Screenshots Gallery

Selected screenshots of regulatory documents

Annotated Case Report Form (<u>Source</u>: Zanamivir trial NAI30031, ACRF Contact, PDF p. 6)

Protocol code Session number	er	Subject number
NAI30031 1		
Dem	nography / Concurrent Medica Screening	ations
Date of assessment day	month year VSD7 R (D7)	
Date of birth day	month year BIFIDT	f (00)
Sex		
Male M	ix R (AI)	
Female F	EX R (AI)	
Race, ✓ one:		
(AI) [VEIRIOZI] W Afgh	gins in the original peoples of Europe, the Mi hanistan, or the white racial groups of Africa. gins in any of the black racial groups of Africa.	•
	gins in the original peoples of the Indian sub-	
	theast Asia, or the Pacific islands.	
1.000	panics of North, Central, or South American	
	ple whose racial group is not represented a in cannot be determined.	bove, or whose predominant
Current smoker Yes Y	NO NO SBSMK 2 (AI)	
Cultent smoker 100	NO NO SBSMK2 (AI)	
Concurrent Medications		950
Enter any concurrent medication CONCURRENT MEDICATIONS p		✓ if done
	Г	SESSION Ø
		TMTSGPL (N3) = 1 TMTSGSL (N3) = 1 TMTSTDT (D7) = V
		TMTSGSL (A13) = 1
		TMTSTDT (U1)= V



Case Report Form

Study Drug: Oseltamivir (Ro 64-0796)

Protocol Number: NV16871

A double-blind, randomized, stratified, placebo-controlled study of oseltamivir in the treatment of influenza in children with asthma.

Patient Initials :	\sqcup	
Patient Number :	لبيا	(enter after Day 1 if patient is randomised)
Centre Number :		I
Investigator Name : (in block capitals)		

Persons supplied with this information must understand that it is **strictly confidential**. Information contained herein cannot be disclosed, submitted for publication or used for any purpose other than the contemplated herein without the sponsors prior authorisation.

Final Version 2, 11th September 2003

Roche	NV16871 Centre Number	- I diloit	ient Baseline Number
Date of Baseline Visit :			
De mo graphic Data	Day months rear		
Date of Birth :	Day Month	Year	
Sex:	☐ Male	Female	
Race :	Tick (✓) one box	only	
	Caucasian / V	Vhite	
	Black		
	Oriental		
	Asian		
	☐ Other	(please specify)	
Asthma History/diag	nosis		
Date of first diagnosis of	asthma :	Day Month Year	
Date of first diagnosis of Current Asthma severity		Day Month Year Tick (✓) current asthma severit	
		Tick (✓) current asthma severit	
		Tick (✓) current asthma severit Mild	
Current Asthma severity :		Tick (✓) current asthma severit ☐ Mild ☐ Moderate ☐ Severe	
Current Asthma severity :	: he protocol to ascertain asi	Tick (✓) current asthma severit ☐ Mild ☐ Moderate ☐ Severe	
Current Asthma severity :	: he protocol to ascertain asi	Tick (✓) current asthma severit ☐ Mild ☐ Moderate ☐ Severe	
Current Asthma severity :	: he protocol to ascertain asi	Tick (✓) current asthma severit ☐ Mild ☐ Moderate ☐ Severe thma severity)	y Frequency (in last 4 weeks)
Current Asthma severity : (refer to appendix 2 of the Recurrent Asthma Sympt	: he protocol to ascertain asi	Tick (✓) current asthma severit ☐ Mild ☐ Moderate ☐ Severe thma severity)	y Frequency (in last 4 weeks)
Current Asthma severity: (refer to appendix 2 of the Recurrent Asthma Symptocough during the night	: he protocol to ascertain asi toms :	Tick (✓) current asthma severit ☐ Mild ☐ Moderate ☐ Severe thma severity)	y Frequency (in last 4 weeks)
Current Asthma severity: (refer to appendix 2 of the Recurrent Asthma Sympt Cough during the night Cough during the day	: he protocol to ascertain asi toms :	Tick (✓) current asthma severit ☐ Mild ☐ Moderate ☐ Severe thma severity)	y Frequency (in last 4 weeks)
Current Asthma severity: (refer to appendix 2 of the Recurrent Asthma Symptocough during the night Cough during the day Wheeze during the night	: ne protocol to ascertain asi toms :	Tick (✓) current asthma severit ☐ Mild ☐ Moderate ☐ Severe thma severity)	y Frequency (in last 4 weeks)
Current Asthma severity: (refer to appendix 2 of the Recurrent Asthma Sympt) Cough during the night Cough during the day Wheeze during the day Wheeze during the day	: the protocol to ascertain as toms : ortness of breath	Tick (✓) current asthma severit ☐ Mild ☐ Moderate ☐ Severe thma severity)	y Frequency (in last 4 weeks)

