ТОВ «Б. БРАУН МЕДІКАЛ УКРАЇНА»

Україна
03124, м. Київ
бул. В. Гавела, 6
Тел. +38 (044) 351-11-30
e-mail: info.bbmua@bbraun.com

LLC «B. BRAUN MEDICAL UKRAINE»

Ukraine
03124, Kiev City
bld. V.Havel, 6
Tel.: +38 (044) 351-11-30

e-mail: info.bbmua@bbraun.com

Вих. № 276
Від 04.03.2024

Державній службі 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 побічної реакції на медичний виріб: Пронтосан, гель для ран, (клас ризику – III) зафіксованої у Великій Британії.

Продукт	Пронтосан X, гель для ран 50 г
Номер за каталогом	400517
Номер серії:	невідомо
Опис	*Опис справи.* Інформація надійшла 21.02.2024 *Характер інциденту:* Ситуація: гель нанесли на венозну виразку ноги, приблизно через 30 хвилин з'явився поширений свербіж, еритематозний висип, набряк язика та губ, відчуття стискання горла та задишка. Парамедики виявили гіпотензію та ввели внутрішньо м'язово адреналін (повторно). Гель змивали з ноги фізіологічним розчином. Згодом розвинулась швидка фібриляція передсердь (? адреналін). Ніяких інших явних тригерів. Немає раніше відомої алергії. *Вжиті коригувальні заходи* Госпіталізований в ВІТ (відділення інтенсивної терапії) для подальшого лікування. *Клінічне оновлення отримано 28.02.2024:* *Чи можна дізнатися номер партії товару?* Недоступний *Чи можна дізнатися дані про пацієнта (вік, стать, попередні захворювання, історію хвороби пацієнта, фактори ризику)?* 61-річний чоловік, хвороба

B BRAUN
SHARING EXPERTISE

ТОВ «Б. БРАУН МЕДІКАЛ УКРАЇНА»

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	Паркінсона, ожиріння, підвищений ІМТ, протромботичний синдром (визначення неясне), алергія невідома. Ліки, які використовував пацієнт, мадопар, едоксабан, праміпіексол і тансулозин. *Який результат у пацієнта? Одужання без наслідків?* Пацієнт повністю одужав і виписаний.
Дата фіксації	21.02.2024

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.

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

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 and 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	Date of submission: 2024-02-29 (e.g. 2012-10-23)	b	Date of incident (e.g. 2012-10-23): 2024-02-16 to 2024-02-16	c	Manufacturer awareness date: 2024-02-21 (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: 400644903

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 Mari	d	Contact's last name Desku
e	Email mari.desku@bbraun.com	f	Phone +41 58 258 51 31
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		

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 Mari	c	Contact's last name Desku
d	Email mari.desku@bbraun.com	e	Phone +41 58 258 51 31
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

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 Wound Gel X

b Nomenclature text/Description of the device and its intended use
Product for Wound Bed Preparation

c	Model:	d	Catalogue/reference number: 400517
e	Serial number:	f	Lot/batch number: UNKNOWN
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	2113812DE04
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:

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: AE, BW, CG, GP, IL, IR, MK, MQ, NA, RE, SZ, TJ, UA, ZA

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)

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)

Information received on 21.02.2024
Nature of Incident:
Presenting: Gel applied to venous leg ulcer, about 30min later developed widespread itch, erythematous rash, tongue and lip swelling, feeling of throat closing and shortness of breath. Found to be hypotensive by paramedics and given IM adrenaline (repeated). Gel washed from leg with saline.
Subsequently went into fast atrial fibrillation (? adrenaline driven).
No other apparent triggers. No previously known allergy.

Remedial Actions taken
Admitted to ITU (intensive therapy unit) for ongoing management.

Clinical update received on 28.02.2024:
Is it possible to find out the batch number of the product? Not available
Is it possible to know patient data (age, gender, pre-existing condition, patient's medical history, risk factors)? 61 year old male, Parkinson's, obesity, elevated BMI, prothrombotic syndrome (definition unclear), no known allergies. Medication used by the patient, madopar, edoxaban, pramipiexole & tansulosin.
What is the patient's outcome? Recovered without sequalae? Patient has made a full recovery and has been discharged.

