



# Public Case Detail

Cases Count: 12

**Case Number : 239860**

**Data Entry Date :** 11/04/2008

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :** 35Y

**Outcome :**

**DOB :**

Not yet recovered

**Causality :** Causality probable

**Information:** The patient had previously experienced an oculogyric crisis when taking aripiprazole which resolved.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Oculogyric crisis		On an unknown date, the patient experienced an oculogyric crisis. Patient's eyes looked upward involuntarily; this lasted for 10-15 minutes then normalised. This was episodic, occurring 3 times in 3 days.	decrease OROS paliperidone dose from 6mg/day to 3mg daily.

## Medicine details :

<b>Invega (Suspected)</b>	<b>Reason :</b>
Tablet	6 Milligram Daily Oral
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>INSULIN NOS (Other drug)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>

# Public Case Detail

Cases Count: 12

**Case Number : 244220**

**Data Entry Date :** 28/08/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 03/08/2008

**Age :** 26Y

**Outcome :** 06/08/2008

**DOB :**

Recovered

**Causality :** Causality possible

**Information:** Medical history of alcohol use, substance abuse with marijuana.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Speech disorder	Incapacity/disability	Seriously thought "blocked" and experienced delayed speech.	Invenga discontinued
Cognitive disorder	Incapacity/disability		
Overdose	Incapacity/disability		

## Medicine details :

<b>Invenga (Suspected)</b>	<b>Reason :</b> Unspecified neurosis		
Tablet	18 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 15/07/2008	<b>Stopped :</b> 06/08/2008	

# Public Case Detail

Cases Count: 12

**Case Number : 245097**

**Data Entry Date :** 02/10/2008

**Gender :** U

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 18/06/2008

**Age :**

**DOB :** 28/08/1978

**Outcome :**

**Causality :** Causality possible

Not yet recovered

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Blood prolactin increased		Patient experienced blood prolactin increased and galactorrhoea.	Paliperidone was decreased to 3mg once a day.
Galactorrhoea			

<b>Medicine details :</b>			
<b>Invega (Suspected)</b>		<b>Reason :</b> Unspecified schizophrenia	
Tablet	6 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 27/05/2008	<b>Stopped :</b>	
<b>RISPERIDONE (Other drug)</b>		<b>Reason :</b> Unspecified schizophrenia	
Tablet			Oral
<b>Batch :</b>	<b>Started :</b> 20/05/2008	<b>Stopped :</b> 27/05/2008	
<b>SODIUM VALPROATE (Other drug)</b>		<b>Reason :</b>	
<b>Batch :</b>	<b>Started :</b> 20/05/2008	<b>Stopped :</b> 04/06/2008	

<b>Laboratory Investigations :</b>				
<b>Type</b>	<b>Range</b>	<b>Date Tested</b>	<b>Result</b>	<b>Details</b>
Prolactin		18/06/2008	1544	Prolactin normal prior to start of paliperidone.
Prolactin		01/08/2008	798	Prolactin normal prior to start of paliperidone.
Computerised axial tomography				CT brain-unremarkable.
Magnetic Resonance Imaging				MRI-no evidence of macroadenoma.

# Public Case Detail

Cases Count: 12

**Case Number : 246708**

**Data Entry Date :** 28/11/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :** 99u

**Outcome :**

**DOB :**

Unknown

**Causality :** Causality possible

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Hypoaesthesia facial		The patient experienced stroke-like symptoms and numbness on one side of his face.	
Cerebrovascular accident			

<b>Medicine details :</b>			
<b>Invega (Suspected)</b>		<b>Reason :</b>	
Tablet			Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

# Public Case Detail

Cases Count: 12

**Case Number : 246862**

**Data Entry Date :** 08/12/2008

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 07/01/1927

**Outcome :**

**Causality :** Causality possible

Recovered

**Information:** History: antipsychotic DOCI report.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Muscle disorder		The patient had previously experienced side effects which "bullt up over time" when takeing an unspecified antipsychotic.	Invega was increased to 6mg from 3mg. Invega discontinued.
Incontinence			
Somnolence			

## Medicine details :

**Invega (Suspected)**

**Reason :**

Tablet

6 Milligram

Daily

Oral

**Batch :**

**Started :**

**Stopped :**

0



# Public Case Detail

Cases Count: 12

**Case Number : 247590**

**Data Entry Date :** 12/01/2009

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :** 19Y

**Outcome :**

**DOB :**

Unknown

**Causality :** Causality possible

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Oculogyric crisis		Oculogyric crisis	Invega withdrawn

<b>Medicine details :</b>			
<b>Invega (Suspected)</b>		<b>Reason :</b>	
Tablet		3 Milligram Daily	Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

# Public Case Detail

Cases Count: 12

**Case Number : 247610**

**Data Entry Date :** 12/01/2009

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :** 99U

**Outcome :**

**DOB :**

Unknown

**Causality :** Causality possible

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus			

**Medicine details :**

Invega (Suspected)	<b>Reason :</b>	
	1 Dose Unspec Daily	Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>