PROTOCOL NO.	SI	LE ID	SUBJECT INIT	IAL SUBJECT ID	
MA-CT-10-002	0	OI .	M-IV	001	
	SCREE	NING (V1	/ -14 to -1 days)		
		SMOKING	HISTORY		
1 Non smoker					
2 Smoker, Date started :			m / yyyy)	Duration : ye	
3 Ex-smoker, Date stopped :		/		Duration: years	
	ost	EOARTHE	RITIC HISTORY		
Date of onset of symptoms:	02/F	E B / 2	O (O · (dd / mmm /	уууу)	
Pate of Diagnosis :	06,19	PR 12	0 \ 0 (dd / mmm /	уууу)	
oints affected check all that apply);	1 Hip 4 Wrist	2 5		Shoulder Other, specify :	
	ARE	A		SIDE	
ndex Joint check only one) :	1 Hip 2 Knee 3 Should	der	1 Left	⊠ ₂ Right	
	5 Neck				
reatment for OA check all that apply) :	□ 0 NA	Ds [1 Corticosteroids 4 Other	2 Hyaluronic Acid	
	Acid is checked, pudy.	olease provid	e all details in the Prior C	oncomitant Medication page and	

PROTOCOL NO.	SITE ID	SUBJECT INITIALS	SU	SUBJECT ID
MA-CT-10-002	100	M-IV		700
	SCREENING (V1 / -14 to -1 days)	l to -1 days)		
	MEDICAL AND SURGICAL HISTORY	AL HISTORY		
Does the subject have any past or ongoing medical /	/ surgical history?	X 1 Yes 2 No If Yes', pleas	if 'Yes', please provide details below :	ails below :
Description	Start Date (dd / mmm / yyyy)	Stop Date (dd / mmm / yyyy)	Ongoing	Any Past/Ongoing medications recorded?
Type I Diabetes Hellitus	UKIUK 11990		×	
Hypestension	UKUK 1995		×	
Underwent Surgery Ar	UKIUK 12007	UKUK 12007		
"If past / ongoing medication is recorded, then please provide details in Prior Concomitant Medication page.	provide details in Prior Concomitant Medic	ation page.		
1 Check this box if supplementary page is used.				
Version 1.0	02-Jun-2010			Page 4

Certificate of analysis (Source: Tamiflu (Oseltamivir) trial WP16263 PDF pp. 422-3) Tamiflu™ (oseltamivir phosphate) Protocol WP16263 Roche Clinical Study Report Research Report 1003328 Prepared by: Approved by: Roche Placebo Capsules Date: 21.09.9 Ro 64-0796/V16 CERTIFICATE OF ANALYSIS Batch: G MZ 0163 No. 07039556 Date of manufacture: August 1999 Batch size: 104'827 capsules Place of manufacture: Hoffmann-la Roche Ltd, Basie, Switzerland Date of analysis: September 1999 Retest date: 08.2002 No. 2 Capsule size Colour of the capsules grey, opaque Body ivory, opaque Cap Capsule contents powder Appearance white Calour Identity of negative Ro 64-0796 corresponds Dehydrocholic acid

