

**DSUR Supplemental Listings**  
**Product : OPC-41061 Tolvaptan**  
**Report Period: 19-May-2015 To 18-May-2016**

Run Date: 02-Jun-2016 08:59

Report Criteria	
Report Period Start Date:	19-May-2015
Report Period End Date:	18-May-2016
Product Family:	OPC-41061 Tolvaptan
Product/Formulation:	None Selected
Study ID:	None Selected
License Number:	None Selected
Blinded/Unblinded:	UNBLINDED
Report Run Mode:	FINAL
Include Cases With Null Event	NO
Receipt Date:	
MedDRA Version:	19.0J

**DSUR Case Clean Up Listing**  
**Product : OPC-41061 Tolvaptan**  
**Report Period: 19-May-2015 To 18-May-2016**

Run Date: 02-Jun-2016 08:59

Case Number	Product/Formulation	Reported Indication	Case Owner
Missing Company And Reported Causality Assessment			
None Reported			
Missing License Level Listedness Assessment			
None Reported			

**DSUR Case Clean Up Listing**  
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**Report Period: 19-May-2015 To 18-May-2016**

Run Date: 02-Jun-2016 08:59

Case Number	Product/Formulation	Reported Indication	Case Owner
<b>Unlocked</b>			
2015_001911	Blinded	Autosomal Dominant Polycystic Kidney Disease	Otsuka
2015_006270	OPC-41061 /Tablet	Autosomal Dominant Polycystic Kidney Disease	Otsuka
2015_006855	OPC-41061 /Tablet	Autosomal dominant polycystic kidney disease	Otsuka
2015_007190	Blinded	Autosomal Dominant Polycystic Kidney Disease	Otsuka
2015_008813	Blinded	Autosomal Dominant Polycystic Kidney Disease	Otsuka
2015_009115	OPC-41061 vs Placebo /Tablet	Autosomal Dominant Polycystic Kidney Disease	Otsuka
2015_010272	Blinded	Nephrosclerosis	Otsuka
2015_010529	Blinded	Autosomal Dominant Polycystic Kidney Disease	Otsuka
2015_011446	Blinded	Autosomal Dominant Polycystic Kidney Disease	Otsuka
2015_011464	Blinded	Autosomal Dominant Polycystic Kidney Disease	Otsuka
2015_012269	OPC-41061 /Tablet	Autosomal Dominant Polycystic Kidney Disease	Otsuka
2015_012422	Blinded	Autosomal dominant polycystic kidney disease	Otsuka
2015_012634	OPC-41061 /Tablet	Autosomal Dominant Polycystic Kidney Disease	Otsuka
2015_012735	OPC-41061 /Tablet	Autosomal Dominant Polycystic Kidney Disease	Otsuka
2015_014817	Blinded	Autosomal Dominant Polycystic Kidney Disease	Otsuka
2015_015058	OPC-41061 /Tablet	Autosomal Dominant Polycystic Kidney Disease	Otsuka
2015_015468	OPC-41061 /Tablet	Autosomal Dominant Polycystic Kidney Disease	Otsuka
2015_015667	Blinded	Autosomal Dominant Polycystic Kidney Disease	Otsuka
2015_016985	Blinded	Autosomal Dominant Polycystic Kidney Disease	Otsuka
2015_017120	Blinded	Autosomal Dominant Polycystic Kidney Disease	Otsuka
2015_017133	Blinded	Autosomal Dominant Polycystic Kidney Disease	Otsuka
2015_017492	OPC-41061 /Tablet	Autosomal Dominant Polycystic Kidney Disease	Otsuka
2016_000808	OPC-41061 /Tablet	Autosomal Dominant Polycystic Kidney Disease	Otsuka
2016_001131	OPC-41061 /Tablet	Autosomal Dominant Polycystic Kidney Disease	Otsuka
2016_001382	OPC-41061 vs Placebo /Tablet	Autosomal dominant polycystic kidney disease	Otsuka
2016_002500	Blinded	Autosomal dominant polycystic kidney disease	Otsuka
2016_002910	OPC-41061 /Tablet	Autosomal Dominant Polycystic Kidney Disease	Otsuka
2016_004091	Blinded	Autosomal Dominant Polycystic Kidney Disease	Otsuka
2016_004208	Blinded	Autosomal dominant polycystic kidney disease	Otsuka
2016_004210	OPC-41061 vs Placebo /Tablet	Autosomal Dominant Polycystic Kidney Disease	Otsuka
2016_005470	OPC-41061 /Tablet	Autosomal Dominant Polycystic Kidney Disease	Otsuka