# Public Case Detail

Cases Count: 12

## Case Number : 247615

**Data Entry Date :** 12/01/2009  
**Hospitalisation :** Admitted to hospital  
**Onset Date :** 30/09/2008  
**Outcome :**  
 Not yet recovered

**Gender :** M  
**Weight (kg) :** 96.5  
**Age :**  
**DOB :** 06/08/1939  
**Causality :** Causality possible

### Information:

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Mania	Caused or prolonged inpatient hospitalisation	After initiating OROS paliperidone therapy, the physician noticed that the patient's mania became worse. Two weeks later on 21/10/08, the physician increased OROS paliperidone to 9 mg daily in an attempt to control the mania. The mania episode worsened again, and the patient was admitted to the hospital.	Paliperidone was withdrawn

<b>Medicine details :</b>			
<b>Invega (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia		
	6 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 30/09/2008	<b>Stopped :</b> 20/10/2008	
<b>ATACAND (Other drug)</b>	<b>Reason :</b>		
	1 Dose Unspec		
<b>Batch :</b>	<b>Started :</b> 18/06/2007	<b>Stopped :</b>	





# Public Case Detail

Cases Count: 12

**Case Number : 247621**

**Data Entry Date :** 12/01/2009

**Hospitalisation :**

**Onset Date :**

**Outcome :**

Unknown

**Gender :** F

**Weight (kg) :** 0

**Age :** 99U

**DOB :**

**Causality :** Causality possible

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Depression		In 2008 since taking Invega the patient developed episodes of depression.	

<b>Medicine details :</b>			
<b>Invega (Suspected)</b>		<b>Reason :</b> Depression	
	6 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b>		<b>Stopped :</b>

# Public Case Detail

Cases Count: 12

## Case Number : 247623

**Data Entry Date :** 12/01/2009  
**Hospitalisation :** Admitted to hospital  
**Onset Date :** 15/08/2008  
**Outcome :**  
 Not yet recovered

**Gender :** F  
**Weight (kg) :** 0  
**Age :** 51Y  
**DOB :**  
**Causality :** Causality possible

### Information:

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Psychotic disorder	Caused or prolonged inpatient hospitalisation	The patient was treated with OROS paliperidone 6 mg, initiated in Jun 2008, for schizophrenia. In mid June 2008, the dosage of paliperidone was increased to 9 mg. During the end of July 2008, treatment with aripiprazole 5 mg was added. In Aug 2008, the patient developed psychotic symptoms and was hospitalised.	

<b>Medicine details :</b>			
<b>Abilify (Suspected)</b>	<b>Reason :</b>		
	5 Milligram Daily	<b>Batch :</b>	<b>Started :</b> 30/06/2008 <b>Stopped :</b>
<b>Invega (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia		
	9 Milligram Daily Oral	<b>Batch :</b>	<b>Started :</b> 15/06/2008 <b>Stopped :</b>

# Public Case Detail

Cases Count: 12

**Case Number : 247626**

**Data Entry Date :** 12/01/2009

**Gender :** F

**Hospitalisation :** Admitted to hospital

**Weight (kg) :** 0

**Onset Date :**

**Age :** 99U

**Outcome :**

**DOB :**

Not yet recovered

**Causality :** Causality possible

**Information:**

**Reaction :**

**Preferred Term**

Psychotic disorder

**Severity**

Caused or prolonged inpatient hospitalisation

**Report Description**

Patient was treated for schizophrenia with 9 mg paliperidone from mid June 08. During July 08 aripiprazole 5 mg was added. In Aug 2008 patient developed psychotic symptoms and was hospitalised. In mid Aug 2008, treatment with quetiapine fumarate was added. On 22 Oct 2008 the dosage of paliperidone was increased to 12 mg. The psychotic symptoms then reappeared. The physician believed that the second episode of psychotic symptoms was due to OROS paliperidone therapy at 12 mg.

**Treatment**

Paliperidone dose reduced.

**Medicine details :**

**Invega (Suspected)**

**Reason :** Unspecified schizophrenia

12 Milligram

Daily

Oral

**Batch :**

**Started :** 22/10/2008

**Stopped :**

**SEROQUEL (Other drug)**

**Reason :** Unspecified schizophrenia

1 Dose Unspec Daily

**Batch :**

**Started :** 15/08/2008

**Stopped :**



# Public Case Detail

Cases Count: 12

**Case Number : 247629**

**Data Entry Date :** 12/01/2009

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 65

**Onset Date :** 03/11/2008

**Age :** 78Y

**DOB :**

**Outcome :**

**Causality :** Causality possible

Not yet recovered

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Tardive dyskinesia		Patient experienced tardive dyskinesia including lip smacking and eye pinching.	Paliperidone was withdrawn
Tardive dyskinesia			

<b>Medicine details :</b>			
<b>Invega (Suspected)</b>		<b>Reason :</b> Unspecified psychosis	
	3 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 02/11/2008	<b>Stopped :</b> 15/11/2008	

Selection Parameters : Date Range: 01/08/2007 To 31/12/2059 Unclear causality excluded GM medicines Only Medicine Names: Paliperidone, Invega