# SUSPECT ADVERSE REACTION REPORT

## I. REACTION INFORMATION

| 1. PATIENT INITIALS (first, last) | 1a. COUNTRY | 2. DATE OF BIRTH | | | 2a. AGE | 3. SEX | 3a. WEIGHT | 4-6 REACTION ONSET | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Day | Month | Year | | | | Day | Month | Year |
| PRIVACY | CHINA | 04 | AUG | 2023 | 8 Weeks | Male | Unk | 02 | OCT | 2023 |

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)

MULTIPLE ORGAN DYSFUNCTION SYNDROME [Multiple organ dysfunction syndrome]
ACUTE RESPIRATORY FAILURE [Acute respiratory failure]
CIRCULATORY FAILURE [Circulatory collapse]
CAPILLARY LEAK SYNDROME [Capillary leak syndrome]
DISSEMINATED INTRAVASCULAR COAGULATION [Disseminated intravascular coagulation]
SEVERE PNEUMONITIS [Pneumonitis]
ACUTE NECROTIZING ENTERITIS [Enteritis necroticans]
CENTRAL NERVOUS SYSTEM INFECTION [Central nervous system

**(Continued on Additional Information Page)**

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☒ PATIENT DIED
  Date: 13-OCT-2023
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION
- ☐ INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY
- ☒ LIFE THREATENING
- ☐ CONGENITAL ANOMALY
- ☐ OTHER

## II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)
#1 ) CUROSURF (PORACTANT ALFA) Endotracheopulmonary instillation, suspension

**(Continued on Additional Information Page)**

20. DID REACTION ABATE AFTER STOPPING DRUG?
☐ YES ☐ NO ☒ NA

15. DAILY DOSE(S)
#1 ) UNK

16. ROUTE(S) OF ADMINISTRATION
#1 ) Intratracheal

17. INDICATION(S) FOR USE
#1 ) ACUTE RESPIRATORY DISTRESS

**(Continued on Additional Information Page)**

21. DID REACTION REAPPEAR AFTER REINTRODUCTION?
☐ YES ☐ NO ☒ NA

18. THERAPY DATES(from/to)
#1 ) 02-OCT-2023 / Unknown

19. THERAPY DURATION
#1 ) Unknown

## III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)

23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)

| From/To Dates | Type of History / Notes | Description |
|---|---|---|
| 27-SEP-2023 to Ongoing | Current Condition | Incarcerated hernia (Incarcerated hernia) |
| 27-SEP-2023 to Ongoing | Current Condition | Testicular torsion (Testicular torsion) |

## IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
Chiesi Farmaceutici SpA
via Palermo, 26/A
Parma, 43122 ITALY

26. REMARKS
Medically Confirmed: No
World Wide #: CN-CHIESI-2025CHF04448

24b. MFR CONTROL NO.
**2025CHF04448**

25b. NAME AND ADDRESS OF REPORTER
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CHINA

24c. DATE RECEIVED BY MANUFACTURER
23-JUN-2025

24d. REPORT SOURCE
☐ STUDY ☐ LITERATURE
☐ HEALTH PROFESSIONAL ☒ OTHER: Spontaneous

DATE OF THIS REPORT
30-JUN-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

## ADDITIONAL INFORMATION

**7+13. DESCRIBE REACTION(S) continued**

infection]
SEVERE TRICUSPID REGURGITATION [Tricuspid valve incompetence]
DECOMPENSATED PHASE OF SEPTIC SHOCK [Septic shock]
PATENT DUCTUS ARTERIOSUS [Patent ductus arteriosus]
CONSIDERING THE OCCURRENCE OF ACUTE RESPIRATORY DISTRESS SYNDROME IN THE CHILD, INTRATRACHEAL ADMINISTRATION OF PULMONARY SURFACTANT CUROSURF WAS GIVEN. [Off label use]

Case Description: Case reference number 2025CHF04448 is a spontaneous case report sent by non-health professional via social media and received through a Chinese affiliate (local country number: CC202506017) which refers to a male patient aged 8 weeks (1 month and 23 days).

