1.3.1 Summary of product characteristics (SmPC)

Summary of products characteristics (SmPC) of ZYNCET (Cetirizine Hydrochloride Tablets 10 mg) is enclosed overleaf.

SUMMARY OF PRODUCTS CHARACTERISTICS

ZYNCET
(Cetirizine Hydrochloride Tablet 10 mg)

1.3.1 SUMMARY OF PRODUCT CHARACTERISTICS (SMPC)

1. Name of the Medicinal Product

1.1 Product name : ZYNCET

1.2 Strength : Cetirizine Hydrochloride Tablets 10 mg

1.3 Pharmaceutical Dosage form : Tablets

Label Claim:

Each film coated tablet contains:

Cetirizine Hydrochloride BP ..... 10 mg

Ingredients	Qty/Dosage (mg)	Function	Reference to Standards
CORE TABLET			
Cetirizine Hydrochloride	10.00	Active	Ph.Eur./BP
Lactose	65.300	Diluent	Ph.Eur./BP
Starch	32.000	Diluent / Disintegrant	Ph.Eur./BP
Povidone [PVP K-30]	2.500	Binder	Ph.Eur./BP
Magnesium Stearate	1.200	Lubricant	Ph.Eur./BP
Starch	4.000	Lubricant	Ph.Eur./BP
Purified Water	--	Solvent	In-House
COATING			
Eudragit E-100	0.900	Film coating agent	O. Sp.
Polyethylene Glycol 6000	0.150	Plasticizer	Ph.Eur./BP
Titanium Dioxide	0.450	Colourant	Ph.Eur./BP
Talc	1.500	Lubricant /Opacifier	Ph.Eur./BP
Methylene Chloride	--	Solvent	Ph.Eur./BP
Acetone	--	Solvent	Ph.Eur./BP
Isopropyl Alcohol	--	Solvent	Ph.Eur./BP
Purified Water	--	Solvent	In-House

SUMMARY OF PRODUCTS CHARACTERISTICS

ZYNCET
(Cetirizine Hydrochloride Tablet 10 mg)

3. Pharmaceutical Form

Oblong, biconvex, white, film coated tablets with score on one side.

4.1 Therapeutic indications :

Cetirizine is indicated for the symptomatic treatment of seasonal allergic rhinitis and perennial allergic rhinitis, allergic conjunctivitis, pruritus and chronic urticaria.

4.2 Posology and method of administration:

For adults and children above 12 years : 10 mg daily.
For children below 12 years : 5 - 10 mg daily.
At present there is no data to suggest that the dose need to be reduced in elderly patients. In patients with renal insufficiency dosage should be reduced to half a tablet (5 mg) daily.

Method of administration : Oral use.

4.3 Contraindications

Cetirizine tablets are contraindicated in patients with a history of hypersensitivity to any of their constituents or hydroxyzine.
Cetirizine is contraindicated in lactating women since the active ingredient is excreted in breast milk.

4.4 Special warning and precautions for use

Studies in healthy volunteers on 20 and 25 mg/day dose of Cetirizine have not revealed effects on alertness or reaction time. However patients are advised not to exceed the recommended dose if driving or operating machinery.

4.5 Interaction with other medicinal products and other forms of interactions

To date there are no known interactions with other drugs. Studies with Diazepam and Cimetidine have revealed no evidence of interactions. As with other antihistamines, it is advisable to avoid excessive alcohol consumption.
Clinically no significant drug interactions have been found with theophylline at a low dose, azithromycin, pseudoephedrine, ketoconazole, or erythromycin. A small decrease in the clearance of cetirizine is caused by a 400 mg dose of theophylline; it is possible that larger theophylline doses could have a greater effect.

ZYNCET
(Cetirizine Hydrochloride Tablet 10 mg)

4.6 Pregnancy and lactation

No adverse effects have been reported from animal studies. There has been little or no use of Cetirizine in pregnancy. As with other drugs, the use of Cetirizine in pregnancy should be avoided.

