

Intake Case Number  
20200800189

Version  
Initial

State  
New

Assigned To  
Load16

Priority  
P4

General

Source  
Spontaneous

Central Receipt Date

Sender Name

Local Submission Date

Category  
AE Case

Case Country  
BRITISH INDIAN OCEAN  
TERRITORY

Sender Email

Version Type  
Initial

First Receipt Date  
01-Apr-2020

Case Processing Unit  
Unit1

Due Date  
08-Apr-2020

Version Disposition

FU Receipt Date  
01-Apr-2020

Sender Type

Local Submission Due Date

Version Comments

Reporter

1. Reporter-1

Title

State / Province

Consent to disclose PII

First Name

Postcode

Consent for F/U

Middle Name

Telephone

Primary Source  
Yes

Last Name

Fax Number

Organization

Email

Department

Country  
BRITISH INDIAN OCEAN  
TERRITORY

Street

Qualification  
Consumer

City

Contact Type  
Reporter

Patient

Name / Initials  
Load16

Hospital Record #  
3ABCD

DOB/ Age/ Group | Fetus  
55 Years

Concomitant Therapies

Gender  
Male

Add'l Relevant Medical  
History

LMP Date  
01-Apr-2020

Weight  
55.0 Kgs

Height  
165.0 Cms

GP Record #  
3ABCD

Specialist Record #  
3ABCD

Patient Medical History

1

Medical History  
Chills and fever

Start Date

End Date

Continuing

Family History

Comments

2

Medical History  
Dark reddish macule

Start Date

End Date

Continuing

Family History

Comments

3

Medical History  
Gum blue line

Start Date

End Date

Continuing

Family History

Comments

4

Medical History  
Green discoloration of skin

Start Date

End Date

Continuing

Family History

Comments

5

Medical History  
blue

Start Date

End Date

Continuing

Family History

Comments

6

Medical History  
Skin bacterial infection

Start Date

End Date

Continuing

Family History

Comments

7

Intake Case Number  
20200800189

Version  
Initial

State  
New

Assigned To  
Load16

Priority  
P4

Medical History  
Skin candida NOS

Start Date

End Date

Continuing

Family History

Comments

8

Medical History  
Skin & subcutaneous tissue abscess

Start Date

End Date

Continuing

Family History

Comments

9

Medical History  
Skin bacterial infection

Start Date

End Date

Continuing

Family History

Comments

10

Medical History  
Rash

Start Date

End Date

Continuing

Family History

Comments

Product

1. Rx CISPLATIN ID

Product Name  
Rx CISPLATIN ID

Dosage Form  
Powder for intraocular instillation solution

Role  
Suspect

Obtain Country

Auth. Number

Auth. Country

Auth. Holder

Cumulative Dose to First Reaction

Exposure Gestation Period

Action Taken

Expiration Date

Replacement Required

Return Required

Refund Requested

Blinded

Add'I Drug Info

Add'I Drug Info Notes

Product Substance

#	Name	Strength
1	CISPLATIN	

2. Rx METFORMIN

Product Name  
Rx METFORMIN

Dosage Form  
Tablet

Role  
Suspect

Obtain Country

Auth. Number

Auth. Country

Auth. Holder

Cumulative Dose to First Reaction

Exposure Gestation Period

Action Taken

Expiration Date

Replacement Required

Return Required

Refund Requested

Blinded

Add'I Drug Info

Add'I Drug Info Notes

Product Substance

#	Name	Strength
1	CRATAEGUS LAEVIGATA EXTRACT	

3. Rx CISPLATIN ID

Product Name  
Rx CISPLATIN ID

Dosage Form  
Powder for intraocular instillation solution

Role  
Suspect

Obtain Country

Auth. Number

Auth. Country

Auth. Holder

Cumulative Dose to First Reaction

Exposure Gestation Period

Action Taken

Expiration Date

Replacement Required

Return Required

Refund Requested

Blinded

Add'I Drug Info

Add'I Drug Info Notes

Intake Case Number  
20200800189

Version  
Initial

State  
New

Assigned To  
Load16

Priority  
P4

Product Substance		
#	Name	Strength
1	CISPLATIN	

4. Ibrance JPV Capsules 50mg

Product Name Ibrance JPV Capsules 50mg	Dosage Form Capsule	Role Suspect	Obtain Country	Auth. Number	Auth. Country	Auth. Holder	Cumulative Dose to First Reaction
Exposure Gestation Period	Action Taken	Expiration Date	Replacement Required	Return Required	Refund Requested	Blinded	Add'I Drug Info
Add'I Drug Info Notes							

