For PPB use only	
1.17	**Product Information**
1.17.1	**Summary Product Characteristics (SPC)**

1. Name of the medicinal product

Tolvaptan Tablets 30mg

2. Qualitative and quantitative composition

Each uncoated tablet contains:

Tolvaptan 30mg

S. No.	Wt. / tablet (mg)	Ingredient	Spec	Overages	Std. Qty for 100,000 tablets (in kg)
1.	30.00	Tolvaptan	IHS	Nil	3.000
2.	70.00	Lactose	BP	Nil	7.000
3.	63.95	Maize Starch	BP	Nil	6.395
4.	1.00	Magnesium Stearate	BP	Nil	0.100
5.	0.05	Brilliant Blue	IHS	Nil	0.005

BP – British Pharmacopoeia & IHS-In-House Specification.

3. Pharmaceutical form

4.

Tablet: A pale blue color circular shape biconvexed uncoated tablet, plain on both the sides of the tablet.

5. Clinical particulars

4.1 Therapeutic indications

Tolvaptan is indicated in adults for the treatment of hyponatremia secondary to the syndrome of inappropriate antidiuretic hormone secretion (SIADH).

4.2 Posology and method of administration

Tolvaptan has to be initiated at a dose of 15 mg and 30mg once daily or as directed by physician.

Method of administration: Oral.
Not recommended for children.

4.3 Contraindications

Anuria, Volume depletion, Hypovolemic hyponatremia, Hypernatremia, Patients who cannot perceive thirst, Pregnancy and Breast-feeding.

4.4 Special warnings and precautions for use

Tolvaptan may cause adverse reactions related to water loss such as thirst, dry mouth and dehydration. Therefore, patients must have access to water and be able to drink sufficient amounts of water. If fluid restricted patients are treated with tolvaptan, extra caution has to be exercised to ensure that patients do not become overly dehydrated.

Dehydration

Volume status must be monitored in patients taking tolvaptan because treatment with tolvaptan may result in severe dehydration, which constitutes a risk factor for renal dysfunction. If dehydration becomes evident, take appropriate action which may include the need to interrupt or reduce the dose of tolvaptan and increase fluid intake.

4.5 Interaction with other medicinal products and other forms of interaction

Medicinal products with high sodium content such as effervescent analgesic preparations and certain sodium containing treatments for dyspepsia may also increase serum sodium concentration.

4.6 Fertility, Pregnancy and lactation

Tolvaptan is contraindicated during pregnancy. Women of childbearing potential have to use effective contraception during tolvaptan treatment.
Lactation: It is unknown whether tolvaptan is excreted in human milk.

4.7 Effects on ability to drive and use machines

However, when driving or using machines it should be taken into account that occasionally dizziness, asthenia or syncope may occur.

4.8 Undesirable effects

Common side effects of Tolvaptan include: Increased thirst or urination, dry mouth, loss of appetite, constipation, weakness, fruity breath odor, drowsiness, dry skin, nausea, or vomiting.

4.9 Overdose

The signs and symptoms of an acute overdose can be anticipated to be those of excessive pharmacologic effect: a rise in serum sodium concentration, polyuria, thirst and dehydration/hypovolemia (profuse and prolonged aquaresis).
Treatment: In patients with suspected tolvaptan overdose, assessment of vital signs, electrolyte concentrations, ECG and fluid status is recommended. Appropriate replacement of water and/or electrolytes must continue until aquaresis abates.

6. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Diuretics, vasopressin antagonists.
Tolvaptan is a selective vasopressin V2-receptor antagonist that specifically blocks the binding of arginine vasopressin (AVP) at the V2-receptor of the distal portions of the nephron. Tolvaptan affinity for the human V2-receptor is 1.8 times that of native AVP.

5.2 Pharmacokinetic properties

Absorption: After oral administration, tolvaptan is rapidly absorbed with peak plasma concentrations occurring about 2 hours after dosing. The absolute bioavailability of tolvaptan is about 56 %. Co-administration of a 60 mg dose with a high-fat meal increases peak concentrations 1.4 fold with no change in AUC and no change in urine output.
Distribution: Tolvaptan binds reversibly (98 %) to plasma proteins.
Elimination: The terminal elimination half-life is about 8 hours and steady-state concentrations of tolvaptan are obtained after the first dose.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber.

7. Pharmaceutical particulars

6.1 List of excipients

Lactose

Maize Starch

Magnesium Stearate

Brilliant Blue

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 Months

6.4 Special precautions for storage

Store below 30°C. Protect from light & moisture.

6.5 Nature and contents of container

Commercial Presentation: 4's, 10's, 20's, 30's & 100's

1 x 4's (4 tablets are packed in one PVC-blister and 1 such PVC-blister is kept in one carton along with package insert).

6.6 Special precautions for disposal and other handling

Not applicable.

8. Marketing authorisation holder and Manufacturing Site Address

Marketing authorisation holder:

Company name: INNOCIA LIFESCIENCES PVT. LTD.,

Address: Block A, No.12, Balaji Nagar, Ambattur, Chennai-600 053

Country: INDIA.

Manufacturing Site:

ATOZ Pharmaceutials Pvt.Ltd.,

No.12, Balaji Nagar, Ambattur, Chennai-600053,

India.

9. Marketing authorisation number(s)

Telephone: 044 26585811, 26585855

Telefax: -

E-Mail: ah@innocialife.com

9. Date of first registration / Renewal of the registration

Date of first Authorization: Not Applicable

Date of Latest Renewal: Not Applicable

10. Date of revision of the text: Not Applicable

11. Dosimetry (If Applicable): Not Applicable

12. Instructions for preparation of radiopharmaceuticals (If Applicable): Not Applicable