4.7 Effects on ability to drive and use machine

4.8 Undesirable effects

There have been occasional reports of mild and transient subjective adverse effects such as headache, dizziness, drowsiness, agitation, dry mouth, gastro-intestinal discomfort, pharyngitis and fatigue. If desired the dose may be taken as 5 mg in the morning and 5 mg in the evening. In objective tests of psychomotor function, the incidence of sedation with Cetirizine was similar to that of placebo.

4.9 Overdose and special antidotes

Drowsiness can be a symptom of overdosage, occurring from administration of 50 mg of Cetirizine as a single dose. In the case of massive overdosage, gastric lavage should be performed together with usual supportive measures. To date there is no specific antidote.

5. Pharmacological Properties
5.1 Pharmacodynamic Properties

Cetirizine is a potent antihistamine with a low potential for drowsiness at pharmacologically active doses and with additional anti-allergic properties. It is a selective H1- antagonist with negligible effects on the other receptors and so is virtually free from anti-cholinergic and anti-serotonin effects. Cetirizine inhibits the histamine mediated 'early' phase of allergic reaction and also reduces the migration of inflammatory cells such as eosinophils and the release of mediators associated with the 'late' allergic response.

5.2 Pharmacokinetic Properties

Peak blood levels of the order of 0.3 mcg/ml are reached between 30 to 60 minutes after oral administration of a 10 mg dose of Cetirizine. Its plasma half-life is approximately 11 hours. Absorption is very consistent from one subject to the next. Its renal clearance is 53ml/min and the excretion half life is approximately 8.3 hours. Cetirizine is strongly bound to plasma proteins.

ZYNCET
(Cetirizine Hydrochloride Tablet 10 mg)

5.3 Preclinical Safety Data

—

6. Pharmaceutical Particulars

6.1 List of excipients :
Lactose BP
Maize starch BP
Povidone BP
Magnesium stearate BP
Eudragit E 100 O.Sp.
Polyethylene Glycol 6000 (Macrogol) BP
Titanium dioxide BP
Purified talc BP
Methylene Chloride BP
Acetone BP
Isopropyl Alcohol BP

6.2 Incompatibilities :

None

6.3 Shelf life: 36 Months

6.4 Special precautions for storage :

Store below 30°C.

Protect from light & moisture.

6.5 Nature and contents of container :

A transparent blister of PVC with a printed aluminum foil as lidding is the container.10 Tablets are packed in this blister.

Inner Carton containing 5 blisters of 10 tablets each along with pack insert. 4 such inner cartons are packed in an outer carton

.

ZYNCET
(Cetirizine Hydrochloride Tablet 10 mg)

7. Marketing Authorization Holder

Unichem Laboratories Limited,

Unichem Bhavan

Prabhat Estate, S.V. Road

Jogeshwari (West)

Mumbai - 400 102

INDIA.

