

ADRS Case Number: 390962 - 30/06/2016 - Posted

ADR Number: 390962
 Status: Posted
 Withdrawal/Rejection Reason:
 Sequence No: 1

Case Date: 30/06/2016
 Duplicates: Single

Previous No: Next No:

Patient Details

Patient ID: [REDACTED] Date of Birth: 28/08/1938 Age:
 Ethnicity: Gender: Male Weight: 0 kg
 Female
 Unknown
 State: QLD Medicare Number:

Reaction Coding

Onset Date: 15/01/2016
 Reaction Outcome: * Not yet recovered F
 Outcome Date:
 Severity Details: incapacity/disability I
 Adverse Reaction Description :

Fungal infection of right knee with *Scedosporium prolificans* following intra-articular corticosteroid injection performed in December 2015

FOLLOW UP:
 Right knee injected with corticosteroid in December 2015.
 15/01/2016 *Scedosporium (inflatum) prolificans* right knee.
 30/3/16 an inpatient in Hospital
 08/04/2016 No growth from right knee fluid
 04/07/16 Further debridement with culture planned

Please note also that in addition to receiving intra-articular Celestone, the patients received intra-articular radiological contrast at the same time.

The product used was Celestone (Merck). No batch numbers were recorded.

Treatment:
 Hospitalisation:*

Lowest Level Term	Adverse Reaction Description
Joint infection	N/A
<i>Scedosporium prolificans</i> infection	N/A
Product quality issue	N/A

Medicine Coding

* Medicine Name:
 Dose:
 Frequency:
 Form:
 Route:
 Begun Date:
 Halted Date:
 Reason for Use:

Medicine Coding

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★ **Medicine Trade Name:**
 ARTG Product:
 ★ **Suspect Code:** Other drug O
Action taken with medicine:
Rechallenge:

Reason for Use:
Dosage Start Code:
Dosage Halt Code:
Batch:
First/Single Indicator: N
Previously Used: N

Medicine Name/Trade Name	Drug Begun Date	Drug Halt Date	Withdrawal Code	Reason for Use	Suspect Code
Celestone	N/A	N/A	N/A	N/A	Suspected
Chronodose	N/A	N/A	N/A	N/A	Suspected
Contrast Medium Nos Saline	N/A	N/A	N/A	N/A	Suspected

Laboratory Coding

Investigation Type
Albumin

Supporting Documents

Title	Type	Location
FI-01	Other	Emailed
FI-01 email 30-06-2016	Other	Emailed
FI-02 MSD	Other	Emailed

Correspondence

Type	Mode	Author	Date
Acknowledgement - General	Not Sent	ADRS New Case	30/06/2016
Acknowledgement - General	Not Sent	Agent	12/07/2016
General Acknowledgement	Emailed on 12/07/2016 1:45:50 PM	[Redacted]	12/07/2016

Comments

Title	Comments	Author	Date
Additional Information	Additional information obtained from radiologist and Gold Coast ID specialist [Redacted] (see trim container 2016/011586): Procedure undertaken for this case and case 377658 (possible the same as 386482) by same radiologist. Right knee injected concomitantly with saline, contrast, local anaesthetic, and Celestone. Awaiting further information from radiologist regarding brand names and batch numbers and details on aseptic technique. CT used for guidance rather than USS. Celestone in break open glass ampoule and only used for single use. Additional information requested from reporter and radiologist (see R16/502251 and R16/519481). This is the second patient on the Gold Coast to develop severe septic arthritis this year due to <i>Scedosporium prolificans</i> following corticosteroid injection performed at Queensland Diagnostic	[Redacted]	14/07/2016
Initial Comment			30/06/2016
Initial information			01/07/2016

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	Imaging. I am very concerned that a batch of intra-articular corticosteroid is contaminated and there may be other unrecognised cases here or elsewhere in Australia Fungal infection of right knee with <i>Scedosporium prolificans</i> following intra-articular corticosteroid injection performed in December 2015 at Queensland Diagnostic Imaging 178 Nerang Street Southport 4215 Tel: [REDACTED]	
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Additional Coding

★ Causality:	Causality possible	03
★ Drug Status:	General marketing	GM
Include/Exclude:	Report included	I
WHO Extract Date:	03/08/2016	03/08/2016
WHO Report:	Successful	
Other Factors:		
Possible Interaction:		
Additional Information:		

Reporter Details

Name:	[REDACTED]	Type:	Specialist
Address:	Gold Coast University Hospital		
Suburb:	Southport	Phone:	[REDACTED]
State/Region:	QLD	Fax:	[REDACTED]
Postcode:	4215	Email:	[REDACTED]
Country:	AUS		

[Case History](#) 

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Fields marked ★ are mandatory

★ Title: FI-01 email 30-06-2016
 Description:
 ★ Delivery Method: Emailed
 Attachment(s): **From:** [REDACTED]
Sent: Thursday, 30 June 2016 11:10 AM
To: ADR Reports
Subject: Scedosporium prolificans infection associated with corticosteroid intra-articular injections

Patient 1

Tel: [REDACTED]

17/02/2016 *Scedosporium (inflatum) prolificans* left hip (Gold Coast University Hospital 1300 744 284)

31/05/2016 *Scedosporium (inflatum) prolificans* right hip (Gold Coast University Hospital)

Radiologist: [REDACTED]
 Queensland Diagnostic Imaging
 2 Lake Street Varsity Lakes [REDACTED]
 Both hips injected with corticosteroid late 2015

Patient 2

Tel: [REDACTED]

Currently (30/3/16) an inpatient in Ward 8 Gold Coast Private Hospital

Right knee injected with corticosteroid in December 2015 at
 Queensland Diagnostic Imaging
 178 Nerang Street Southport 4215 Tel: [REDACTED]

15/01/2016 *Scedosporium (inflatum) prolificans* right knee (Sullivan and Nicolaidis Pathology [REDACTED])
 08/04/2016 No growth from right knee fluid
 04/07/16 Further debridement with culture planned

[REDACTED]
 Gold Coast University Hospital

1 Hospital Boulevard
Southport QLD 4215

Tel: [REDACTED]

Web: www.goldcoast.health.qld.gov.au

Intranet: gchwcb.sth.health.qld.gov.au

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Fields marked * are mandatory

* Title: FI-02 MSD

Description:

* Delivery Method: Emailed

Attachment(s): From: Pharmacovigilance, Australia [

mailto:

Sent: Monday, 11 July 2016 7:09 PM

To:

Cc:

Subject: RE: Celestone Chronodose ADR report due to possible product contamination [SEC=UNCLASSIFIED]

Proprietary

Dear [REDACTED]

Thank you for alerting us regarding this report. We look forward to further information such as a Public Case Details form, in addition to batch details to facilitate further investigations, as it becomes available. I have assigned this second case a local MSD PV ref of AUS-16-1760, if you could quote this in subsequent correspondence

Regards

[REDACTED]