ESCITALOPRAM- escitalopram tablet, film coated
Northwind Pharmaceuticals

Label display

NDC: 51655-151-52

MFG: 0093-5852-05

Escitalopram 20 mg

30 tablets

Rx only

Lot#:

Exp. Date:

Each tablet contains: escitalopram oxalate, USP equivalent to 20 mg escitalopram

Dosage: See package insert

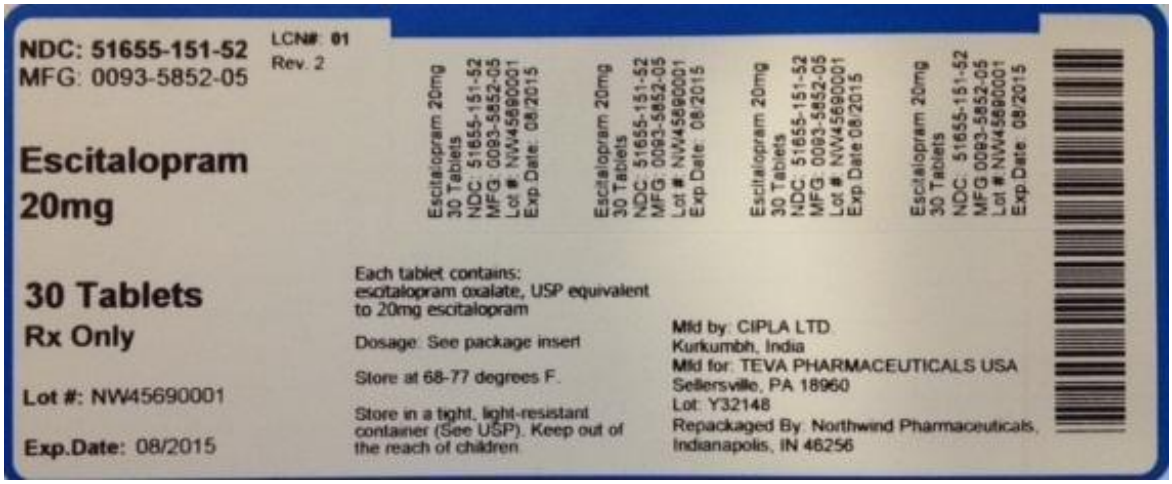
Store at 6877 degrees F.

Store in a tight, light-resistant container (See USP). Keep out of the reach of children.

Mfg by: Cipla Ltd, Kurkumbh, India

Mfg for: Teva Pharmaceuticals USA, Sellersville, PA 18960 Lot#:

Repackaged by Northwind Pharmaceuticals, Indianapolis, IN 46256



Indications and usage

Escitalopram is a selective serotonin reuptake inhibitor (SSRI) indicated for:

Acute and Maintenance Treatment of Major Depressive Disorder (MDD) in adults and adolescents aged 12 to 17 years

Acute Treatment of Generalized Anxiety Disorder (GAD) in adults

Contraindications

Serotonin Syndrome and MAOIs: Do not use MAOIs intended to treat psychiatric disorders with escitalopram or within 14 days of stopping treatment with escitalopram.

Do not use escitalopram within 14 days of stopping an MAOI intended to treat psychiatric disorders. In addition, do not start escitalopram in a patient who is being treated with linezolid or intravenous methylene blue.

Pimozide: Do not use concomitantly.

Known hypersensitivity to escitalopram or citalopram or any of the inactive ingredients

Warnings and Precautions

Clinical Worsening/Suicide Risk: Monitor for clinical worsening, suicidality and unusual change in behavior, especially during the initial few months of therapy or at times of dose changes .

Serotonin Syndrome: Serotonin syndrome has been reported with SSRIs and SNRIs, including escitalopram, both when taken alone, but especially when coadministered with other serotonergic agents (including triptans, tricyclic antidepressants, fentanyl, lithium, tramadol, tryptophan, buspirone and St. John's Wort). If such symptoms occur, discontinue escitalopram and initiate supportive treatment. If concomitant use of escitalopram with other serotonergic drugs is clinically warranted, patients should be made aware of a potential increased risk for serotonin syndrome, particularly during treatment initiation and dose increases.

Discontinuation of Treatment with Escitalopram: A gradual reduction in dose rather than abrupt cessation is recommended whenever possible.

Seizures: Prescribe with care in patients with a history of seizure.

Activation of Mania/Hypomania: Use cautiously in patients with a history of mania.

Hyponatremia: Can occur in association with SIADH (5.6).Abnormal Bleeding: Use caution in concomitant use with NSAIDs, aspirin, warfarin or other drugs that affect coagulation.

Interference with Cognitive and Motor Performance: Use caution when operating machinery.

Use in Patients with Concomitant Illness: Use caution in patients with diseases or conditions that produce altered metabolism or hemodynamic responses

ESCITALOPRAM

escitalopram tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:51655-151(NDC:0093-5852)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ESCITALOPRAM OXALATE (UNII: 5U85DBW7LO) (ESCITALOPRAM - UNII:4O4S742ANY)	ESCITALOPRAM	20 mg

Product Characteristics			
Color	white	**Score**	2 pieces
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	5852;20
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51655-151-52	30 in 1 BOTTLE, DISPENSING		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076765	03/21/2014	

Labeler - Northwind Pharmaceuticals (036986393)

Registrant - Northwind Pharmaceuticals (036986393)

Establishment

Name	Address	ID/FEI	Business Operations
Northwind Pharmaceuticals		036986393	repack(51655-151)

Revised: 6/2014 Northwind Pharmaceuticals