8. Manufacturer's Name
Unichem Laboratories Limited

Unit-II, Village Bhatauli Kalan,

Baddi, Dist. Solan (H.P) – 173 205,

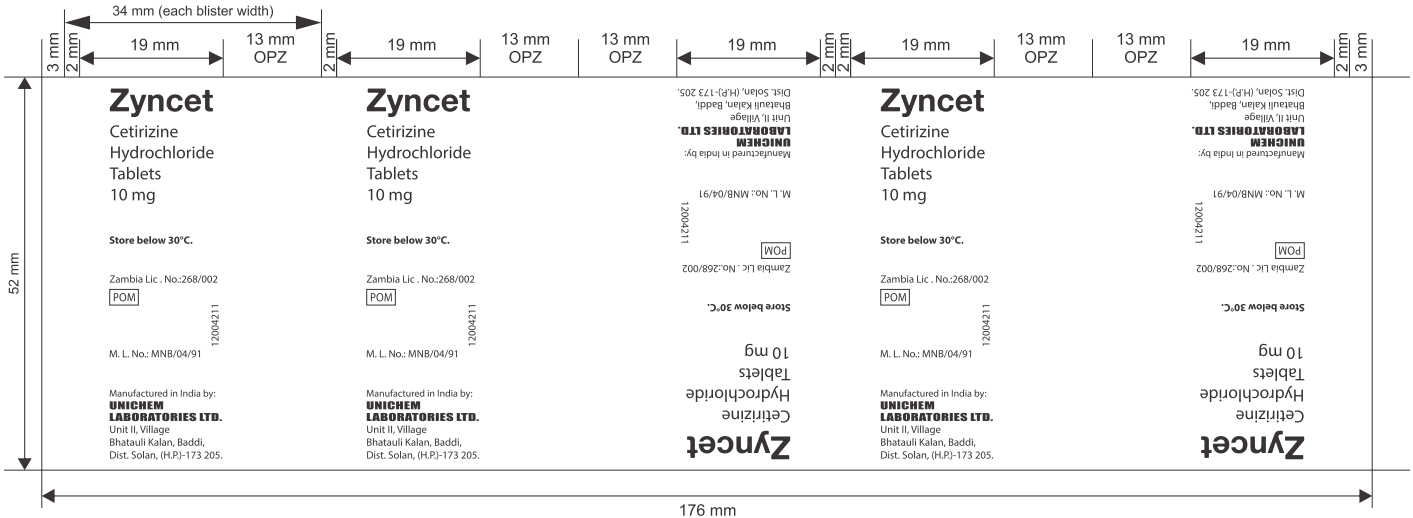
Himachal Pradesh, INDIA

9. Date of first authorization/renewal of the authorization: ---

10. Date of revision of the text: Not applicable

1.3.2 Labelling (primary and secondary packaging)

Enclosed overleaf Printed Foil and Carton for ZYNCET (Cetirizine Hydrochloride Tablets 10 mg)



Company Name : UNICHEM LABORATORIES LTD.		**Date:** 9-9-2015 - 22-4-2016
Agency Name: UNICHEM ARTLAB		**Foil Width:** 176 mm (Repeat Length 52 mm)
Product: Zyncet Tablet Foil (Machinable Artwork)	**Packing**: 5 X 10 Tablets	**Combi Pack Blister size:** 170 x 78 mm
Item Code: 12004211	**Location:** Baddi Unit II	**Layout No.:** BFBQS-7267 dated 06-06-2004
Specification: 0.025mm Aluminium thickness blister foil with 4-6 gsm VMCH coating		**Text :** Common Export text with 30°C.
Colours: Single colour Black (K 100)		
Reason: The brand name font & the rest text font has been synchronized with the approved fonts on cartons. The text of the artwork has been streamlined with the concurrence of IBD & RA.		

IMPORTANT NOTE : THE PRINTER CAN ASK FOR PRINTED SAMPLE AS COLOUR REFERENCE FOR BETTER REPRODUCTION OF COLOUR SCHEME. DOUBTS REGARDING FONTS/DESIGN/COLOUR SCHEME OR ANY OTHER DISCREPANCY REGARDING THE ARTWORK FILE, DO CONTACT THE PACKAGING DEVELOPMENT DEPARTMENT.

Company Name : UNICHEM LABORATORIES LTD.		**Date:** 30-6-2017
Agency Name: UNICHEM ARTLAB		**Size:** 183 x 66 x 87 mm
Product: Zyncet Carton	**Packing:** 4 x (5 x 10) Tablets	**Barcode:** 8901315202313
Item Code: 13009277	**Location:** Baddi II	**Pharmacode:** 3935
Specification: 300 gsm Folding Box Board (CFB)-ITC Cyber XL, with aqua varnish. Lock bottom.		Country specific text with 30°C.
Market: Nigeria		
Reason: New artwork specific to Nigeria developed with deletion of design element as per required by NAFDAC authority.		

