B|BRAUN
SHARING EXPERTISE

ТОВ «Б. БРАУН МЕДІКАЛ УКРАЇНА»

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Вих. № 579
Від 14.04.2021

Державна служба України з лікарських засобів та контролю за наркотиками

Шановні колеги!

Компанія **ТОВ «Б. Браун Медікал Україна»**, яка є Уповноваженим представником в Україні виробника **Б.Браун Медікал АГ, Швейцарія** повідомляємо наступне:

Компанією було отримано повідомлення від виробника щодо передбачуваних побічних реакцій на медичний виріб: Пронтосан, розчин для іригації ран, (клас ризику – III) в Швейцарії.

1 випадок:

Продукт	Пронтосан розчин
Номер серії:	невідомо
Опис	Пацієнтка звернулася у клініку Diabetic Foot Ulcer Clinic при Західній загальній лікарні в Единбурзі (провідний клініцист, старший лікар-подіатр Лорна Джаррет) у травні 2019 р. Клініцисти отримали консультацію лікаря, який призначив пероральний прийом гідрокортизону та виписав антигістамін для прийому вдома протягом 5 днів. Пацієнта попросили повідомити лікаря загальної практики, якщо проблема не зникне. Реакцію зводили до пов'язки, накладеної після використання препарату Пронтосан, оскільки раніше пацієнт виявляв чутливість до острівних пов'язок. 31 травня під час наступного візиту дільничної медсестри рану пацієнта обробили засобом «Пронтосан», і відразу йому стало дуже погано. Пов'язка до цього моменту не застосовується, лише Пронтосан.

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	У пацієнта з'явилася нудота і він почервонів. Частота серцевих скорочень почастішала, насичення киснем зменшилося, з'явилася діарея та блювота. Викликали швидку допомогу, артеріальний тиск знизився ще більше, в швидкій допомозі ввели адреналін та антигістамінні препарати. Пацієнт отримував стероїди в лікарні.
Дата фіксації	17.03.2021

Вищезазначені реакції є передбачуваними і зазначені в інструкції з використання медичного виробу.

Звіти щодо дослідження цих повідомлень виробником надаємо.

З повагою,

Директор
ТОВ «Б.Браун Медікал Україна» Шаповалоа А.Б.

Уповноважена особа з якості
ТОВ «Б.Браун Медікал Україна» Денис А.В.

Україна * м. Київ * Товариство з обмеженою відповідальністю «Б. БРАУН МЕДІКАЛ УКРАЇНА» Ідентифікаційний код 30798085

Виконавець: Денис А.В.
+38 067 4459004

Manufacturer Incident Report (MIR) for Serious Incidents (MDR/IVDR) and Incidents (AIMDD/MDD/IVDD)

Reporting Template **Version 7.2.1**

European Union Medical Devices Vigilance System

Section 1: Administrative information

1.1 Corresponding competent authority

a Name of receiving national competent authority (NCA)

Medicines & Healthcare products Regulatory Agency (MHRA)

b EUDAMED number of NCA

c Reference number assigned by NCA for this incident

d Reference number assigned by EUDAMED for this incident

1.2 Date, type, and classification of incident report

a	b	c
Date of submission: 2021-04-09 (e.g. 2012-10-23)	Date of incident (e.g. 2012-10-23): 2019-05-01 to 2019-05-31	Manufacturer awareness date: 2021-03-17 (e.g. 2012-10-23)

d Type of report

- ○ Initial
- ○ Follow up
- ◉ Combined initial and final
- ○ Final (Reportable incident)
- ○ Final (Non-reportable incident)

e In case of initial and follow-up reports, please indicate the expected date of the next report

(e.g. 2012-10-23)

f Classification of incident

- ○ Serious public health threat
- ○ Death
- ○ Unanticipated serious deterioration in state of health
- ◉ All other reportable incidents