Concomitant medication has not been provided.

The patient was admitted to the hospital for treatment due to a right scrotal mass for over 1 month and pain for over 1 day (scrotal mass and pain) On the day of admission, after undergoing scrotal ultrasound and inguinal ultrasound examinations, the hospital made a preliminary diagnosis of right-sided incarcerated indirect inguinal hernia (incarcerated hernia) and right testicular torsion with necrosis (testicular torsion) on 27-Sep-2023.

The patient underwent procedures for laparoscopic ligation of hernial sac [bilateral] (high ligation of hernial sac), right scrotal exploration (scrotal exploration), right testicular torsion reduction (testicular torsion) + right spermatic cord and testicular resection (spermatic cord operation), left testicular fixation (testicular operation) + pedicled flap revision (pedicled pectoralis major myocutaneous flap surgery) surgery (all on 27-Sep-2023). During the operation, it was observed that the right scrotum was significantly swollen (scrotum swelling), the right testis was twisted 720° within the tunica vaginalis (testis torsion) with black discoloration and ischemic necrosis, and no normal testicular tissue was visible; the left testis had good blood supply, with no obvious torsion or ischemic necrosis.

After the operation, the patient was given gastrointestinal decompression, artificial anal dilation. On the first day after surgery, the patient developed fever, initially low-grade fever, which later turned into high fever.

The following drugs are known to have been taken by the patient prior to the event onset: Dexamethasone was added for fever to relieve inflammation (fever) and Glycerol Enema for assisted defecation (defecation disorder).

At the time of events, the patient was suffering electrolyte disturbance, mixed acid-base disturbance (acid base balance disorder) intestinal adhesion, multiple serious effusion cavity (all since 30-Sep-2023).

On 30-Sep-2023, due to significant abdominal distension, hardness, decreased bowel sounds (1 time/minute), tympanic sound on percussion, 10 ml of light-yellow gastric juice with a small amount of coffee grounds drained through the nasogastric tube, and yellow urine drained through the urinary catheter. After the treatment, the patient underwent exploratory laparotomy [abdominal cavity] (laparotomy), small bowel stoma (stoma care), intestinal adhesion lysis and arrangement (intestinal adhesion lysis) surgery on the same day.

On an unspecified date, immediately after the operation, the patient was transferred to the PICU (pediatric intensive care unit). After being transferred to another department, the patient continued to undergo gastrointestinal decompression. With the assistance of invasive mechanical ventilation in PSIMV (pressure-synchronized intermittent mandatory ventilation) mode (PIP (peak inspiratory pressure): 10 cmH20, PEEP (positive end-expiratory pressure): 4 cmH20, FiO2 (fraction of inspired oxygen):40 percent, RR (respiratory rate): 25), the patient's oxygen saturation could be maintained above 95 percent.

On 01-Oct-2023, in the morning, an attempt was made to wean the patient off the ventilator, but the patient could not tolerate it. The patient was again placed on invasive mechanical ventilation that night.

On 02-Oct-2023, the patient was given Curosurf [poractant alfa] (endotracheopulmonary instillation, suspension, intratracheal) for acute respiratory distress syndrome.

As per local RSI, Curosurf is indicated for treatment of premature infants with, or at risk for respiratory distress syndrome. Since the occurrence of acute respiratory distress syndrome in the child, intratracheal administration of pulmonary surfactant Curosurf was given.

On 02-Oct-2023, based on the patient's symptoms and physical signs, the patient experienced life-threatening event of decompensated phase of septic shock (shock septic). The patient was hospitalized for the event.

The patient was treated with immediate resuscitation with balanced salt solution [calcium chloride+ magnesium chloride+ potassium chloride+ sodium acetate+ sodium chloride+ sodium citrate] at 100 ml for over 20 minutes to expand blood volume (blood volume expansion). Adjust the pump speed to 5ug/kg/min. Meropenem (injection) and Teicoplanin (injection) to enhance anti-infection therapy (anti-infective therapy), continue methylprednisolone (IV) at dose of 5 mg/kg for anti-inflammatory treatment. The resuscitation was successful.