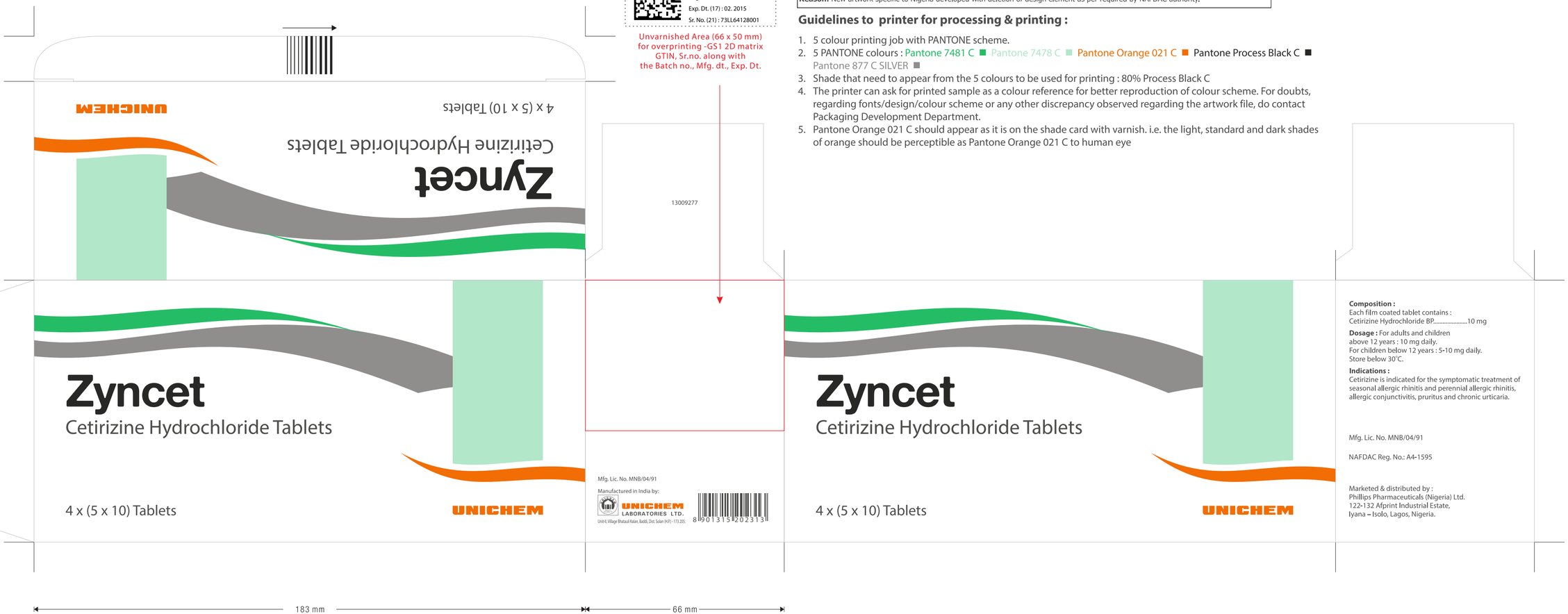
Guidelines to printer for processing & printing :

1. 5 colour printing job with PANTONE scheme.
2. 5 PANTONE colours : Pantone 7481 C ■ Pantone 7478 C ■ Pantone Orange 021 C ■ Pantone Process Black C ■ Pantone 877 C SILVER ■
3. Shade that need to appear from the 5 colours to be used for printing : 80% Process Black C
4. The printer can ask for printed sample as a colour reference for better reproduction of colour scheme. For doubts, regarding fonts/design/colour scheme or any other discrepancy observed regarding the artwork file, do contact Packaging Development Department.
5. Pantone Orange 021 C should appear as it is on the shade card with varnish. i.e. the light, standard and dark shades of orange should be perceptible as Pantone Orange 021 C to human eye

Representation.

GTIN (01) : 28901315000006
B. No. (10) : ABC 011001
Mfg. Dt. (11) : 01. 2013
Exp. Dt. (17) : 02. 2015
Sr. No. (21) : 73LL64128001

Unvarnished Area (66 x 50 mm) for overprinting -GS1 2D matrix GTIN, Sr.no. along with the Batch no., Mfg. dt., Exp. Dt.



Composition :
Each film coated tablet contains :
Cetirizine Hydrochloride BP.....10 mg

Dosage : For adults and children above 12 years : 10 mg daily.
For children below 12 years : 5-10 mg daily.
Store below 30°C.

Indications :
Cetirizine is indicated for the symptomatic treatment of seasonal allergic rhinitis and perennial allergic rhinitis, allergic conjunctivitis, pruritus and chronic urticaria.