1.3 Submitter information

1.3.1 Submitter of the report

a ◉ Manufacturer ○ Authorised representative ○ Other, please specify

b Manufacturer's reference number for this incident

CC 400507398

h	Street	i	Street number
j	Address complement	k	PO Box
l	City name	m	Postal code

1.3.4	**Submitter's details if not also manufacturer or authorised representative**

a	Registered commercial name of company B. Braun Medical AG		
b	Contact's first name Seraphina	c	Contact's last name Weibel
d	Email seraphina.weibel@bbraun.com	e	Phone +41 58 258 52 60
f	Country CH - Switzerland		
g	Street Seesatz	h	Street number 17
i	Address complement	j	PO Box
k	City name Sempach	l	Postal code 6204

2.4 Risk class of device when placed on market

a ○ This device has been placed on the market before the implementation of the MDD/AIMDD/IVDD

b

MDD/AIMDD

- ○ active implant
- ◉ class III
- ○ class IIb
- ○ class IIa
- ○ class I
- ○ class Is
- ○ class Im
- ○ class Ism
- ○ custom-made

IVDD

- ○ IVD Annex II List A
- ○ IVD Annex II List B
- ○ IVD devices for self-testing
- ○ IVD general

c

MDR

- ○ class III
- ○ class IIb
- ○ class IIa
- ○ class I

Type (Multiple choice)

- ☐ implantable
- ☐ active device
- ☐ intended to administer and/or remove a medicinal product
- ☐ sterile conditions
- ☐ measuring function
- ☐ reusable surgical instruments
- ☐ software
- ☐ systems
- ☐ procedure packs
- ☐ custom-made
- ☐ non-medical purpose

IVDR

- ○ class D
- ○ class C
- ○ class B
- ○ class A

Type (Multiple choice)

- ☐ self-testing
- ☐ near-patient testing
- ☐ professional testing
- ☐ companion diagnostic
- ☐ reagent
- ☐ software
- ☐ instrument
- ☐ sterile conditions

2.5 Market distribution of device (region/country)

(according to the best knowledge of the manufacturer)

a ☐ All EEA, Switzerland and Turkey

☒ AT	☒ BE	☐ BG	☒ CH	☐ CY	☐ CZ	☒ DE	☐ DK	☐ EE	☒ ES	☐ FI	☒ FR	☒ GB
☐ GR	☐ HR	☐ HU	☒ IE	☐ IS	☒ IT	☐ LI	☐ LT	☐ LU	☐ LV	☐ MT	☒ NL	☐ NO
☐ PL	☒ PT	☐ RO	☒ SE	☐ SI	☐ SK	☒ TR						

Others: AR, CL, CO, PE, MX, PY, ZA, EC, MY, MT, SV, NA, LU, M

2.6 Use of accessories, associated devices or other devices

a Relevant accessories used with the device being reported on (please list with corresponding Manufacturer if different from device being reported on)

b Relevant associated devices used with the device being reported on (please list with corresponding Manufacturer if different from device being reported on)

3.3 Patient information

a IMDRF 'Health Effect' terms and codes (Annex E, F)
Coding with IMDRF terms is a mandatory requirement.

	Choice 1 *(most relevant)*	Choice 2	Choice 3	Choice 4	Choice 5	Choice 6
IMDRF 'Clinical signs, symptoms, and conditions codes' (Annex E)	Code: E040201	Code: E1714	Code: E1020	Code: E1204	Code: E1032	Code:
IMDRF 'Health impact' codes (Annex F)	Code: F2303	Code: F08	Code:	Code:	Code:	Code:

If you think the incident is unique and a suitable IMDRF term is missing, briefly explain:

b Age of patient at the time of the incident
years ☐ months ☐ days ☐

c Gender ○ Female ○ Male ○ Unknown ○ Not applicable

d Body weight (kg)

e List any of the patient's prior health condition or medication that may be relevant to this incident