**DSUR Case Clean Up Listing**  
**Product : OPC-41061 Tolvaptan**  
**Report Period: 19-May-2015 To 18-May-2016**

Run Date: 02-Jun-2016 08:59

Case Number	Product/Formulation	Reported Indication	Case Owner
<b>Unlocked</b>			
2016_005970	OPC-41061 /Tablet	Autosomal Dominant Polycystic Kidney Disease	Otsuka
2016_006284	OPC-41061 /Tablet	Autosomal Dominant Polycystic kidney disease	Otsuka
2016_006538	Blinded	Autosomal Dominant Polycystic Kidney Disease	Otsuka
2016_006684	OPC-41061 /Tablet	Autosomal Dominant Polycystic Kidney Disease	Otsuka
2016_007222	OPC-41061 /Tablet	Autosomal Dominant Polycystic Kidney Disease	Otsuka
2016_007463	Blinded	Autosomal dominant polycystic kidney disease	Otsuka
2016_007466	OPC-41061 /Tablet	Autosomal Dominant Polycystic Kidney Disease	Otsuka
2016_007469	OPC-41061 /Tablet	Autosomal dominant polycystic kidney disease	Otsuka
2016_007471	OPC-41061 /Tablet	Autosomal Dominant Polycystic Kidney Disease	Otsuka
2016_007901	OPC-41061 /Tablet	Autosomal dominant polycystic kidney disease	Otsuka
2016_009122	Blinded	Autosomal dominant polycystic kidney disease	Otsuka
2016_009663	OPC-41061 /Tablet	Autosomal dominant polycystic kidney disease	Otsuka
2016_009823	Blinded	Autosomal Dominant Polycystic Kidney Disease	Otsuka
2016_010014	OPC-41061 /Tablet	Autosomal Dominant Polycystic Kidney Disease	Otsuka
2016_010181	Blinded	Autosomal Dominant Polycystic Kidney Disease	Otsuka
2016_010266	Blinded	Renal failure chronic	Otsuka
2016_010578	Blinded	Autosomal dominant polycystic kidney disease	Otsuka
2016_010583	Blinded	Autosomal Dominant Polycystic Kidney Disease	Otsuka
2016_010843	Blinded	Autosomal Dominant Polycystic Kidney Disease	Otsuka
2016_010946	OPC-41061 vs Placebo /Tablet	Autosomal Dominant Polycystic Kidney Disease	Otsuka
2016_011031	OPC-41061 vs Placebo /Tablet	autosomal dominant polycystic kidney disease	Otsuka
2016_011076	OPC-41061 /Tablet	Autosomal Dominant Polycystic Kidney Disease	Otsuka
2016_011127	OPC-41061 /Tablet	Autosomal Dominant Polycystic Kidney Disease	Otsuka
2016_011955	OPC-41061 /Tablet	Autosomal Dominant Polycystic Kidney Disease	Otsuka
2016_011958	OPC-41061 /Tablet	Autosomal Dominant Polycystic Kidney Disease	Otsuka
<b>Uncoded Event</b>			
<b>None Reported</b>			

**DSUR Case Clean Up Listing**  
**Product : OPC-41061 Tolvaptan**  
**Report Period: 19-May-2015 To 18-May-2016**

Run Date: 02-Jun-2016 08:59

Case Number	Product/Formulation	Reported Indication	Case Owner
Uncoded Indication Terms			
None Reported			