Mfg. Lic. No. MNB/04/91

NAFDAC Reg. No.: A4-1595

Marketed & distributed by :
Phillips Pharmaceuticals (Nigeria) Ltd.
122-132 Afprint Industrial Estate,
Iyana – Isolo, Lagos, Nigeria.

Representation.

GTIN (01) : 28901315000006
B. No. (10) : ABC 011001
Mfg. Dt. (11) : 02. 2018
Exp. Dt. (17) : 01. 2020
Sr. No. (21) : 73LL64128001

Unvarnished Area (177 x 32 mm)
for overprinting -GS1 2D matrix
GTIN, Sr.no. along with
the Batch no., Mfg. dt., Exp. Dt.

177 mm

Company Name : UNICHEM LABORATORIES LTD.		**Date:** 30-6-2017, 13-3-18
Agency Name: UNICHEM ARTLAB		**Size:** 82 x 15 x 177 mm
Product: Zyncet Tablets Carton	**Packing:** 5 x 10 Tablets	**Barcode:** 8901315202320
Item Code: 13009276	**Location:** Baddi II	**Pharmacode:** 3934
Specification: 300 gsm Folding Box Board (CFB)-ITC Cyber XL, with aqua varnish.		Country specific text with 30°C.
Market: Nigeria		
Reason: New artwork specific to Nigeria developed with deletion of design element as per required by NAFDAC authority. 13-03-18 Generic name modified by adding strength on front panel, as per changes received from Regulatory - Phillips Pharmaceuticals, Nigeria		

Guidelines to printer for processing & printing :

1. 5 colour printing job with PANTONE scheme.
2. 5 PANTONE colours : Pantone 7481 C ■ Pantone 7478 C ■ Pantone Orange 021 C ■ Pantone Process Black C ■ Pantone 877 C SILVER ■
3. Shade that need to appear from the 5 colours to be used for printing : 80% Process Black C
4. The printer can ask for printed sample as a colour reference for better reproduction of colour scheme. For doubts, regarding fonts/design/colour scheme or any other discrepancy observed regarding the artwork file, do contact Packaging Development Department.
5. Pantone Orange 021 C should appear as it is on the shade card with varnish. i.e. the light, standard and dark shades of orange should be perceptible as Pantone Orange 021 C to human eye

1.3.3 Package insert and patient information leaflet

Enclosed overleaf Package Insert for ZYNCET (Cetirizine Hydrochloride Tablets 10 mg)

150 mm

For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory.