Quality Control & Assurance

Basel, Switzerland

RD087377.DOC

ba-Ro.64-0796.Cap.V16_IIE.2.2.CAN.07039556

1/1



FINAL STUDY REPORT MODULES

This report consists of 5 modules

Those not supplied in this submission are obtainable from the sponsor on request

MODULE I: CORE REPORT AND STUDY PUBLICATIONS

Introduction Rationale Objectives Methodology Efficacy Results Safety Results

Discussion / Conclusions

Appendices

MODULE II: PRESTUDY DOCUMENTS AND STUDY METHODOLOGY

Protocol and Amendment History

Blank CRF

Patient Information Sheet

Glossary of Original and Preferred Terms

Randomization List

Reporting Analysis Plan (RAP)

Certificates of Analysis List of Investigators

List of Responsible Ethics Committees

MODULE III: INDIVIDUAL PATIENT LISTINGS OF DEMOGRAPHIC AND

EFFICACY DATA

Demographic Data Listings Previous and Concomitant Diseases Previous and Concomitant Medications

Efficacy Listings

MODULE IV: INDIVIDUAL PATIENT LISTINGS OF SAFETY DATA

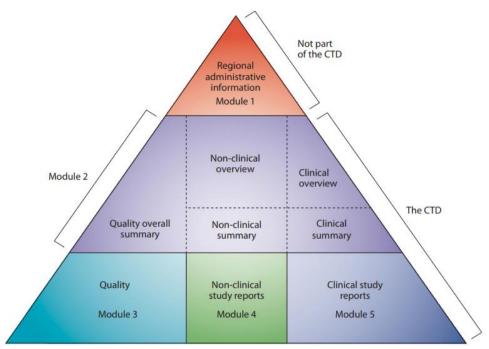
Laboratory Parameters Vital Signs Data

MODULE V: STATISTICAL REPORT

N-181376 / Protocol M76001

Module I - 1

CTD Triangle



The CTD triangle. The Common Technical Document is organized into five modules. Module 1 is region specific and modules 2, 3, 4 and 5 are intended to be common for all regions.



Home

Food

Drugs

Medical Devices

Radiation-Emitting Products

Vaccines, Blood & Biologics

Drug Approval Package

▶ FDA Home ▶ Drugs ▶ Drug Approvals and Databases ▶ Drugs@FDA

SIVEXTRO (tedizolid phosphate) Tablets Company: Cubist Pharmaceuticals, Inc.

Application No.: 205435 Approval Date: 6/20/2014

Persons with disabilities having problems accessing the PDF files below may call (301) 796-3634 for assistance.

- Approval Letter(s) (PDF)
- Printed Labeling (PDF)
- Summary Review (PDF)
- Officer/Employee List (PDF)
- Office Director Memo (PDF)
- Cross Discipline Team Leader Review (PDF)
- Medical Review(s) (PDF)
- Chemistry Review(s) (PDF)
- Pharmacology Review(s) (PDF)
- Statistical Review(s) (PDF)
- Microbiology Review(s) (PDF)
- Clinical Pharmacology Biopharmaceutics Review(s) (PDF)
- Risk Assessment and Risk Mitigation Review(s) (PDF)
- Proprietary Name Review(s) (PDF)
- Other Review(s) (PDF)
- Administrative Document(s) & Correspondence (PDF)

Date created: July 16, 2014 Back to Top Drugs@FDA HIGHLIGHTS OF PRESCRIBING INFORMATION These highlights do not include all the information needed to use DALVANCE[®] safely and effectively. See full prescribing information for DALVANCE,

DALVANCE (dalbavancin) for injection, for intravenous use Initial U.S. Approval: 2014

----RECENT MAJOR CHANGES----

Dosage and Administration (2)

01/2016

---INDICATIONS AND USAGE---DALVANCE is indicated for acute bacterial skin and skin structure infections (ABSSSI) caused by designated susceptible strains of Gram-positive microorganisms, (1.1)

To reduce the development of drug-resistant bacteria and maintain the effectiveness of DALVANCE and other antibacterial drugs, DALVANCE should be used only to treat infections that are proven or strongly suspected to be caused by susceptible bacteria. (1,2)

--- DOSAGE AND ADMINISTRATION-

Dosage in patients with normal or impaired renal function (2.1, 2.2):

Estimated CrCl	Single Dose Regimen	Two-Dose Regimen
≥ 30 mL/min or on regular hemodialysis	1500 mg	1000 mg followed one week later by 500 mg
< 30 mL/min and not on regular hemodialysis	1125 mg	750 mg followed one week later by 375 mg

- Administer by intravenous infusion over 30 minutes (2.1, 2.3)
- See Full Prescribing Information for instructions on reconstitution of lyophilized powder and preparation of injection (2.3)

...DOSAGE FORMS AND STRENGTHS.

