PROFESSIONAL INFORMATION FOR CETAWAY:

SCHEDULING STATUS:

S2

PROPRIETARY NAME AND DOSAGE FORM:

CETAWAY film-coated tablets

COMPOSITION:

Active Ingredients:

Each film coated tablet contains 5 mg Levocetirizine dihydrochloride.

Inactive Ingredients:

Colloidal silica anhydrous, lactose monohydrate, magnesium stearate, microcrystalline cellulose and Opadry white.

CETAWAY also contains sugar: lactose monohydrate.

PHARMACOLOGICAL CLASSIFICATION:

A 5.7.1 Antihistaminic

PHARMACOLOGICAL ACTION:

Pharmacodynamic Properties:

Levocetirizine, the R-enantiomer of cetirizine, is a histamine H1 receptor antagonist.

Pharmacokinetic Properties:

Levocetirizine is absorbed after oral administration with peak blood levels reached 0,9 hours after oral administration. Plasma levels rise in a linear manner between 2,5 mg and 20 mg. The rate of absorption of levocetirizine is decreased by food, but not the extent. The extent of metabolism is less than 14 % of the dose. The plasma half-life is approximately 8 hours in adults. The main route of excretion is via urine, accounting for approximately 85 % of the dose. Approximately 13 % is excreted in the faeces. Levocetirizine is 90 % bound to human plasma proteins.

Special Populations:

Patients with renal impairment:

The total body clearance of levocetirizine is progressively reduced based on severity of renal impairment (see **DOSAGE AND DIRECTIONS FOR USE**).

INDICATIONS:

CETAWAY is indicated for the relief of symptoms associated with the following allergic conditions in adults:

- Seasonal allergic rhinitis
- Perennial allergic rhinitis
- Chronic idiopathic urticaria

Safety and efficacy have not been demonstrated beyond six weeks.

CONTRAINDICATIONS:

- History of hypersensitivity to levocetirizine or any of the constituents of **CETAWAY** or to any piperazine derivative.
- Patients with severe renal impairment at less than 10 ml/min creatinine clearance and patients undergoing hemodialysis.
- **CETAWAY** is contraindicated in children as safety and efficacy have not been demonstrated.
- Pregnancy and lactation.

WARNINGS and SPECIAL PRECAUTIONS:

CETAWAY lacks significant sedative effects. Patients should, however, be warned that a small number of individuals may experience sedation. It is therefore advisable to determine individual response before driving or performing complicated tasks.

Caution is recommended with intake of alcohol (see **INTERACTIONS**).

Effects on ability to drive and use machines:

Some patients could experience somnolence, fatigue and asthenia during therapy with **CETAWAY**. Therefore, patients intending to drive, engage in potentially hazardous activities or operate machinery should take their response to **CETAWAY** into account.

Information on excipients of CETAWAY:

CETAWAY contains lactose. Patients with rare hereditary problems of galactose intolerance, e.g. galactosemia, the Lapp lactase deficiency or glucose-galactose malabsorption should not take **CETAWAY**.

INTERACTIONS:

No interactions / studies have been performed with levocetirizine, including no studies with CYP3A4 inducers.

Studies with ketoconazole, erythromycin, azithromycin, cimetidine and pseudoephedrine have shown no evidence of clinically relevant adverse interactions.

It is advisable to avoid excessive alcohol consumption, as simultaneous intake of **CETAWAY** and alcohol or other CNS depressants may increase the CNS depressant effects.

Theophylline: decreases the clearance of cetirizine with 16 %.

Ritonavir: In a multiple dose study of ritonavir (600 mg twice daily) and cetirizine (10 mg daily) the extent of exposure to cetirizine was increased by about 40 % while the disposition of ritonavir was decreased by 11 %.

PREGNANCY AND LACTATION:

CETAWAY is contraindicated in pregnancy as safety has not been demonstrated.

CETAWAY is contraindicated in women who are breastfeeding their babies, since the active ingredient is excreted in breastmilk.

DOSAGE AND DIRECTIONS FOR USE:

The film-coated tablet must be taken orally, swallowed with liquid and may be taken with or without food. It is recommended to take the daily dose in one single intake.