3.4 Initial reporter (can be healthcare professional of facility, patient, lay user)

a Role of initial reporter
◉ Healthcare professional ○ Patient ○ Lay user ○ Other, please specify

b Name of healthcare facility where incident occurred

c Healthcare facility report number (if applicable)

d Contact's first name

e Contact's last name

f Email

g Phone

h Country
GB - Great Britain

i Street

j Street number

k Address complement

l PO Box

m City name

n Postal code

e IMDRF 'Cause Investigation' terms and codes (Annex B, C, D)

Coding with IMDRF terms is a mandatory requirement.	Choice 1 *(most relevant)*	Choice 2	Choice 3	Choice 4	Choice 5	Choice 6	Choice 7	Choice 8
IMDRF Cause investigation: Type of investigation (Annex B)	Code: B13	Code: B12	Code	Code	Code	Code	Code	Code

IMDRF Cause investigation: Investigation findings (Annex C)	Code: C19	Code	Code	Code	Code	Code

IMDRF Cause investigation: Investigation conclusion (Annex D)	Code: D12	Code	Code	Code	Code	Code

If you think the incident is unique and a suitable IMDRF term is missing, briefly explain:

f IMDRF Component codes (Annex G)

Coding with IMDRF terms is a mandatory requirement.

	Choice 1 *(most relevant)*	Choice 2	Choice 3	Choice 4	Choice 5	Choice 6
IMDRF 'Component' codes (Annex G)	Code	Code	Code	Code	Code	Code

If you think the incident is unique and a suitable IMDRF term is missing, briefly explain:

g Description of remedial action/corrective action/preventive action/field safety corrective action (FSCA)
(For a FSCA, fill in the FSCA form)

No sample is available. Therefore, no analytical testing is possible.

Allergic and anaphylactic reactions are known side effects, as stated in the IfU. Since there is no trend, no further actions are initated at the moment.

h Time schedule for the implementation of the identified actions

i Final comments from the manufacturer on cause investigation and conclusion

c Enter the number of similar incidents and devices on the market for the indicated time periods

You must use yearly time periods unless:

A: a different time period has been specified by the European vigilance Working Group

B: the device has not been on the European market for more than three years

	Time period (N) Year to date = incident year (e.g. 2012-10-23)		Time period (N-1) calendar year one year before incident (e.g. 2012-10-23)		Time period (N-2) calendar year two years before incident (e.g. 2012-10-23)		Time period (N-3) calendar year three years before incident (e.g. 2012-10-23)	
Start date	2021-01-01		2020-01-01		2019-01-01		2018-01-01	
End date	2021-02-28		2020-12-31		2019-12-31		2018-12-31	
	Number of similar incidents	Number of devices on market	Number of similar incidents	Number of devices on market	Number of similar incidents	Number of devices on market	Number of similar incidents	Number of devices on market
Country of incident	1	149,766	0	1,239,674	0	1,253,972	2	1,091,168
EEA + CH + TR	0	420,646	1	2,426,249	3	2,324,051	3	2,141,750
World	1	815,174	2	4,715,767	3	4,877,970	5	4,421,593

d Comments on how similar incidents and associated number of devices on the market were determined

Reported adverse reactions to Prontosan Solution.

Section 5: General comments

3.1 a - Provide a comprehensive description of the incident

The patient attended the Diabetic Foot Ulcer Clinic at Western General Hospital, Edinburgh (lead clinician Senior Podiatrist Lorna Jarret) in May 2019 and had a reaction resulting in her becoming widely un-well and presenting a rash. The clinicians called for a doctor who prescribed oral hydrocortisone plus giving her an anti-histamine to take home that should be taken for 5 days. She was asked to report to GP if the problem persisted. The reaction was put down to the dressing applied after the Prontosan was used, as the patient had previously shown to be sensitive to island dressings.
On 31st of May 2019 at the follow up visit by the District Nurses the Patient was treated with a Prontosan Soak and immediately became very un- well. No dressing applied by this point, just the Prontosan.
The patient developed nausea and became flushed. Her heart rate increased, oxygen saturation decreased and she developed diarrhoea and vomiting.
An ambulance was called, her blood pressure dropped further and she was given adrenaline and anti-histamines in the ambulance. The patient received steroids in hospital.