For injection: 500 mg of lyophilized powder in a vial for reconstitution (3)

...CONTRAINDICATIONS... Hypersensitivity to dalbavancin (4)

......WARNINGS AND PRECAUTIONS...

- Serious hypersensitivity (anaphylactic) and skin reactions have been reported with glycopeptide antibacterial agents, including DALVANCE; exercise caution in patients with known hypersensitivity to glycopeptides. (5.1)
- · Rapid intravenous infusion of glycopeptide antibacterial agents can cause reactions. (5,2)
- ALT elevations with DALVANCE treatment were reported in clinical trials. (5.3)
- · Clostridium difficile-associated diarrhea (CDAD) has been reported with nearly all systemic antibacterial agents, including DALVANCE, Evaluate if diarrhea occurs. (5.4)

...ADVERSE REACTIONS..

The most common adverse reactions in patients treated with DALVANCE were nausea (4.7%), headache (3.8%), and diarrhea (3.4%). (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Durata Therapeutics, Inc. at 1-855-387-2825 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

-- USE IN SPECIFIC POPULATIONS-Dosage adjustment is required in patients whose creatinine clearance is less than 30 mL/min and who are not receiving regularly scheduled hemodialysis.

See 17 for PATIENT COUNSELING INFORMATION

Revised 01/2016

FULL PRESCRIBING INFORMATION: CONTENTS*

- INDICATION AND USAGE
 - 1.1 Acute Bacterial Skin and Skin Structure Infections 1.2 Usage
- 2 DOSAGE AND ADMINISTRATION

 - 2.1 Recommended Dosage Regimen
 2.2 Dosage in Patients with Renal Impairment
- 2.3 Preparation and Administration DOSAGE FORMS AND STRENGTHS
- CONTRAINDICATIONS
- WARNINGS AND PRECAUTIONS
- Hypersensitivity Reactions
 Infusion-Related Reactions
- 5.3 Hepatic Effects
- 5.3 Hepatic Effects
 5.4 Clostridium difficile-Associated Diarrhea
 5.5 Development of Drug-Resistant Bacteria
 ADVERSE REACTIONS
 6.1 Clinical Trials Experience

- DRUG INTERACTIONS
 - 7.1 Drug-Laboratory Test Interactions
 7.2 Drug-Drug Interactions

- 8 USE IN SPECIFIC POPULATIONS

(2.2, 8.6)

- 8.1 Pregnancy 8.2 Lactation
- 8.4 Pediatric Use
- 8.5 Geriatric Use
- 8.6 Renal Impairment 8.7 Hepatic Impairment 10 OVERDOSAGE
- 11 DESCRIPTION
- 12 CLINICAL PHARMACOLOGY
 - 12.1 Mechanism of Action 12.2 Pharmacodynamics 12.3 Pharmacokinetics

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- 13 NONCLINICAL TOXICOLOGY
- 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility 13.2 Animal Toxicology and/or Pharmacology 14 CLINICAL STUDIES
- 15 REFERENCES
- 16 HOW SUPPLIED/STORAGE AND HANDLING 17 PATIENT COUNSELING INFORMATION

^{*}Sections or subsections omitted from the full prescribing information are not listed

Olazax

olanzapine

About

Authorisation details

Product information

Assessment history

Next tab »

This is a summary of the European public assessment report (EPAR). It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the studies performed, to reach its recommendations on how to use the medicine.

If you need more information about your medical condition or your treatment, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis for the CHMP recommendations, read the scientific discussion (also part of the EPAR).

- Expand all items in this list
- What is Olazax?
- **■** What is Olazax used for?
- How is Olazax used?
- How does Olazax work?
- How has Olazax been studied?
- What are the benefit and risk of Olazax?
- **⊞** Why has Olazax been approved?
- Other information about Olazax



This EPAR was last updated on 19/04/2017.