## ADDITIONAL INFORMATION

**7+13. DESCRIBE REACTION(S) continued**

On 03-Oct-2023, the patient experienced life-threatening event capillary leak syndrome. The patient was hospitalized for the event.

The patient was treated with Albumin [albumin human] and furosemide, intermittent infusions were given. The urine output was minimal, and the edema did not improve. The patient also had severe metabolic acidosis.

On 04-Oct-2023, to improve oxygenation and correct acidosis, the ventilator mode was changed to HF0 mode. Subsequently, the patient's hypoxemia and hypercapnia improved, and acidosis and electrolyte imbalances were corrected to some extent.

On 06-Oct-2023, the patient experienced rigidity and convulsions in the left upper limb, staring eyes, upward rolling of the eyeballs, and slight head rubbing. A lumbar puncture was performed, and the cerebrospinal fluid was found to be yellowish and turbid, the possibility of intracranial infection cannot be ruled out.

The patient was treated with Meropenem (injection) and Vancomycin (injection) continued for anti-infection treatment, along with Sodium Valproate [valproate sodium] for anticonvulsant therapy.

On an unspecified date in Oct-2023, the patient experienced life-threatening events of disseminated intravascular coagulation, severe pneumonitis, acute necrotizing enteritis, Patent ductus arteriosus

On 11-Oct-2023, the patient was diagnosed with multiple organ dysfunction syndrome. The family was informed of the patient's critical condition: prolonged hypoxia, multi-organ dysfunction, possible intracranial infection, and the potential for varying degrees of neurological sequelae such as intellectual disability, paralysis, motor dysfunction, and cognitive impairment, with a poor long-term prognosis. The family acknowledged the situation and requested cessation of all current treatments and removal of all tubes, including the endotracheal tube.

On 13-Oct-2023, the patient was diagnosed with event of acute respiratory failure.

On 13-Oct-2023, at 1:14 a.m, the patient died. As the family had requested no resuscitation measures and all tubes had been removed, a bedside electrocardiogram was performed, which showed asystole. The patient's heartbeat and breathing stopped. The cause of death was multiple organ dysfunction syndrome, acute respiratory failure and circulatory failure. It was unknown if the autopsy was performed.

Relevant laboratory and instrumentation tests were shown in proper section.

The patient's outcome was unknown for the event of off label use. At the time of report, the patient was not recovered yet from the events of shock septic, capillary leak syndrome, disseminated intravascular coagulation, pneumonitis, enteritis necroticans, Central nervous system infection, Patent ductus arteriosus and tricuspid regurgitation.

The reporter did not assess the causal relationship between the events and Curosurf.

Further information is expected.