The incident was not reported at the time but on discussion with the local Tissue Viability Nurse, Linda Primmer, at a meeting in March 2021, it was felt that this should be reported as a serious reaction and I was contacted as the local Territory Manager

4.2 a - Description of the manufacturer's evaluation concerning possible root causes/causative factors and conclusion

This report has been identified as B. Braun Medical AG internal report number CC 400507398.

The instructions for use of the product have been checked and the following side effects are listed:
"In very rare cases, there may be a mild burning sensation after application of Prontosan, but this usually dissipates after a few minutes. Prontosan can cause allergic reactions such as itching (urticatia) and rashes (exanthema). In rare cases (less than 1 out of 10,000), anaphylactic shock has been reported."

The product quantities sold in 2020 for Prontosan Solution were over 4.7 million. No negative trend can be observed.

4.2 d - Results of the assessment:

Risk-Analysis Document has been checked:
RA-400403-505 Version 15
Nr. 8 Biological Safety contains Local skin irritations or allergic reactions (worst case anaphylactical shock)
No update of the Risk Analysis is necessary.

4.2 g - Description of remedial action/corrective action/preventive action/field safety corrective action (FSCA)

No sample is available. Therefore, no analytical testing is possible.

Allergic and anaphylactic reactions are known side effects, as stated in the IfU. Since there is no trend, no further actions are initated at the moment.

Coded summary of report (will be auto populated from previous selections)

Medical device name

Prontosan

Basic UDI-DI	Unknown		
UDI device identifier	Unknown	UDI production identifier	Unknown

IMDRF adverse event reporting terms and codes

IMDRF=International Medical Device Regulators Forum. Coding with IMDRF terms is a mandatory requirement.

IMDRF clinical signs, symptoms, conditions codes	E040201	E1714	E1020	E1204	E1032			
IMDRF health impact codes	F2303	F08						
IMDRF Medical device problem codes	A24							
IMDRF Component codes								
IMDRF Cause investigation: Type of investigation	B13	B12						
IMDRF Cause investigation: Investigation findings.	C19							
IMDRF Cause investigation: Investigation conclusion.	D12							

Submission of this report does not represent a conclusion by the manufacturer and / or authorised representative or the national competent authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.

I affirm that the information given above is correct to the best of my knowledge.

Before signing and submitting

Check the form | Save as PDF

Date

Signature/Digital Signature

schesech Digital unterschrieben von schesech Datum: 2021.04.09 13:47:28 +02'00'

Send as XML file — Submit XML by Email

Send as PDF file — Submit PDF by Email

4.3 Similar incidents (for Final (Reportable incident))

4.3.1 Use of IMDRF terms and codes for identifying similar incidents

a Identification of similar incidents using IMDRF Adverse Event Reporting terms and codes
Tick-mark which code or combination of codes were used for identifying similar incidents.

	Choice 1
IMDRF code relating to most relevant 'Medical device problem' (Annex A)	☒
IMDRF code relating to most relevant 'Investigation finding' (Annex C, 'Cause investigation')	☐

☐ Other – enter description of what similar incidents are based on and the rationale why the above IMDRF codes were not used

4.3.2 Use of in-house terms/codes for identifying similar incidents (only for transition period)

a If similar incident were not identified by IMDRF codes but by in-house codes, please provide the codes and terms below.