▶ More detail is available in the summary of product characteristics



European Medicines Agency Evaluation of Medicines for Human Use

Doc.Ref.: EMEA/774081/2009

ASSESSMENT REPORT FOR

OLAZAX

International Nonproprietary Name: olanzapine

Procedure No. EMEA/H/C/1087

Assessment Report as adopted by the CHMP with all information of a commercially confidential nature deleted.

7 Westferry Circus, Canary Wharf, London E14 4HB, UK Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 85 45 E-mail: mail@emea.europa.eu http://www.emea.europa.eu

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Medical Officer Review (Source)

Clinical Review Sarah M. Connelly, MD NDA 205834 Ledipasvir/Sofosbuvir Fixed-Dose Combination

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Clinical Review Sarah M. Connelly, MD NDA 205834 Ledipasvir/Sofosbuvir Fixed-Dose Combination

Table 3 Overview of Phase 2 and Pivotal Phase 3 LDV/SOF Trials

Trial Number	Trial Design	Population	Regimen and Duration	Number Enrolled	Primary Efficacy Endpoint
		Pivotal Phase 3 LDV	//SOF Trials		
GS-US-337- 0102 (ION-1)	Randomized, open-label, international, multicenter trial	GT 1 Treatment-naïve ≤20% may have had cirrhosis at screening	LDV/SOF: 12 or 24 weeks LDV/SOF+RBV: 12 or 24 weeks	865	SVR12
GS-US-337- 0109 (ION-2)	Randomized, open-label, multicenter trial	GT 1 Treatment- experienced, including prior PI- failures ≤ 20% may have had cirrhosis at screening	LDV/SOF: 12 or 24 weeks LDV/SOF+RBV: 12 or 24 weeks	440	SVR12
GS-US-337- 0108 (ION-3)	Randomized, open-label, multicenter trial	GT 1 Treatment-naïve, non-cirrhotic	LDV/SOF: 8 or 12 weeks LDV/SOF+RBV: 8 weeks	647	SVR12
		Phase 2 LDV/SO	F Trials		
GS-US-337- 0118 (LONESTAR)	Open-label Single center trial	GT 1 Treatment-naïve and Treatment- experienced, including prior Pl- failures; ≤50% of treatment- experienced subjects may have had cirrhosis at screening	LDV/SOF: 8 or 12 weeks LDV/SOF+RBV: 8 or 12 weeks	100	SVR12
GS-US-337- 0122 (ELECTRON- 2; Cohort 2, Groups 3 and 4)	Open-label Two center trial (New Zealand)	GT 3 Treatment-naïve Subjects may have had cirrhosis	LDV/SOF: 12 weeks LDV/SOF+RBV: 12 weeks	51	SVR12
P7977-0523 (ELECTRON; Part 4, Groups 12 and 13; Part 6, Groups 16- 18, 20, and 21)	Open-label Two center trial (New Zealand)	GT 1, 2 or 3 Treatment-naïve and Treatment- experienced Subjects may have had cirrhosis at screening	LDV+SOF: 12 weeks LDV/SOF: 12 weeks LDV/SOF+RBV: 6 or 12 weeks	102	SVR12

Patient Information Leaflet (Source)

Package leaflet: Information for the patient

Xydalba 500 mg powder for concentrate for solution for infusion dalbavancin

This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effect(s) you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

- What Xvdalba is and what it is used for
- 2. What you need to know before you are given Xydalba
- 3. How you will be given Xydalba
- Possible side effects
- How to store Xydalba
- 6. Contents of the pack and other information

What Xydalba is and what it is used for

Xydalba contains the active substance dalbavancin, which is an antibiotic of the glycopeptide group.

Xydalba is used to treat adults with infections of the skin or in the layers of flesh below the skin.

Xydalba works by killing certain bacteria, which can cause serious infections. It kills these bacteria by interfering with the formation of bacterial cell walls.

If you also have other bacteria that cause your infection, your doctor may decide to treat you with other antibiotics in addition to Xydalba.