Case comments:
This male neonate aged 8 weeks experienced multiple organ dysfunction syndrome, acute respiratory failure, circulatory failure, capillary leak syndrome, disseminated intravascular coagulation, “severe pneumonitis” (pneumonitis), “acute necrotizing enteritis” (enteritis necroticans), central nervous system infection, “severe tricuspid regurgitation” (tricuspid regurgitation), “decompensated phase of septic shock” (shock septic), patent ductus arteriosus and “considering the occurrence of acute respiratory distress syndrome in the child, intratracheal administration of pulmonary surfactant Curosurf was given” (off label use) while being treated with Curosurf [poractant alfa] (endotracheopulmonary instillation, suspension, intratracheal use) for acute respiratory distress syndrome.
The events capillary leak syndrome, disseminated intravascular coagulation, “severe pneumonitis”, “acute necrotizing enteritis”, central nervous system infection, “severe tricuspid regurgitation”, “decompensated phase of septic shock” and patent ductus arteriosus were assessed as serious (seriousness criterion: life threatening and hospitalization).
The events multiple organ dysfunction syndrome, acute respiratory failure and circulatory failure were assessed as serious (seriousness criterion: death).
The event “considering the occurrence of acute respiratory distress syndrome in the child, intratracheal administration of pulmonary surfactant Curosurf was given” was considered as non-serious by convention.
The patent ductus arteriosus is a listed adverse reaction for Curosurf according to the reference safety information.
The multiple organ dysfunction syndrome, acute respiratory failure, circulatory failure, capillary leak syndrome, disseminated intravascular coagulation, pneumonitis, enteritis necroticans, central nervous system infection, tricuspid regurgitation and shock septic are not listed adverse reactions for Curosurf according to the reference safety information. According to the local RSI, the off label use was considered as unlisted.
The adverse reaction of patent ductus arteriosus is expected as per US Prescribing Information.
The adverse reactions of multiple organ dysfunction syndrome, acute respiratory failure, circulatory failure, capillary leak syndrome, disseminated intravascular coagulation, pneumonitis, enteritis necroticans, central nervous system infection, tricuspid regurgitation and shock septic and are unexpected as per US Prescribing Information. The pharmaceutical product complaint and prescribed overdose were considered as unexpected by convention. The off label use was considered as unexpected as per US Prescribing Information.
The adverse reactions of shock septic and patent ductus arteriosus are expected as per Canadian product monograph.
The adverse reactions of multiple organ dysfunction syndrome, acute respiratory failure, circulatory failure, capillary leak syndrome,

## ADDITIONAL INFORMATION

**7+13. DESCRIBE REACTION(S) continued**

disseminated intravascular coagulation, pneumonitis, enteritis necroticans, central nervous system infection and tricuspid regurgitation are unexpected as per Canadian product monograph. The off label use was considered as unexpected as per Canadian product monograph.
With reference to reported events of multiple organ dysfunction syndrome, acute respiratory failure, circulatory failure, capillary leak syndrome, disseminated intravascular coagulation, pneumonitis, enteritis necroticans, central nervous system infection, tricuspid regurgitation, shock septic and patent ductus arteriosus, consequences of the patient's underlying critical condition with severe systemic illness, intestinal obstruction, surgical complications, age of the patient with higher risk for rapid clinical deterioration and subsequent sepsis could provide plausible explanation. Hence, causal role of suspect drug seems not related.
The company has assessed causal relationship between Curosurf and multiple organ dysfunction syndrome, acute respiratory failure, circulatory failure, capillary leak syndrome, disseminated intravascular coagulation, pneumonitis, enteritis necroticans, central nervous system infection, tricuspid regurgitation, shock septic, patent ductus arteriosus as not related in accordance with the WHO-UMC causality assessment method.
As per local RSI, Curosurf is indicated for treatment of premature infants with, or at risk for respiratory distress syndrome. Since Curosurf was prescribed considering occurrence of acute respiratory distress syndrome, this constituted an event of off label use. Causality was assessed as not applicable for off label use as this was not an event per se.
The single individual case report does not modify the benefit / risk balance of this product. Therefore, no changes in the label or other measures are recommended at this point. However, the company will continue to monitor all respective reports received and based on cumulative experience, will re-evaluate the available evidence on an ongoing basis.