Product Substance		
#	Name	Strength
1	IBRUTINIB	

5. Depromel 75mg tablet

Product Name Depromel 75mg tablet	Dosage Form Tablet	Role Suspect	Obtain Country	Auth. Number	Auth. Country	Auth. Holder	Cumulative Dose to First Reaction
Exposure Gestation Period	Action Taken	Expiration Date	Replacement Required	Return Required	Refund Requested	Blinded	Add'I Drug Info
Add'I Drug Info Notes							

Product Substance		
#	Name	Strength
1	FLUVOXAMINE MALEATE	

Event

1. Headache

Reported Reaction headach	Reported Language English	Translated Reaction	Reaction (Coded) Headache	Highlighted by Reporter	Seriousness Criteria	Start Date	End Date
Duration	Outcome	Medically Confirmed	Country BRITISH INDIAN OCEAN TERRITORY	Hospitalization Start Date	Hospitalization End Date		

2. Nausea aggravated

Reported Reaction nau	Reported Language English	Translated Reaction	Reaction (Coded) Nausea aggravated	Highlighted by Reporter	Seriousness Criteria	Start Date	End Date
Duration	Outcome	Medically Confirmed	Country BRITISH INDIAN OCEAN TERRITORY	Hospitalization Start Date	Hospitalization End Date		

3. Migraine headache

Reported Reaction migrai	Reported Language English	Translated Reaction	Reaction (Coded) Migraine headache	Highlighted by Reporter	Seriousness Criteria	Start Date	End Date
Duration	Outcome	Medically Confirmed	Country BRITISH INDIAN OCEAN TERRITORY	Hospitalization Start Date	Hospitalization End Date		

4. Tinea incognito



Intake Case Number	Version	State	Assigned To	Priority
20200800189	Initial	New	Load16	P4

Intake Case Number	Version	State	Assigned To	Priority
20200800189	Initial	New	Load16	P4

<b>Intake Case Number</b>	<b>Version</b>	<b>State</b>	<b>Assigned To</b>	<b>Priority</b>
20200800189	Initial	New	Load16	P4

Intake Case Number	Version	State	Assigned To	Priority
20200800189	Initial	New	Load16	P4

<b>Intake Case Number</b>	<b>Version</b>	<b>State</b>	<b>Assigned To</b>	<b>Priority</b>
20200800189	Initial	New	Load16	P4

[illegible]

### Reporter Comments

#### Sender Comments

### Additional Notes

## Attachments

#	Receipt Date	Attachment Type	File Name	Process Status	Case Version	Protected
1	15-Apr-2020	Autopsy Report	C:\PV\InTake\4.6.0.3\scripts\Script1_Cas eCreation\cioms_scanned.pdf	Pending	Initial	
2	15-Apr-2020	Additional PMDA R3 fields	C:\PV\InTake\4.6.0.3\scripts\Script1_Cas eCreation\cioms_scanned.pdf	Pending	Initial	
3	15-Apr-2020	Chest X-ray	C:\PV\InTake\4.6.0.3\scripts\Script1_Cas eCreation\cioms_scanned.pdf	Pending	Initial	