Adults or children 12 years of age or older:

The daily recommended dose is one 5 mg tablet.

Adults with renal impairment: (see **Pharmacokinetic Properties: Patients with renal impairment**)

The dosing intervals must be individualised according to renal function. Use the table below to adjust the dosage intervals as indicated.

The patient's creatinine clearance (CLcr) can be estimated from the serum creatinine determination using the modified formula of Cockroft and Gault:

$$\text{CLcr (ml/min)} = \frac{(140 - \text{age in years}) \times \text{weight in kg}}{\text{Serum creatinine } (\mu\text{mol/l})} \times 0{,}85 \text{ (for females)}$$

Dosage in patients with renal impairment		
Renal status	**Creatinine clearance (CLcr)**	**Dose**
Moderate impairment	30 to 49 ml/min	5 mg every second day
Severe impairment	< 30 ml/min	5 mg every third day
End stage renal disease/ receiving dialysis	< 10 ml/min	Contraindicated

Patients with hepatic impairment:

No dosage adjustment is needed in patients with hepatic impairment.

SIDE EFFECTS:

The following side effects have been reported:

System Organ Class	**Frequency**	**Side Effects**
Immune system disorders	Frequency unknown:	hypersensitivity reactions including anaphylaxis and angioedema
Metabolism and nutrition disorders	Frequency unknown:	increased weight
Psychiatric disorders	Frequent:	sleep disorders
	Frequency unknown:	aggression, agitation, hallucinations, depression

Nervous system disorders	Frequent: Frequency unknown:	headache, somnolence convulsions, paraesthesia, dizziness
Eye disorders	Frequency unknown:	visual disturbances, blurred vision
Cardiac disorders	Frequency unknown:	palpitations, tachycardia
Respiratory, thoracic and mediastinal disorders	Frequency unknown:	dyspnoea
Gastrointestinal disorders	Frequent: Less frequent:	dry mouth, diarrhoea, constipation Nausea, gastro-intestinal discomfort, abdominal pain, vomiting
Hepato-biliary disorders	Frequency unknown:	hepatitis, abnormal liver function tests
Skin and subcutaneous tissue disorders	Less frequent:	hypersensitivity skin reactions, urticaria, pruritus, fixed drug eruptions
Musculoskeletal, connective tissue and bone disorders	Frequency unknown:	myalgia
Renal and urinary disorders	Frequency unknown:	dysuria
General disorders and administrative site conditions	Frequent: Less frequent:	fatigue asthenia, malaise

KNOWN SYMPTOMS OF OVERDOSE AND PARTICULARS OF ITS TREATMENT:

(see **SIDE EFFECTS AND WARNINGS and SPECIAL PRECAUTIONS**)

Symptoms of overdose:

Drowsiness is an expected symptom of overdosage.

Overdosage in children may produce agitation and restlessness followed by drowsiness.

Treatment of overdose:

There is no known specific antidote to levocetirizine. Treatment is symptomatic and supportive.

Levocetirizine is not effectively removed by haemodialysis.

IDENTIFICATION:

White, round, biconvex film-coated tablets with bevelled edges.

PRESENTATION:

CETAWAY is packed into two different blister strips:

- Silver OPA/Al/PVC and aluminium foil blister strips.
- Clear transparent PVC/PVDC and aluminium foil blister strips.

7 or 10 tablets are packed into a blister strip.

- 1 blister strip of 7 tablets is packed into an outer carton.
- 1 or 3 blister strips of 10 tablets are packed into an outer carton

Not all pack sizes and pack types are marketed.

STORAGE INSTRUCTIONS:

Store at or below 25 °C.

Protect from moisture.

Keep blister strip in outer carton until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

A46/5.7.1/0389

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Unicorn Pharmaceuticals (Pty) Ltd

Corner Searle & pontac streets

8001

Cape Town

South Africa

DATE OF PUBLICATION OF PACKAGE INSERT:

Date of registration: 27 July 2017

Date of revision: 24 January 2019