**13. Lab Data**

| # | Date | Test / Assessment / Notes | Results | Normal High / Low |
|---|---|---|---|---|
| 1 | 30-SEP-2023 | Abdomen scan<br>SEE RELEVANT TEST | | |
| 2 | 30-SEP-2023 | Abdominal cavity drainage<br>SEE RELEVANT TEST | | |
| 3 | 27-SEP-2023 | Abdominal exploration<br>SEE RELEVANT TEST | | |
| 4 | 04-OCT-2023 | Blood lactic acid | 1.2 millimole per litre | |
| 5 | 02-OCT-2023 | Blood pressure measurement<br>56/15 MMHG<br>AT 13:10 | | |
| 6 | 02-OCT-2023 | Blood pressure measurement<br>94/51 MMHG<br>30 MINUTES LATER | | |
| 7 | 03-OCT-2023 | Blood pressure measurement<br>90/35 MMHG | | |
| 8 | SEP-2023 | Body temperature<br>AT ITS HIGHEST POINT, | 39.1 degree Celsius | |
| 9 | 02-OCT-2023 | Cardiac resynchronisation therapy<br>LESS THAN 2 SECOND | | |
| 10 | 13-OCT-2023 | Electrocardiogram<br>ASYSTOLE | | |
| 11 | | Electrolyte imbalance | 40 percent | |
| 12 | 02-OCT-2023 | Electrolyte imbalance | 100 percent | |
| 13 | 03-OCT-2023 | Electrolyte imbalance<br>CORRECTED TO SOME EXTENT | | |
| 14 | 02-OCT-2023 | Heart rate | 133 heart beats per minute | |
| 15 | 03-OCT-2023 | Heart rate | 145 heart beats per minute | |

## ADDITIONAL INFORMATION

**13. Lab Data**

| # | Date | Test / Assessment / Notes | Results | Normal High / Low |
|---|---|---|---|---|
| 16 | 13-OCT-2023 | Heart rate<br>PROGRESSIVELY DECREASED | heart beats per minute | |
| 17 | 03-OCT-2023 | Laboratory test<br>INCREASED | | |
| 18 | 30-SEP-2023 | Oxygen saturation<br>MAINTAIN ABOVE 95% | 95 percent | |
| 19 | 02-OCT-2023 | Oxygen saturation<br>THE FLUCTUATION WAS AROUND 85-90% | | |
| 20 | 03-OCT-2023 | Oxygen saturation<br>DROPPED | 65 percent | |
| 21 | 03-OCT-2023 | Oxygen saturation<br>MAINTENED AT AROUND 75-78% | | |
| 22 | 04-OCT-2023 | Oxygen saturation<br>RISING TO AROUND 90% | | |
| 23 | 04-OCT-2023 | Oxygen saturation<br>MAINTAIN AROUND 70% | | |
| 24 | 13-OCT-2023 | Oxygen saturation<br>BECAME UNDETECTABLE | | |
| 25 | 13-OCT-2023 | Oxygen saturation<br>BECAME UNDETECTABLE | | |
| 26 | 04-OCT-2023 | PCO2<br>40 MMHG | | |
| 27 | 04-OCT-2023 | PO2<br>44 MMHG | | |
| 28 | | Peak nasal inspiratory flow abnormal | 10 centimetre of water | |
| 29 | 02-OCT-2023 | Peak nasal inspiratory flow abnormal | 22 centimetre of water | |
| 30 | | Percussion test<br>TYMPANIC SOUND | | |
| 31 | | Positive end-expiratory pressure | 4 centimetre of water | |
| 32 | 02-OCT-2023 | Positive end-expiratory pressure | 8 centimetre of water | |
| 33 | | Respiratory rate<br>25 | | |
| 34 | 02-OCT-2023 | Respiratory rate | 40 breaths per minute | |
| 35 | 03-OCT-2023 | Respiratory rate | 40 breaths per minute | |
| 36 | | Ultrasound abdomen<br>SEE RELEVANT TEST | | |
| 37 | 30-SEP-2023 | Ultrasound abdomen | | |

## ADDITIONAL INFORMATION

**13. Lab Data**

| # | Date | Test / Assessment / Notes | Results | Normal High / Low |
|---|---|---|---|---|
| | | SEE RELEVANT TEST | | |
| 38 | 27-SEP-2023 | Ultrasound scan<br>INCARCERATED HERNIA; 2. RIGHT TESTICULAR TORSION | | |
| 39 | 27-SEP-2023 | Ultrasound scan<br>INCARCERATED HERNIA; 2. RIGHT TESTICULAR TORSION | | |
| 40 | 03-OCT-2023 | Urine output<br>MINIMAL | | |
| 41 | 04-OCT-2023 | pH body fluid<br>6.98 | | |