	Choice 1	
Code/term for most relevant medical device problem	Code	
	Term	
Code/term for most relevant root cause evaluation	Code	
	Term	

☐ Other – enter description of what similar incidents are based on and the rationale why the above codes were not used

4.3.3 Number of similar incidents and devices on the market

a Indicate on which basis similar incidents were identified regarding the device or device variant:

◉ Model ○ Software ○ Lot/Batch ○ Product platform ○ Other variant

Details of the selection made above

Prontosan Solution

b Indicate to what criteria the number of devices on the market (also known as denominator data) is based on (tick the most appropriate):

◉ Devices placed on the market or put into service
○ Units distributed within each time period
○ Number of tests performed
○ Number of episodes of use (for reusable devices)
○ Active installed base
○ Units distributed from the date of declaration of conformity/CE mark approval to the end date of each time period
○ Number of devices implanted
○ Other -describe

Section 4: Manufacturer analysis

4.1 Manufacturer's preliminary comments

a	For **initial** and **follow-up** reports: preliminary results and conclusions of manufacturer's investigation
b	Initial actions (corrective and/or preventive) implemented by the manufacturer
c	What further investigations do you intend in view of reaching final conclusions?

4.2 Cause investigation and conclusion

a	**For Final (Reportable incident):** Description of the manufacturer's evaluation concerning possible root causes/causative factors and conclusion

This report has been identified as B. Braun Medical AG internal report number CC 400507398.

The instructions for use of the product have been checked and the following side effects are listed:
"In very rare cases, there may be a mild burning sensation after application of Prontosan, but this usually dissipates after a few minutes. Prontosan can cause allergic reactions such as itching (urticatia) and rashes (exanthema). In rare cases (less than 1 out of 10,000), anaphylactic shock has been reported."

The product quantities sold in 2020 for Prontosan Solution were over 4.7 million. No negative trend can be observed.

b	**For Final (Non-reportable incident):** Fill out rationale for why this is considered not reportable
c	Is root cause confirmed? ◉ Yes ○ No
d	Has the risk assessment been reviewed? ◉ Yes ○ No If 'No', rationale for no review required:
	If the risk assessment has been reviewed, is it still adequate? ◉ Yes ○ No Results of the assessment:

Risk-Analysis Document has been checked:
RA-400403-505 Version 15
Nr. 8 Biological Safety contains Local skin irritations or allergic reactions (worst case anaphylactical shock)
No update of the Risk Analysis is necessary.

Section 3: Incident information derived from healthcare professional/facility/patient/lay user/other

3.1 Nature of incident

a Provide a comprehensive description of the incident, including (1) what went wrong with the device (if applicable) and (2) a description of the health effects (if applicable), i.e. clinical signs, symptoms, conditions as well as the overall health impact (i.e. Death; life-threatening; hospitalization – initial or prolonged; required intervention to prevent permanent damage; disability or permanent damage; congenital anomaly/Birth defects; indirect harm; no serious outcome)

The patient attended the Diabetic Foot Ulcer Clinic at Western General Hospital, Edinburgh (lead clinician Senior Podiatrist Lorna Jarret) in May 2019 and had a reaction resulting in her becoming widely un-well and presenting a rash. The clinicians called for a doctor who prescribed oral hydrocortisone plus giving her an anti-histamine to take home that should be taken for 5 days. She was asked to report to GP if the problem persisted. The reaction was put down to the dressing applied after the Prontosan was used, as the patient had previously shown to be sensitive to island dressings.
On 31st of May 2019 at the follow up visit by the District Nurses the Patient was treated with a Prontosan Soak and immediately became very un- well. No dressing applied by this point, just the Prontosan.
The patient developed nausea and became flushed. Her heart rate increased, oxygen saturation decreased and she developed diarrhoea and vomiting.
An ambulance was called, her blood pressure dropped further and she was given adrenaline and anti-histamines in the ambulance. The patient received steroids in hospital.

The incident was not reported at the time but on discussion with the local Tissue Viability Nurse, Linda Primmer, at a meeting in March 2021, it was felt that this should be reported as a serious reaction and I was contacted as the local Territory Manager

3.2 Medical device problem information

a IMDRF Medical device problem codes (Annex A)
Coding with IMDRF terms is a mandatory requirement.