**DSUR Index of Cases**  
**Product : OPC-41061 Tolvaptan**  
**Report Period: 19-May-2015 To 18-May-2016**

Run Date: 02-Jun-2016 08:59

Case Numbers
2015_000496 ; 2015_000914 ; 2015_001411 ; 2015_001867 ; 2015_001911 ; 2015_001913 ; 2015_001919 ; 2015_002006 ; 2015_002007 ; 2015_002353 ; 2015_002736 ; 2015_003092 ; 2015_003096 ; 2015_003174 ; 2015_003388 ; 2015_004354 ; 2015_004466 ; 2015_004515 ; 2015_004565 ; 2015_005056 ; 2015_005583 ; 2015_005585 ; 2015_005819 ; 2015_005936 ; 2015_005937 ; 2015_006107 ; 2015_006152 ; 2015_006270 ; 2015_006416 ; 2015_006550 ; 2015_006600 ; 2015_006606 ; 2015_006751 ; 2015_006752 ; 2015_006845 ; 2015_006849 ; 2015_006851 ; 2015_006855 ; 2015_006897 ; 2015_006929 ; 2015_006974 ; 2015_007190 ; 2015_007194 ; 2015_007312 ; 2015_007327 ; 2015_007334 ; 2015_007475 ; 2015_007561 ; 2015_007595 ; 2015_007596 ; 2015_007606 ; 2015_007618 ; 2015_007622 ; 2015_007684 ; 2015_007887 ; 2015_007948 ; 2015_008318 ; 2015_008464 ; 2015_008471 ; 2015_008551 ; 2015_008715 ; 2015_008813 ; 2015_009115 ; 2015_009119 ; 2015_009241 ; 2015_009583 ; 2015_009854 ; 2015_009866 ; 2015_010264 ; 2015_010265 ; 2015_010272 ; 2015_010367 ; 2015_010371 ; 2015_010471 ; 2015_010529 ; 2015_010609 ; 2015_011121 ; 2015_011231 ; 2015_011402 ; 2015_011411 ; 2015_011446 ; 2015_011460 ; 2015_011464 ; 2015_011678 ; 2015_011818 ; 2015_011901 ; 2015_012136 ; 2015_012259 ; 2015_012269 ; 2015_012422 ; 2015_012453 ; 2015_012516 ; 2015_012518 ; 2015_012520 ; 2015_012632 ; 2015_012634 ; 2015_012735 ; 2015_012828 ; 2015_013091 ; 2015_013096 ; 2015_013142 ; 2015_013295 ; 2015_013301 ; 2015_013352 ; 2015_013610 ; 2015_013678 ; 2015_013679 ; 2015_013708 ; 2015_013927 ; 2015_014116 ; 2015_014124 ; 2015_014358 ; 2015_014360 ; 2015_014427 ; 2015_014530 ; 2015_014649 ; 2015_014817 ; 2015_015058 ; 2015_015094 ; 2015_015158 ; 2015_015173 ; 2015_015197 ; 2015_015333 ; 2015_015468 ; 2015_015469 ; 2015_015497 ; 2015_015498 ; 2015_015504 ; 2015_015667 ; 2015_015687 ; 2015_015692 ; 2015_015924 ; 2015_015926 ; 2015_016035 ; 2015_016058 ; 2015_016059 ; 2015_016380 ; 2015_016450 ; 2015_016482 ; 2015_016614 ; 2015_016617 ; 2015_016711 ; 2015_016800 ; 2015_016807 ; 2015_016985 ; 2015_016986 ; 2015_016988 ; 2015_017029 ; 2015_017120 ; 2015_017123 ; 2015_017124 ; 2015_017126 ; 2015_017127 ; 2015_017133 ; 2015_017209 ; 2015_017210 ; 2015_017361 ; 2015_017395 ; 2015_017399 ; 2015_017487 ; 2015_017492 ; 2015_017770 ; 2015_017960 ; 2016_000222 ; 2016_000808 ; 2016_000984 ; 2016_001131 ; 2016_001230 ; 2016_001382 ; 2016_001395 ; 2016_001709 ; 2016_001710 ; 2016_001712 ; 2016_001823 ; 2016_002070 ; 2016_002442 ; 2016_002443 ; 2016_002444 ; 2016_002500 ; 2016_002502 ; 2016_002506 ; 2016_002509 ; 2016_002559 ; 2016_002561 ; 2016_002563 ; 2016_002749 ; 2016_002910 ; 2016_003281 ; 2016_003366 ; 2016_003745 ; 2016_003832 ; 2016_004091 ; 2016_004167 ; 2016_004205 ; 2016_004208 ; 2016_004210 ; 2016_004212 ; 2016_004815 ; 2016_005148 ; 2016_005149 ; 2016_005326 ; 2016_005335 ; 2016_005464 ; 2016_005470 ; 2016_005968 ; 2016_005970 ; 2016_005985 ; 2016_005986 ; 2016_006271 ; 2016_006274 ; 2016_006282 ; 2016_006284 ; 2016_006459 ; 2016_006460 ; 2016_006538 ; 2016_006541 ; 2016_006544 ; 2016_006624 ; 2016_006684 ; 2016_006878 ; 2016_006895 ; 2016_006899 ; 2016_007211 ; 2016_007222 ; 2016_007462 ; 2016_007463 ; 2016_007465 ; 2016_007466 ; 2016_007468 ; 2016_007469 ; 2016_007471 ; 2016_007521 ; 2016_007522 ; 2016_007899 ; 2016_007900 ; 2016_007901 ; 2016_007903 ; 2016_007904 ; 2016_007905 ; 2016_007906 ; 2016_007920 ; 2016_007922 ; 2016_007923 ; 2016_008132 ; 2016_008133 ; 2016_008224 ; 2016_008512 ; 2016_008636 ; 2016_008909 ; 2016_009091 ; 2016_009122 ; 2016_009406 ; 2016_009663 ; 2016_009823 ; 2016_009876 ; 2016_009880 ; 2016_010010 ; 2016_010014 ; 2016_010036 ; 2016_010146 ; 2016_010156 ; 2016_010181 ; 2016_010266 ; 2016_010269 ; 2016_010285 ; 2016_010578 ; 2016_010583 ; 2016_010610 ; 2016_010843 ; 2016_010887 ; 2016_010918 ; 2016_010946 ; 2016_011031 ; 2016_011076 ; 2016_011127 ; 2016_011151 ; 2016_011234 ; 2016_011236 ; 2016_011955 ; 2016_011958 ; US-2012-11042 ; US-2013-11751 ; US-2013-12107 ; US-2014-10942 ; US-2014-12223 ; US-2014-13210 ; US-2015-10005 ; US-2015-10083 ; US-2015-10127 ; US-2015-11240 ; US-2015-11612 ; US-2015-11630