**13. Relevant Tests**

UNKNOWN DATE:ABDOMINAL ULTRASOUND:INTESTINAL OBSTRUCTION, METABOLIC DISORDER, ANEMIA, INTESTINAL ADHESION, AND PERITONEAL EFFUSION
27-SEP-2023:ABDOMINAL EXPLORATION:APPROXIMATELY 60 ML OF LIGHT YELLOW CLEAR FLUID IN THE ABDOMINAL CAVITY, WITH NO OBVIOUS FECAL FLUID; THE SMALL INTESTINE WAS INCARCERATED THROUGH THE RIGHT INTERNAL RING, WITH NO PERFORATION OR NECROSIS OF THE INCARCERATED BOWEL, AND THE BLOOD SUPPLY TO AN AREA OF THE BOWEL WALL ABOUT 1.0*1.0 CM WAS SLIGHTLY DARK, BUT PERISTALSIS WAS PRESENT. THE REST OF THE BOWEL SHOWED NO OBVIOUS SIGNS OF PERFORATION OR NECROSIS, AND SOME BOWEL SEGMENTS WERE ADHERENT. BOTH INTERNAL RING OPENINGS WERE NOT CLOSED, EACH ABOUT 1.0*1.0 CM IN SIZE, WITH OBVIOUS CONGESTION AND EDEMA OF THE SURROUNDING PERITONEUM. THE RIGHT SPERMATIC CORD IN THE ABDOMINAL CAVITY WAS DARK IN COLOR AND HAD POOR BLOOD SUPPLY.
30-SEP-2023:ABDOMINAL CAVITY:APPROXIMATELY 25 ML OF LIGHT YELLOW CLEAR ASCITES WAS FOUND. THE COLON WAS EMPTY, AND THE SMALL INTESTINE SHOWED NO OBVIOUS SIGNS OF PERFORATION. THE BOWEL WAS WIDELY DISTENDED WITH GAS, ESPECIALLY FROM 50 CM AWAY FROM THE LIGAMENT OF TREITZ TO 50 CM AWAY FROM THE ILEOCECAL VALVE. THE BLOOD SUPPLY AND PERISTALSIS WERE POOR, WITH MULTIPLE FOCAL ISCHEMIC LESIONS. THE BOWEL WALL ABOUT 50 CM AWAY FROM THE ILEOCECAL VALVE WAS THICKENED AND EDEMATOUS, AND THE PROXIMAL BOWEL CONTAINED YELLOW, VISCOUS, GRANULAR STOOL AND GAS.
30-SEP-2023:ULTRASOUND ABDOMEN:INTESTINAL OBSTRUCTION, INTERNAL ENVIRONMENT DISORDER, ANEMIA, INTESTINAL ADHESIONS, ABDOMINAL FLUID ACCUMULATION
30-SEP-2023:ABDOMINAL STANDING POSITION:INTESTINAL OBSTRUCTION, INTERNAL ENVIRONMENT DISORDER, ANEMIA, INTESTINAL ADHESIONS, ABDOMINAL FLUID ACCUMULATION

**14-19. SUSPECT DRUG(S) continued**

| 14. SUSPECT DRUG(S) (include generic name) | 15. DAILY DOSE(S);<br>16. ROUTE(S) OF ADMIN | 17. INDICATION(S) FOR USE | 18. THERAPY DATES (from/to);<br>19. THERAPY DURATION |
|---|---|---|---|
| #1 ) CUROSURF (PORACTANT ALFA) Endotracheopulmonary instillation, suspension; Regimen #1 | UNK; Intratracheal | ACUTE RESPIRATORY DISTRESS SYNDROME (Acute respiratory distress syndrome) | 02-OCT-2023 / Unknown; Unknown |