	Choice 1 *(most relevant)*	Choice 2	Choice 3	Choice 4	Choice 5	Choice 6
IMDRF 'Medical device problem codes'	Code: A24	Code	Code	Code	Code	Code

If you think the incident is unique and a suitable IMDRF term is missing, briefly explain:

b Number of patients involved

c What is the current location of the device?

- ○ Healthcare facility/carer
- ○ Distributor
- ○ Patient/user
- ○ Discarded
- ○ In transit to manufacturer
- ○ Remains implanted
- ○ Manufacturer
- ○ Unknown
- ◉ Other: used up

d Operator of device at the time of the incident

- ○ Healthcare professional
- ○ Patient/lay user
- ○ Other, please describe

e Usage of device (as intended)

- ○ Initial use
- ○ Reuse of a single use medical device
- ○ Reuse of a reusable medical device
- ○ Re-serviced/refurbished/fully refurbished
- ○ Problem noted prior use
- ○ Other:

f Remedial actions taken by healthcare facility, patient or user subsequent to the incident

Section 2: Medical device information

2.1 Unique Device Identification (UDI)

a	UDI device identifier/Eudamed ID: Unknown	b	UDI production identifier: Unknown
c	Basic UDI-DI/Eudamed-DI: Unknown	d	Unit of use UDI-DI:

2.2 Categorisation of device

a Medical device terminology

◯ EMDN ◯ GMDN ◯ UMDNS(ECRI) ◯ GIVD/EDMS ◯ Other, please specify

b Medical device nomenclature code

2.3 Description of device and commercial information

a Medical device name (brand/trade /proprietary or common name)

Prontosan

b Nomenclature text/Description of the device and its intended use

Prontosan Wound Irrigation Solution

c	Model	d	Catalogue/reference number
e	Serial number	f	Lot/batch number
g	Software version	h	Firmware version
i	Device manufacturing date (e.g. 2012-10-23)	j	Device expiry date (e.g. 2012-10-23)
k	Date when device was implanted (e.g. 2012-10-23) to	l	Date when device was explanted (e.g. 2012-10-23) to

m If precise implant/explant dates are unknown, provide the duration of implantation

Number of years | Number of months | Number of days

n	Implant facility	o Explant facility

p

	Notified body (NB) ID number(s) (if applicable)	Notified body (NB) certificate number(s) of device (if applicable)
1	0344	2113812CE01
2		

q Please indicate the date of one of the following:

◯ First declaration of conformity
◯ The device first CE marked
◯ First placed on the market
◯ First put into service
◯ If software, date first made available

Year | Month

c	If this incident involves multiple devices from the same manufacturer, please list the respective reference numbers of the other MIR forms you have submitted - NCA's local reference number - EUDAMED's reference number - Manufacturer's reference number		
d	If this incident is covered under an FSCA, please provide the relevant numbers: - NCA's local FSCA reference number - EUDAMED's FSCA reference number - Manufacturer's FSCA reference number		
e	Periodic Summary Report (PSR) ID		
f	If the incident occurred within a PMCF/PMPF investigation; please provide the Eudamed ID of that PMCF/PMPF investigation		
1.3.2	**Manufacturer information**		
a	Manufacturer organisation name B. Braun Medical AG		
b	Single registration number		
c	Contact's first name Seraphina	d	Contact's last name Weibel
e	Email seraphina.weibel@bbraun.com	f	Phone +41 58 258 52 60
g	Country CH - Switzerland		
h	Street Seesatz	i	Street number 17
j	Address complement	k	PO Box
l	City name Sempach	m	Postal code 6204
1.3.3	**Authorised representative information**		
a	Authorised representative organisation name		
b	Single Registration Number		
c	Contact's first name	d	Contact's last name
e	Email	f	Phone
g	Country		