Intake Case Number  
20200800189

Version  
Initial

State  
New

Assigned To  
Load16

Priority  
P4

#	Reported Description	Coded Description	SOC	HLGT	HLT	PT	LLT	MedDra Version
Medical History								
1	fever	Chills and fever	General disorders and administration site conditions (10018065)	Body temperature conditions (10005908)	Febrile disorders (10016286)	Pyrexia (10037660)	Chills and fever (10008533)	20.0
2	redd	Dark reddish macule	Skin and subcutaneous tissue disorders (10040785)	Epidermal and dermal conditions (10014982)	Dermal and epidermal conditions NEC (10012424)	Macule (10025421)	Dark reddish macule (10011862)	20.0
3	blue	Gum blue line	Injury, poisoning and procedural complications (10022117)	Exposures, chemical injuries and poisoning (10071947)	Poisoning and toxicity (10035777)	Metal poisoning (10027439)	Gum blue line (10018772)	20.0
4	gree	Green discoloration of skin	Skin and subcutaneous tissue disorders (10040785)	Epidermal and dermal conditions (10014982)	Dermal and epidermal conditions NEC (10012424)	Skin discolouration (10040829)	Green discoloration of skin (10070807)	20.0
6	skin	Skin bacterial infection	Infections and infestations (10021881)	Bacterial infectious disorders (10004018)	Bacterial infections NEC (10004047)	Skin bacterial infection (10052891)	Skin bacterial infection (10052891)	20.0
7	skin	Skin candida NOS	Infections and infestations (10021881)	Fungal infectious disorders (10017528)	Candida infections (10007134)	Skin candida (10054152)	Skin candida NOS (10040809)	20.0
8	skin	Skin & subcutaneous tissue abscess	Infections and infestations (10021881)	Infections - pathogen unspecified (10021879)	Skin structures and soft tissue infections (10040786)	Subcutaneous abscess (10042343)	Skin & subcutaneous tissue abscess (10040784)	20.0
9	skin	Skin bacterial infection	Infections and infestations (10021881)	Bacterial infectious disorders (10004018)	Bacterial infections NEC (10004047)	Skin bacterial infection (10052891)	Skin bacterial infection (10052891)	20.0
10	rash	Rash	Skin and subcutaneous tissue disorders (10040785)	Epidermal and dermal conditions (10014982)	Rashes, eruptions and exanthems NEC (10052566)	Rash (10037844)	Rash (10037844)	20.0
Event(s)								
1	headach	Headache	Nervous system disorders (10029205)	Headaches (10019231)	Headaches NEC (10019233)	Headache (10019211)	Headache (10019211)	20.0
2	nau	Nausea aggravated	Gastrointestinal disorders (10017947)	Gastrointestinal signs and symptoms (10018012)	Nausea and vomiting symptoms (10028817)	Nausea (10028813)	Nausea aggravated (10048364)	20.0
3	migrai	Migraine headache	Nervous system disorders (10029205)	Headaches (10019231)	Migraine headaches (10027603)	Migraine (10027599)	Migraine headache (10027602)	20.0
4	tin	Tinea incognito	Infections and infestations (10021881)	Fungal infectious disorders (10017528)	Tinea infections (10043870)	Tinea infection (10060889)	Tinea incognito (10073466)	20.0
5	red	Red blood cell analysis	Investigations (10022891)	Haematology investigations (incl blood groups) (10018851)	Red blood cell analyses (10038148)	Red blood cell analysis (10062748)	Red blood cell analysis (10062748)	20.0
Test(s)								
1	wit	With hydrocephalus, spina bifida, cervical region	Congenital, familial and genetic disorders (10010331)	Neurological disorders congenital (10029299)	Central nervous system disorders congenital NEC (10009713)	Spina bifida (10041524)	With hydrocephalus, spina bifida, cervical region (10047993)	20.0
2	blo	Blocked tear duct congenital	Congenital, familial and genetic disorders (10010331)	Eye disorders congenital (10015920)	Lacrimal system disorders congenital (10023638)	Dacryostenosis congenital (10011850)	Blocked tear duct congenital (10005276)	20.0
3	iro	Iron binding capacity total low	Investigations (10022891)	Water, electrolyte and mineral investigations (10047843)	Mineral and electrolyte analyses (10027637)	Iron binding capacity total decreased (10022963)	Iron binding capacity total low (10022966)	20.0
4	thy	Thyreostatic therapy	Surgical and medical procedures (10042613)	Endocrine gland therapeutic procedures (10014705)	Thyroid therapeutic procedures (10043755)	Thyreostatic therapy (10065359)	Thyreostatic therapy (10065359)	20.0
5	neo	Neointimal hyperplasia	Vascular disorders (10047065)	Vascular disorders NEC (10047066)	Non-site specific vascular disorders NEC (10047067)	Vascular wall hypertrophy (10072810)	Neointimal hyperplasia (10076851)	20.0
6	blue	Blue baby syndrome	Respiratory, thoracic and mediastinal disorders (10038738)	Neonatal respiratory disorders (10028971)	Neonatal hypoxic conditions (10028947)	Cyanosis neonatal (10011705)	Blue baby syndrome (10069412)	20.0