**DSUR Index of Cases by SOC**  
**Product : OPC-41061 Tolvaptan**  
**Report Period: 19-May-2015 To 18-May-2016**

Run Date: 02-Jun-2016 08:59

System Organ Class	Preferred Term	Case Number
Infections and infestations	Bacteraemia	2016_003366
	Cat scratch disease	2016_005970
	Cellulitis	2015_006416
		2016_002070
	Diabetic gangrene	2016_007522
	Diverticulitis	2015_010609
		2016_001710
	Enteritis infectious	2015_007622
	Erysipelas	2016_006895
	Gastroenteritis	2016_010583
	HIV infection	2016_007211
	Hepatic cyst infection	2015_009854
	Influenza	2016_006541
	Ophthalmic herpes zoster	2016_004212
	Otitis media	2016_010181
	Pneumonia	2016_000984
		2016_007211
		2016_007903
	Pyelonephritis	2015_007190
		2015_007684
		2015_008551
		2016_001382
		2016_004167
	Renal cyst infection	2016_008909
		2015_008471
		US-2014-12223
	Respiratory tract infection	US-2015-11630
		2016_004210
	Sinusitis	2015_015468

**DSUR Index of Cases by SOC**  
**Product : OPC-41061 Tolvaptan**  
**Report Period: 19-May-2015 To 18-May-2016**

Run Date: 02-Jun-2016 08:59

System Organ Class	Preferred Term	Case Number
<b>Infections and infestations</b>		
	Upper respiratory tract infection	2015_012136
	Urinary tract infection	2015_017960 2016_002500
	Urosepsis	2015_012634
	Viral upper respiratory tract infection	2015_017126
<b>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</b>		
	Basal cell carcinoma	2015_001913 2016_008512
	Brain neoplasm benign	2015_006929
	Colon cancer	2016_002563
	Meningioma	2016_006624
	Prostate cancer	2015_006606
	Squamous cell carcinoma	2016_008512
	Uterine leiomyoma	2015_001411
<b>Blood and lymphatic system disorders</b>		
	Anaemia	2016_010887
	Neutropenia	2016_008133
	Thrombocytopenia	2016_010946
<b>Endocrine disorders</b>		
	Adrenal mass	2016_010610
<b>Metabolism and nutrition disorders</b>		
	Hyperkalaemia	2016_006284
	Hyponatraemia	2015_013142 2016_003832
<b>Psychiatric disorders</b>		
	Confusional state	2015_013096
	Major depression	US-2014-10942
<b>Nervous system disorders</b>		
	Carotid artery aneurysm	2015_016807