What you need to know before you are given Xydalba

Do not use Xydalba if you are allergic to dalbavancin or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before being given Xydalba:

- If you have or have had kidney problems. Depending on the condition of your kidney, your doctor may have to reduce your dose.
- If you are suffering from diarrhoea, or you have previously suffered from diarrhoea
 when being treated with antibiotics.
- If you are allergic to other antibiotics such as vancomycin or teicoplanin.

Diarrhoea during or after treatment

If you develop diarrhoea during or after your treatment, tell your doctor at once. Do not take any medicine to treat your diarrhoea without first checking with your doctor.

Statistical Officer Review (Source)



U.S. Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research Office of Translational Sciences Office of Biostatistics

STATISTICAL REVIEW AND EVALUATION

CLINICAL STUDIES

022526 / N0062 **NDA** #:

Drug Name: Addyi™ (Flibanserin 100 mg q.h.s.)

Treatment of hypoactive sexual desire disorder (HSDD) in Indication(s):

premenopausal women

Sprout Pharmaceuticals, Inc. Applicant:

Submission: 02/18/2015 Date(s):

> PDUFA: 08/18/2015

Review Priority: Resubmission class2

Division of Biometrics III Biometrics Division:

Kate Dwyer, Ph.D. Statistical Reviewer:

Mahboob Sobhan, Ph.D. Concurring Reviewers:

Medical Division: Division of Bone, Reproductive and Urologic Products, HFD-580

Catherine Sewell, MD, Clinical Reviewer Clinical Team:

Olivia Easley, MD, Clinical Reviewer

Christina Chang, MD, Clinical Team leader

Jennifer Mercier Project Manager:

Keywords: NDA review, ROC analysis

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SmithKline Beecham Pharmaceuticals Clinical Research & Development

1250 South Collegeville Road P.O. Box 5089 Collegeville, PA 19426-0989

STUDY DRUG: BRL 29060/PAROXETINE (PAXIL)

A MULTI-CENTER, DOUBLE-BLIND, PLACEBO CONTROLLED STUDY OF PAROXETINE AND IMIPRAMINE IN ADOLESCENTS WITH UNIPOLAR MAJOR DEPRESSION

PROTOCOL NUMBER 29060/329

PROTOCOL August 20, 1993 Date of approval: August

26, 1993

Amendment #1: March 24, 1994 Date Amendment Approved: April 17,

1994

Amendment #2: October 2, 1996 Date Amendment Approved: October

29, 1996

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Summary of Product Characteristics (Source)

1. NAME OF THE MEDICINAL PRODUCT

Olazax 5 mg tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 5 mg olanzapine.

Excipient with known effect: Each tablet contains 0.23 mg aspartame

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL form

Tablet

Yellow coloured circular flat bevelled edge tablets with 'B' debossed on one side.

4. Clinical particulars

4.1 Therapeutic indications

Adults

Olanzapine is indicated for the treatment of schizophrenia.

Olanzapine is effective in maintaining the clinical improvement during continuation therapy in patients who have shown an initial treatment response.

Olanzapine is indicated for the treatment of moderate to severe manic episode. In patients whose manic episode has responded to olanzapine treatment, olanzapine is indicated for the prevention of recurrence in patients with bipolar disorder (see section 5.1).

4.2 Posology and method of administration

Adults

Schizophrenia: The recommended starting dose for olanzapine is 10 mg/day.

Manic episode: The starting dose is 15 mg as a single daily dose in monotherapy or 10 mg daily in combination therapy (see section 5.1).

Preventing recurrence in bipolar disorder:

The recommended starting dose is 10 mg/day.

For patients who have been receiving olanzapine for treatment of manic episode, continue therapy for preventing recurrence at the same dose. If a new manic, mixed, or depressive episode occurs, olanzapine treatment should be continued (with dose optimisation as needed), with supplementary therapy to treat mood symptoms, as clinically indicated.

During treatment for schizophrenia, manic episode and recurrence prevention in bipolar disorder, daily dosage may subsequently be adjusted on the basis of individual clinical status within the range 5-20 mg/day. An increase to a dose greater than the recommended starting dose is advised only after appropriate clinical reassessment and should generally occur at intervals of not less than 24 hours. Olanzapine can be given without regards for meals as absorption is not affected by food. Gradual tapering of the dose should be considered when discontinuing olanzapine.