Zyncet

Cetirizine Hydrochloride Tablets

COMPOSITION:
Each film coated tablet contains :
Cetirizine Hydrochloride BP ..... 10 mg
Excipients: Lactose, Maize Starch, Povidone, Magnesium Stearate, Maize Starch, Eudragit E 100, Polyethylene Glycol 6000, Titanium Dioxide, Purified Talc, Dichloromethane, Acetone & Isopropyl Alcohol.
DOSAGE FORM: Tablets
CATEGORY OF DISTRIBUTION : Prescription Preparation.
THERAPEUTIC CLASS: Antihistamine.
DESCRIPTION OF PRODUCT: Oblong, biconvex, white, film coated tablets with score on one side.
DESCRIPITION :
Cetirizine is a potent antihistamine with a low potential for drowsiness at pharmacologically active doses and with additional anti-allergic properties. It is a selective H_1 - antagonist with negligible effects on the other receptors and so is virtually free from anti-cholinergic and anti-serotonin effects. Cetirizine inhibits the histamine mediated 'early' phase of allergic reaction and also reduces the migration of inflammatory cells such as eosinophils and the release of mediators associated with the 'late' allergic response.
PHARMACOKINETICS :
Peak blood levels of the order of 0.3 mcg/ml are reached between 30 to 60 minutes after oral administration of a 10 mg dose of Cetirizine. Its plasma half-life is approximately 11 hours. Absorption is very consistent from one subject to the next. Its renal clearance is 53ml/min and the excretion half life is approximately 8.3 hours. Cetirizine is strongly bound to plasma proteins (93 %).
INDICATIONS :
Cetirizine is indicated for the symptomatic treatment of seasonal allergic rhinitis and perennial allergic rhinitis, allergic conjunctivitis, pruritus and chronic urticaria.
CONTRAINDICATIONS :
Cetirizine tablets are contraindicated in patients with a history of hypersensitivity to any of their constituents or hydroxyzine.
Cetirizine is contraindicated in lactating women since the active ingredient is excreted in breast milk.
PRECAUTIONS :
Studies in healthy volunteers on 20 and 25 mg/day dose of Cetirizine have not revealed effects on alertness or reaction time. However patients are advised not to exceed the recommended dose if driving or operating machinery.
PREGNANCY :
No adverse effects have been reported from animal studies. There has been little or no use of Cetirizine in pregnancy. As with other drugs, the use of Cetirizine in pregnancy should be avoided.
DRUG INTERACTIONS :
To date there are no known interactions with other drugs. Studies with Diazepam and Cimetidine have revealed no evidence of interactions. As with other antihistamines, it is advisable to avoid excessive alcohol consumption.
Clinically no significant drug interactions have been found with theophylline at a low dose, azithromycin, pseudoephedrine, ketoconazole, or erythromycin. A small decrease in the clearance of cetirizine is caused by a 400 mg dose of theophylline; it is possible that larger theophylline doses could have a greater effect.
ADVERSE EFFECTS :
There have been occasional reports of mild and transient subjective adverse effects such as headache, dizziness, drowsiness, agitation, dry mouth, gastro-intestinal dis-comfort, pharyngitis and fatigue. If desired the dose may be taken as 5 mg in the morning and 5 mg in the evening. In objective tests of psychomotor function, the incidence of sedation with Cetirizine was similar to that of placebo.
DOSAGE AND ADMINISTRATION :
For adults and children above 12 years : 10 mg daily.
For children below 12 years : 5 - 10 mg daily.
At present there is no data to suggest that the dose need to be reduced in elderly patients. In patients with renal insufficiency dosage should be reduced to half a tablet (5 mg) daily.
OVERDOSAGE :
Drowsiness can be a symptom of overdosage, occurring from administration of 50 mg of Cetirizine as a single dose. In the case of massive overdosage, gastric lavage should be performed together with usual supportive measures. To date there is no specific antidote.
STORAGE :
Store below 30°C.
Protect from light & moisture.
Keep all medicines out of reach of children.
NATURE & CONTENT OF CONTAINER (PRESENTATION):
A transparent blister of PVC with a printed aluminum foil as lidding is the container.
10 Tablets are packed in this blister. Blisters & a leaflet in turn are packed in a carton/s.
SHELF LIFE: 24/36 Months. (Please refer on the pack).

Zambia Lic. No. 268/002

POM

Manufactured in India by :

UNICHEM LABORATORIES LTD.
Unit-II, Village Bhatauli Kalan, Baddi, Dist. Solan (H.P.) - 173 205.

13007871
Date of Publication: September, 2015

150 mm

Page 1. Front Page 115 mm

Page 2. Back Page 115 mm

Company Name : UNICHEM LABORATORIES LTD.		**Date:** 28-10-2015
Agency Name: Unicorn Creation		
Product: Zyncet Tablets Leaflet		**Size:** 115 x 150 mm (L x H)
Item Code: 13007871	**Location:** Baddi Unit II	**No.of Folds :** 4 horizontal
Specification: 54 gsm Maplitho Paper		**Prefolded size :** 115 x 30 mm
Colour Code: 1, text in black		**Text :** Common export text with 30°C
Comments: Leaflet artwork developed in accordance with the approved silver wave design on carton. Ahead of the existing add 23.10.2015 : Monohydrate following 'Lactose' in excipients deleted. 28.10.2015 : 'Purified Water' in excipients deleted.		

IMPORTANT NOTE : THE PRINTER CAN ASK FOR PRINTED SAMPLE AS COLOUR REFERENCE FOR BETTER REPRODUCTION OF COLOUR SCHEME. DOUBTS REGARDING FONTS/DESIGN/COLOUR SCHEME OR ANY OTHER DISCREPANCY REGARDING THE ARTWORK FILE, DO CONTACT THE PACKAGING DEVELOPMENT DEPARTMENT.