**DSUR Index of Cases by SOC**  
**Product : OPC-41061 Tolvaptan**  
**Report Period: 19-May-2015 To 18-May-2016**

Run Date: 02-Jun-2016 08:59

System Organ Class	Preferred Term	Case Number
<b>Nervous system disorders</b>	Carotid artery dissection	2015_016807
	Cerebellar ischaemia	2016_002910
	Cerebral artery thrombosis	2016_006624
	Cerebral atrophy	2015_004565
	Cerebrovascular accident	2016_004205
		2016_006624
	Dizziness	2015_015468
	Dyskinesia	2015_014124
	Epilepsy	2015_009119
	Headache	2015_015468
	Intracranial aneurysm	2015_012632
		2015_013091
	Intracranial pressure increased	2016_004208
	Lumbar radiculopathy	2016_001823
	Parkinson's disease	2015_005819
	Ruptured cerebral aneurysm	2016_002444
	Seizure	2015_002353
	Subarachnoid haemorrhage	2015_017123
		2016_002442
	Syncope	2016_011031
	Thrombotic cerebral infarction	2015_006107
	Transient ischaemic attack	2015_007190
		2015_009115
		2016_009663
<b>Eye disorders</b>	Macular hole	2015_015197
	Retinal detachment	2015_007475
	Visual impairment	2015_015468

**DSUR Index of Cases by SOC**  
**Product : OPC-41061 Tolvaptan**  
**Report Period: 19-May-2015 To 18-May-2016**

Run Date: 02-Jun-2016 08:59

System Organ Class	Preferred Term	Case Number
<b>Ear and labyrinth disorders</b>		
	Vertigo	2015_006751 2015_015468
<b>Cardiac disorders</b>		
	Acute myocardial infarction	2015_009866
	Angina pectoris	2015_011411
	Aortic valve incompetence	2015_005583
	Arteriosclerosis coronary artery	2016_007465
	Atrial fibrillation	2016_005470 2016_007521
	Bundle branch block left	2016_006899
	Cardiac disorder	2015_012422
	Cardiac failure	2016_000984
	Cardiac failure congestive	2016_000222
	Left ventricular dysfunction	2016_006899
	Myocardial infarction	2016_011127 2016_011958
	Pericarditis	US-2015-11612
<b>Vascular disorders</b>		
	Accelerated hypertension	2015_006600
	Arterial stenosis	2015_009241
	Deep vein thrombosis	2016_011955
	Hypertension	2015_017120 2016_007469 2016_009880
	Hypertensive crisis	2015_006550
<b>Respiratory, thoracic and mediastinal disorders</b>		
	Asthma	2015_007194 2015_017126
	Dry throat	2015_014530

**DSUR Index of Cases by SOC**  
**Product : OPC-41061 Tolvaptan**  
**Report Period: 19-May-2015 To 18-May-2016**

Run Date: 02-Jun-2016 08:59

System Organ Class	Preferred Term	Case Number
<b>Respiratory, thoracic and mediastinal disorders</b>		
	Epistaxis	2015_012259
	Haemothorax	US-2015-10005
	Pleurisy	2016_002561
	Pulmonary embolism	2015_017487 2016_007211
	Sleep apnoea syndrome	2015_010272
<b>Gastrointestinal disorders</b>		
	Abdominal pain	2015_013295 2016_007468
	Abdominal pain lower	2016_006284
	Dry mouth	2015_014530
	Gastritis	2015_006855 2016_007463
	Gastroesophageal reflux disease	2015_006600
	Ileus	2016_010843
	Inguinal hernia	2015_003388 2015_005056 2015_010371
	Inguinal hernia, obstructive	2015_015158
	Intestinal obstruction	2016_001230
	Nausea	2015_010529 2015_012269
<b>Hepatobiliary disorders</b>		
	Cholecystitis	2015_006974
	Cholelithiasis	2016_007899
	Hepatic function abnormal	2015_014427 2015_016482
	Liver injury	2016_009406
<b>Skin and subcutaneous tissue disorders</b>		

**DSUR Index of Cases by SOC**  
**Product : OPC-41061 Tolvaptan**  
**Report Period: 19-May-2015 To 18-May-2016**

Run Date: 02-Jun-2016 08:59

System Organ Class	Preferred Term	Case Number
<b>Skin and subcutaneous tissue disorders</b>		
	Rash	2016_000808
	Rash maculo-papular	2016_005968
	Rash pruritic	2015_001911
	Skin ulcer	2015_006845
<b>Musculoskeletal and connective tissue disorders</b>		
	Arthritis	2016_006282
	Back pain	2015_010265
		2015_012520
		2015_015058
	Cervical spinal stenosis	2016_002559
	Osteoarthritis	2016_002749
<b>Renal and urinary disorders</b>		
	Acute kidney injury	2015_010609
		2016_001395
		2016_003745
		2016_004210
		2016_010583
	Haematuria	2015_007948
	Nephrolithiasis	2015_008464
		2015_016059
	Pollakiuria	2015_016058
	Polyuria	2016_005335
		2016_007471
		2016_010285
	Renal colic	2015_008715
		2015_016711
	Renal cyst haemorrhage	2016_003281
		2016_006274
		2016_007906

