

Report information

Report header	Visual impairment: Linezolid			
Type of report	Date first received at regional centre	Version		
spontaneous	2016-02-27	1		
Literature reference				
Type of sender	Sender	Contact person	Sender's report no.	Worldwide unique no.
regional pharmacovigilance center	MAMC, New Delhi	Shalini Chawla	MAMC/FEB-2016/042	IN-IPC-2016-09468
Reporter qualification	Country of occurrence	Country of primary source		
physician	India	India		
Serious case?	no			

Patient characteristics

Initials	Sex	Date of birth	Age at onset	Age group	Weight (kg)	Height (cm)	Death date
YK	male		26 year(s)	adult	53		
Death cause							
Death cause after autopsy							
Comment on death	Not applicable						

Relevant Medical History

	Start date	Stop date	Continuing
Relevant medical history - free text	No family history of tuberculosis, no smoking habit. MDR-TB failure in 2014.		

Reaction(s)/Event(s) (WHO-ART)

	Onset date	End date	Duration	Treatment	Outcome
Visual impairment	2016-01-24			3	not recovered/not resolved
Neuropathy	2016-01-24			3	not recovered/not resolved

Treatment: 1=no treatment, 2=non-medical treat., 3=medical treatment, 4=dialysis, 5=surgery, 6=unknown

Causality of Drug to Reaction (CIOMS V)

	Visual impairment	Neuropathy	ADRs labelled	Interact
Linezolid	Probable/Likely	Probable/Likely	yes	
Isoniazid	Possible	Probable/Likely	yes	

Suspected Drugs: Details

	GF Batchno	Strength	Route	Dose	Dosage regimen	StartDate EndDate	Duration of use	Action taken	Re- chall	Susp ingred	Indication (ICD-10)
Linezolid <i>Linezolid</i>	Unspec Not available	Unspec	oral	600 mg	1 per 1 day(s)	2014-09-22 2016-02-27	524 day(s)	1		AI	Respiratory tuberculosis unspecified, confirmed bacteriologically and histologically
Additional information	Indication: Extensively drug resistance tuberculosis. High dose Isoniazid and Linezolid were replaced with Clarithromycin.										
Isoniazid <i>Isoniazid</i>	Unspec Not available	Unspec	oral	900 mg	1 per 1 day(s)	2014-09-22 2016-02-27	524 day(s)	1		AI	Respiratory tuberculosis unspecified, confirmed bacteriologically and histologically
Additional information	Indication: Extensively drug resistance tuberculosis. High dose Isoniazid and Linezolid were replaced with Clarithromycin.										

Suspected Ingredient: AI=Active Ingredient, PR=Preservative, AX=Antioxidant, ST=Stabilizer, CL=Color, FA=Flavouring agent,
SO=Solvent, CO=Constituent, EP=Excess percent

Action taken: 1=drug withdrawn, 2=dose reduced, 3=dose increased, 4=dose not changed, 5=unknown, 6=not applicable

Rechallenge Info: A=reaction recurred, B=no recurrence, C=effect unknown

Concomitant Drugs

	GF Batchno	Strength	Route	Dose	Dosage regimen	StartDate EndDate	Duration of use	Indication (ICD-10)
Moxifloxacin <i>Moxifloxacin hydrochloride</i>	Unspec Not available	Unspec	oral	400 mg	1 per 1 day(s)	2014-09-22 -		Respiratory tuberculosis unspecified, confirmed bacteriologically and histologically
Additional information	Indication: Extensively drug resistance tuberculosis (XDR-TB).							
Clofazimine <i>Clofazimine</i>	Unspec Not available	Unspec	oral	200 mg	1 per 1 day(s)	2014-09-22 -		Respiratory tuberculosis unspecified, confirmed bacteriologically and histologically
Additional information	Indication: Extensively drug resistance tuberculosis (XDR-TB).							
Pas <i>Aminosalicylate sodium</i>	Unspec Not available	Unspec	oral	12 g	1 per 1 day(s)	2014-09-22 -		Respiratory tuberculosis unspecified, confirmed bacteriologically and histologically
Additional information	Indication: Extensively drug resistance tuberculosis (XDR-TB).							
Amoxyclav <i>Amoxicillin sodium/ Clavulanate potassium</i>	Unspec Not available	Unspec	oral	1 g	2 per 1 day(s)	2014-09-22 -		Respiratory tuberculosis unspecified, confirmed bacteriologically and histologically
Additional information	Indication: Extensively drug resistance tuberculosis (XDR-TB).							

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Capreomycin <i>Capreomycin sulfate</i>	Unspec Not available	Unspec	intramuscular	1 g	1 per 1 day(s)	2014-09-22 -	Respiratory tuberculosis unspecified, confirmed bacteriologically and histologically
Additional information	Indication: Extensively drug resistance tuberculosis (XDR-TB).						

Description and Assessment

Reporter's comment

C/O Diminished vision (color blindness) and numbness in the lower limb.

Case narrative

A 26-year-old male patient weighed 53 kg who developed visual impairment and neuropathy while receiving linezolid and isoniazid.

The relevant medical history included, MDR-TB failure in 2014. The patient started receiving linezolid 600 mg once daily since 22 September 2014 and stopped on 27 February 2016 for XDR-TB, isoniazid 900 mg once daily since 22 September 2014 and stopped on 27 February 2016 for XDR-TB. The concomitant medicines included, moxifloxacin 400 mg once daily since 22 September 2014 for XDR-TB, clofazimine 200 mg once daily since 22 September 2014 for XDR-TB, PAS 12 g once daily since 22 September 2014 for XDR-TB, amoxycylave 1 g twice daily since 22 September 2014 for XDR-TB, capreomycin 1 g once daily since 22 September 2014 for XDR-TB. The patient experienced adverse events of diminished vision and numbness in the lower limb started on 24 January 2016.

The clinical outcome of adverse events were Not recovered.

Causality assessed as Probable for Linezolid and Possible for Isoniazid.

Sender's comment

Reasonable possibility of a relationship between the suspected medicines and the adverse events.

References

Not available

Appendix - Tests and procedures

Results of tests and procedures - free text

25/2/2016 -Blurring of disc margins. -S/O B/E disc edema. -Fundus response B/E Vision Rt-3/60, Lf-2/60

Test type	range	more information
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