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:

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

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	Code	Code	Code	Code	Code
IMDRF 'Health impact' codes (Annex F)	Code	Code	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: 61 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

Parkinson's, obesity, elevated BMI, prothrombotic syndrome (definition unclear), no known allergies. Medication used by the patient, madopar, edoxaban, pramipiexole & tansulosin.

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
Raigmore Hospital

c Healthcare facility report number (if applicable)

d Contact's first name: Mark

e Contact's last name: Mitchelson

f Email: mark.mitchelson@nhs.scot

g Phone:

h Country
GB - Great Britain

i Street: Old Perth Road

j Street number:

k Address complement:

l PO Box:

m City name: Inverness

n Postal code: IV2 3UJ

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 400644903.

The Instruction for use (IfU) of the product has been checked and the following side effects are listed:
"In very rare cases, there may be a mild burning sensation after application of Pron- tosan® Wound Gel X, but this usually dissipates after a few minutes. Prontosan® Wound Gel X can cause allergic reactions such as itching (urticaria) and rashes (exanthema). In very rare cases (less than 1 out of 10,000), anaphylactic shock has been reported with Prontosan® Wound Gel X products."

The product quantities sold in 2023 for Prontosan Wound Gel X were over 450'000 units. There is no evidence of a trend.

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:

Product Risk analysis Document-No. RA-88270-Prontosan-Wound-Gel-X Version 16 has been checked, chapter B1.1: Nr. 8 Intolerance against ingredients. Local skin irritation or allergic reactions (worst case: anaphylactical shock). No update of the Risk Analysis is necessary.

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 B11	Code B13	Code B17	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 initiated at the moment.

h Time schedule for the implementation of the identified actions

i Final comments from the manufacturer on cause investigation and conclusion

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

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

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	2024-01-01		2023-01-01		2022-01-01		2021-01-01	
End date	2024-01-31		2023-12-31		2022-12-31		2021-12-31	
	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	0	5,360	0	54,120				
EEA + CH + TR	0	28,127	0	324,762				
World	0	38,040	0	458,003				

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

Section 5: General comments

3.1 a - Provide a comprehensive description of the incident

Information received on 21.02.2024
Nature of Incident:
Presenting: Gel applied to venous leg ulcer, about 30min later developed widespread itch, erythematous rash, tongue and lip swelling, feeling of throat closing and shortness of breath. Found to be hypotensive by paramedics and given IM adrenaline (repeated). Gel washed from leg with saline.
Subsequently went into fast atrial fibrillation (? adrenaline driven).
No other apparent triggers. No previously known allergy.

Remedial Actions taken
Admitted to ITU (intensive therapy unit) for ongoing management.

Clinical update received on 28.02.2024:
Is it possible to find out the batch number of the product? Not available
Is it possible to know patient data (age, gender, pre-existing condition, patient's medical history, risk factors)? 61 year old male, Parkinson's, obesity, elevated BMI, prothrombotic syndrome (definition unclear), no known allergies. Medication used by the patient, madopar, edoxaban, pramipiexole & tansulosin.
What is the patient's outcome? Recovered without sequalae? Patient has made a full recovery and has been discharged.

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 400644903.

The Instruction for use (IfU) of the product has been checked and the following side effects are listed:
"In very rare cases, there may be a mild burning sensation after application of Pron- tosan® Wound Gel X, but this usually dissipates after a few minutes. Prontosan® Wound Gel X can cause allergic reactions such as itching (urticaria) and rashes (exanthema). In very rare cases (less than 1 out of 10,000), anaphylactic shock has been reported with Prontosan® Wound Gel X products."

The product quantities sold in 2023 for Prontosan Wound Gel X were over 450'000 units. There is no evidence of a trend.

4.2 d - Results of the assessment:

Product Risk analysis Document-No. RA-88270-Prontosan-Wound-Gel-X Version 16 has been checked, chapter B1.1:
Nr. 8 Intolerance against ingredients. Local skin irritation 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 initiated at the moment.