**DSUR Index of Cases by SOC**  
**Product : OPC-41061 Tolvaptan**  
**Report Period: 19-May-2015 To 18-May-2016**

Run Date: 02-Jun-2016 08:59

System Organ Class	Preferred Term	Case Number
<b>Renal and urinary disorders</b>		
	Renal cyst ruptured	2016_001131 2016_011151
	Renal haemorrhage	2015_016059
	Renal impairment	2015_002007 2015_016711 2016_011234 US-2015-10127
	Renal pain	2015_000914 2015_016986 2016_006274
<b>Pregnancy, puerperium and perinatal conditions</b>		
	Stillbirth	US-2014-13210
<b>Congenital, familial and genetic disorders</b>		
	Congenital hepatic fibrosis	2015_017127
<b>General disorders and administration site conditions</b>		
	Adverse drug reaction	2016_006878
	Catheter site extravasation	2015_011231
	Chest pain	2015_011460 2015_017487 2016_007900
	Decreased activity	2015_007887
	Fatigue	2015_007312
	Malaise	2015_007887
	Peripheral swelling	US-2013-12107
	Pyrexia	2015_002006 2015_014817 2016_007468
	Thirst	2015_013301 2016_010014

**DSUR Index of Cases by SOC**  
**Product : OPC-41061 Tolvaptan**  
**Report Period: 19-May-2015 To 18-May-2016**

Run Date: 02-Jun-2016 08:59

System Organ Class	Preferred Term	Case Number
Investigations	Alanine aminotransferase increased	2015_001911 2015_006851 2015_013679 2016_006271 2016_006684
	Aspartate aminotransferase increased	2015_001911 2015_006851 2015_013679 2016_006684
	Blood alkaline phosphatase increased	2015_001911
	Blood bicarbonate decreased	2015_009583
	Blood creatinine increased	2015_007312 2015_012828 2015_017209
	Gamma-glutamyltransferase increased	2015_001911 2015_012269
	Hepatic enzyme increased	2015_006152 2015_008813 2015_015094 2016_002502 2016_006538 2016_006895 2016_010578
	Liver function test abnormal	2015_002736 2016_006544 2016_009823
	Liver function test increased	2015_004466 2015_005936 2015_010367

**DSUR Index of Cases by SOC**  
**Product : OPC-41061 Tolvaptan**  
**Report Period: 19-May-2015 To 18-May-2016**

Run Date: 02-Jun-2016 08:59

System Organ Class	Preferred Term	Case Number
<b>Investigations</b>		
		2015_010471
		2016_004815
	Occult blood	2016_002563
	Transaminases increased	2015_011121
		2015_016035
<b>Injury, poisoning and procedural complications</b>		
	Accidental overdose	2015_007327
		2015_007618
	Ankle fracture	2015_007595
	Brain contusion	2015_004354
	Fall	2015_012632
		US-2015-10083
	Incisional hernia	2015_016617
		2016_010156
	Incorrect dose administered	2016_007462
	Jaw fracture	2015_012632
	Ligament rupture	2015_013352
	Maternal exposure during pregnancy	2015_003096
	Meniscus injury	2015_015692
	Overdose	2015_015498
		2016_008132
		2016_010269
	Shunt occlusion	2016_010266
	Shunt stenosis	2015_012453
		2015_014360
		2015_017770
	Subcutaneous haematoma	2015_014116
	Subdural haematoma	2015_015504
		2015_017029

**DSUR Index of Cases by SOC**  
**Product : OPC-41061 Tolvaptan**  
**Report Period: 19-May-2015 To 18-May-2016**

Run Date: 02-Jun-2016 08:59

<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Case Number</b>
<b>Injury, poisoning and procedural complications</b>		
	Traumatic tooth displacement	2015_012632
	Wound	2015_006845
<b>Surgical and medical procedures</b>		
	Arterial aneurysm repair	2016_007922
	Renal transplant	2016_007923
		2016_010918
	Umbilical hernia repair	2016_011236



## Total Number of Cases, SAEs and SARs during the Reporting Period

Run Date: 02-Jun-2016 09:00

Product : OPC-41061 Tolvaptan  
Report Period: 19-May-2015 To 18-May-2016

Total Number of Cases during the Reporting Period	292
Total Number of SAEs during the Reporting Period	252
Total Number of SARs during the Reporting Period	67