Intake Case Number 20200800189	Version Initial	State New	Assigned To Load16	Priority P4				
7	teet	Brittle teeth	Gastrointestinal disorders (10017947)	Dental and gingival conditions (10044018)	Dental disorders NEC (10044037)	Teeth brittle (10043173)	Brittle teeth (10006374)	20.0
8	bla	Black colored sweating	Skin and subcutaneous tissue disorders (10040785)	Skin appendage conditions (10040798)	Apocrine and eccrine gland disorders (10002982)	Sweat discolouration (10042652)	Black colored sweating (10004970)	20.0
9	fire	Fire accident	Injury, poisoning and procedural complications (10022117)	Injuries NEC (10022114)	Non-site specific injuries NEC (10029511)	Accident (10000369)	Fire accident (10072097)	20.0
10	dep	Dependence addictive	Psychiatric disorders (10037175)	Psychiatric disorders NEC (10037176)	Substance related and addictive disorders (10079102)	Drug use disorder (10079381)	Dependence addictive (10012336)	20.0
11	mar	Marantic endocarditis	Cardiac disorders (10007541)	Endocardial disorders (10014662)	Endocarditis NEC (10014680)	Endocarditis noninfective (10062608)	Marantic endocarditis (10058147)	20.0
12	dig	Digestive tract X-ray NOS normal	Investigations (10022891)	Gastrointestinal investigations (10017971)	Gastrointestinal and abdominal imaging procedures (10017963)	X-ray gastrointestinal tract normal (10061584)	Digestive tract X-ray NOS normal (10012987)	20.0
13	tri	Tri-iodothyronine free abnormal	Investigations (10022891)	Endocrine investigations (incl sex hormones) (10014706)	Thyroid analyses (10043692)	Tri-iodothyronine free abnormal (10053794)	Tri-iodothyronine free abnormal (10053794)	20.0
14	tsh	TSH decrease	Investigations (10022891)	Endocrine investigations (incl sex hormones) (10014706)	Pituitary analyses anterior (10035089)	Blood thyroid stimulating hormone decreased (10005832)	TSH decrease (10044714)	20.0
15	t3	T3 normal	Investigations (10022891)	Endocrine investigations (incl sex hormones) (10014706)	Thyroid analyses (10043692)	Tri-iodothyronine normal (10044598)	T3 normal (10043054)	20.0
16	iod	Iodide intoxication	Injury, poisoning and procedural complications (10022117)	Exposures, chemical injuries and poisoning (10071947)	Poisoning and toxicity (10035777)	Toxicity to various agents (10070863)	Iodide intoxication (10022902)	20.0
17	flu	Flu prevention	Surgical and medical procedures (10042613)	Therapeutic procedures and supportive care NEC (10043413)	Prophylactic procedures NEC (10036896)	Antiviral prophylaxis (10049087)	Flu prevention (10016792)	20.0
18	bod	Body image disorder	Psychiatric disorders (10037175)	Anxiety disorders and symptoms (10002861)	Obsessive-compulsive disorders and symptoms (10068758)	Body dysmorphic disorder (10052793)	Body image disorder (10005892)	20.0
19	den	Factor V Leiden carrier	Congenital, familial and genetic disorders (10010331)	Chromosomal abnormalities and abnormal gene carriers (10008804)	Abnormal gene carriers (10052636)	Factor V Leiden carrier (10075652)	Factor V Leiden carrier (10075652)	20.0
20	yellow	Yellow nail syndrome	Skin and subcutaneous tissue disorders (10040785)	Skin appendage conditions (10040798)	Nail and nail bed conditions (excl infections and infestations) (10028685)	Yellow nail syndrome (10048244)	Yellow nail syndrome (10048244)	20.0