**23. OTHER RELEVANT HISTORY continued**

| From/To Dates | Type of History / Notes | Description |
|---|---|---|
| 27-SEP-2023 to Ongoing | Current Condition | Necrosis (Necrosis); |
| 30-SEP-2023 to Ongoing | Current Condition | Intestinal obstruction (Intestinal obstruction); |
| 30-SEP-2023 to Ongoing | Current Condition | Electrolyte disturbance (Electrolyte imbalance); |
| 30-SEP-2023 to Ongoing | Current Condition | Acid-base balance disorder (Acid base balance abnormal); |
| 30-SEP-2023 to Ongoing | Current Condition | Intestinal adhesions (Abdominal adhesions); |
| 27-SEP-2023 to 27-SEP-2023 | Procedure | High ligation of hernial sac (Inguinal hernia repair); |

## ADDITIONAL INFORMATION

**23. OTHER RELEVANT HISTORY continued**

| From/To Dates | Type of History / Notes | Description |
|---|---|---|
| 27-SEP-2023 to 27-SEP-2023 | Procedure | Scrotal exploration (Scrotal exploration); |
| 27-SEP-2023 to 27-SEP-2023 | Procedure | Testicular torsion (Testicular torsion); |
| 27-SEP-2023 to 27-SEP-2023 | Procedure | Spermatic cord operation (Spermatic cord operation); |
| 27-SEP-2023 to 27-SEP-2023 | Procedure | Testicular operation (Testicular operation); |
| 27-SEP-2023 to 27-SEP-2023 | Procedure | Pedicled pectoralis major myocutaneous flap surgery (Head and neck plastic surgery); |
| Unknown | Historical Condition<br>FOR OVER 1 MONTH | Scrotal mass (Scrotal mass); |
| Unknown | Historical Condition<br>OVER 1 DAY | Pain (Pain); |
| Unknown | Historical Condition | Scrotum swelling (Scrotal swelling); |
| Unknown | Historical Condition | Testis torsion (Testicular torsion); |
| 30-SEP-2023 to 30-SEP-2023 | Procedure | Laparotomy (Laparotomy); |
| 30-SEP-2023 to 30-SEP-2023 | Procedure | Stoma care (Stoma care); |
| 30-SEP-2023 to 30-SEP-2023 | Procedure | Intestinal adhesion lysis (Abdominal adhesiolysis); |
| Unknown | Historical Condition | Gastrointestinal decompression (Gastrointestinal decompression); |
| Unknown | Historical Condition | Defecation disorder (Defaecation disorder); |
| SEP-2023 to Unknown | Historical Drug<br><br>DOSE:UNK<br>DOSE UNIT:UNK<br>FREQUENCY:UNK<br>ROUTE:UNK<br>FORM:UNK<br>CONC:UNK | DEXAMETHASONE (Dexamethasone); Drug Indication: Fever (Pyrexia) |
| SEP-2023 to Unknown | Historical Drug<br><br>DOSE:UNK<br>DOSE UNIT:UNK<br>FREQUENCY:UNK<br>ROUTE:UNK<br>FORM:UNK<br>CONC:UNK | GLYCEROL ENEMA (Glycerol); Drug Indication: Defecation disorder (Defaecation disorder) |
| Unknown | Procedure | Invasive mechanical ventilation (Mechanical ventilation); |
| 30-SEP-2023 to Ongoing | Current Condition | Peritoneal effusion (Ascites); |
| 27-SEP-2023 to 27-SEP-2023 | Procedure | Anal dilation procedure (Anal dilation procedure); |
| 2023 to 2023 | Historical Condition | Hospitalization (Hospitalisation); |

## ADDITIONAL INFORMATION

**23. OTHER RELEVANT HISTORY continued**

| From/To Dates | Type of History / Notes | Description |
|---|---|---|
| 2023 to 2023 | Historical Condition | Fever (Pyrexia); |
| 2023 to 2023 | Historical Condition | Ascites (Ascites); |
| Unknown | Procedure | EMERGENCY SURGERY (); |
| Unknown | Historical Condition | Abdominal distension (Abdominal distension); |
| Unknown | Historical Condition | Bowel sounds abnormal (Gastrointestinal sounds abnormal); |