as such use is not recommended.

**How to use your inhaler:**

Before using your **CICLOVENT** inhaler for the first time, or if it has not been used for a week or more, “test fire” it by releasing three puffs into the air. As **CICLOVENT** is a solution aerosol you do not have to shake it. Proceed as follows:

- Remove the mouthpiece cover.
- Place the mouthpiece of the inhaler in your mouth and close your lips around it.
- Start breathing in slowly and deeply through your mouth.
- After starting to inhale, press the canister down firmly and fully to release one spray while continuing to breathe in slowly and deeply.
- After breathing in, remove the **CICLOVENT** inhaler from your mouth and hold your breath for approximately 10 seconds, or as long as it is comfortable.
- Breathe out slowly and replace the cover of the mouthpiece.
- Do not breathe out into the **CICLOVENT** inhaler.
- Clean your **CICLOVENT** inhaler at least once a week by wiping the mouthpiece with a clean, dry cloth or tissue. Do NOT wash or place any part of your **CICLOVENT** inhaler in water.

If you have the impression that the effect of **CICLOVENT** is too strong or too weak, tell your doctor or pharmacist.

**If you used more CICLOVENT than you should:**

In the event of an overdosage, or if someone else has used your medicine by mistake, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

**If you forget to use CICLOVENT:**

Use **CICLOVENT** as prescribed. If you miss a dose of **CICLOVENT**, use it as soon as possible. However, if you do not remember the missed dose until the next day, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to compensate for the forgotten individual dose.

**POSSIBLE SIDE-EFFECTS:**

**CICLOVENT** can have side-effects.

**Not all side-effects reported for CICLOVENT are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using CICLOVENT, please consult your doctor, pharmacist or other healthcare professional for advice.**

If any of the following happens, stop taking **CICLOVENT** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Paradoxical constriction of your airways, causing wheezing or coughing, which may occur immediately after dosing. Use your “reliever” and consult your doctor immediately.
- Severe allergic reactions presenting with wheezing, hives or itching, swelling of the face, lips, tongue, throat, or whole body, tightness of the chest, or skin rash.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **CICLOVENT**. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Hoarseness.
- Cough after inhalation.
- Unpleasant (bad) taste in the mouth.
- Thrush in your mouth and throat. To try and prevent this, rinse your mouth or gargle with water and spit it out immediately after taking your dose.
- Rash and eczema (dermatitis).
- Burning, inflammation, irritation and dryness of the mouth.

These are all serious side effects. You may need urgent medical attention.

**CICLOVENT**, particularly at high doses and if prescribed for prolonged periods, may affect the normal production of steroids in your body. This may give rise to systemic corticosteroid effects [i.e. suppression of your adrenal glands, decrease in bone mineral density (bone strength), slowing of growth in teenagers, loss of vision due to abnormal high pressure in the eye (glaucoma) and possible clouding of the lens of the eye causing blurred vision (cataract)].

If you notice any side-effects not mentioned in this leaflet, please inform your doctor or pharmacist.

## STORING AND DISPOSING OF CICLOVENT:

Store at or below 30 °C.

**STORE ALL MEDICINES OUT OF REACH OF CHILDREN.**

The container contains a pressurised liquid. Do not expose to temperatures above 50 °C. Do not pierce the canister. Do not refrigerate or freeze.

Do not use after the expiry date stated on the packaging material.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems, for example toilets.

## PRESENTATION OF CICLOVENT:

**CICLOVENT 80:** Carton containing a metered dose inhaler, of 60 or 120 doses, consisting of plain silver aluminium container without any coating, fitted with a silver metallic metering valve and a plastic actuator having a maroon body and buff cap.

**CICLOVENT 160:** Carton containing a metered dose inhaler, of 60 or 120 doses, consisting of plain silver aluminium container without any coating, fitted with a silver metallic metering valve and a plastic actuator having a maroon body and grey cap.

## IDENTIFICATION OF CICLOVENT:

Clear solution free from visible particles.

## REGISTRATION NUMBERS:

**CICLOVENT 80:** 43/21.5.1/1168

**CICLOVENT 160:** 43/21.5.1/1169

**NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATES OF REGISTRATION:**

CIPLA MEDPRO (PTY) LTD

Rosen Park

Pasita Street, Rosen Heights

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