B|BRAUN
SHARING EXPERTISE

ТОВ «Б. БРАУН МЕДІКАЛ УКРАЇНА»

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Вих. № 663-1
Від 23.07.19

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 підозрюваних передбачуваних побічних реакцій на медичний виріб: Пронтосан, розчин для іригації ран, (клас ризику – III) в Швейцарії.

1 випадок:

Продукт	Пронтосан, розчин для іригації ран 350 мл, номер за каталогом: 400403
Номер серії:	Невідомий
Опис	Пацієнтка 1980р народження, з маммологією. та після променевої терапії, уже кілька тижнів має рану на грудях .. 11 або 18/06/2019: перший раз застосовано Пронтосан, розчин, відчувала себе не досить добре, проблем не було. Пізніше пацієнтка згадала, що не відчувала себе добре і трохи свербіло навколо рани. Медсестра також спробувала нанести Пронтосан на марлю і приклала це на кілька годин до шкіри, проблем і реакцій не виявлено. 25/6/2019: Другий раз (невідомо, чому існує розрив у застосуванні Пронтосану протягом 2 тижнів) пацієнтка поступила приблизно через півгодини по використанні Пронтосану з

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	симптомами свербіж, не почувала себе добре, і у неї набряк рот, що було схоже на шок. Її транспортували до лікарні (Альріжне), де вона пробула 2 дні. Інформації про лікування немає (швидше за все спостереження, інфузія).
Дата фіксації	2019-07-05

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.

Виконавець: Денис А.В.
+38 067 4459004

import XML | fix + save

fill with test data Initial

fill with test data I+F

fill with test data Follow Up

fill with test data Final

new case, keep base data

Report Form
Manufacturer's Incident Report
Medical Devices Vigilance System
(MEDDEV 2.12/1 rev 7)

Version 2.26en
2012-12-04

1 Administrative information

Recipient (Name of NCA) Dutch Healthcare Inspectorate	Stamp box
Address of National Competent Authority Stadsplateau 1 3521 AZ Utrecht	

Date of this report
2019-07-23

Reference number assigned by the manufacturer
CC 400437996

Reference number assigned by NCA

Type of report
- ○ Initial report
- ○ Follow-up report
- ◉ Combined initial and final report
- ○ Final report

Does the incident represent a serious public health threat?
- ○ yes
- ◉ no

Classification of incident
- ○ Death
- ○ Unanticipated Serious Deterioration in State of Health
- ◉ All other reportable incidents

Identify to what other NCA's this report was also sent
FDA

2 Information on submitter of the report

Status of submitter
- ◉ Manufacturer
- ○ Authorised Representative within EEA and Switzerland and Turkey
- ○ Others: (identify the role)

3 Manufacturer information

new

Name B. Braun Medical AG	
Contact Name Theiler Jennifer	
Address Seesatz 17	
Postcode 6204	**City** Sempach
Phone +41 58 258 56 89	**Fax**
E-mail jennifer.theiler@bbraun.com	**Country** CH - Switzerland

4 Authorised Representative Information

new

Name B. Braun Medical B.V.	
Contact Name Paul Geelen	
Address Euterpehof 10	
Postcode 5342 ew	**City** Oss
Phone 0031412672423	**Fax** 0031412672490
E-mail paul.geelen@bbraun.com	**Country** NL - Netherlands

5 Submitter's information

new

Name B. Braun Medical AG	
Contact Name Theiler Jennifer	
Address Seesatz 17	
Postcode 6204	**City** Sempach
Phone +41 58 258 56 89	**Fax**
E-mail jennifer.theiler@bbraun.com	**Country** CH - Switzerland

6 Medical device information

new

Class

- ○ AIMD Active implants
- ◉ MDD Class III
- ○ MDD Class IIb
- ○ MDD Class IIa
- ○ MDD Class I
- ○ IVD Annex II List A
- ○ IVD Annex II List B
- ○ IVD Devices for self-testing
- ○ IVD General

Nomenclature system (preferable GMDN) GMDN	**Nomenclature code**
Nomenclature text PRONTOSAN LOESUNG RUNDFLAS. "WEST" 350ML	
Commercial name/ brand name / make Prontosan	
Model number	**Catalogue number** 400403
Serial number(s) (if applicable)	**Lot/batch number(s) (if applicable)** UNKNOWN
Software version number (if applicable)	
Device Mfr Date	**Expiry date**
Implant date (For implants only)	**Explant date (For implants only)**
Duration of Implantation (For implants only. To be filled if the exact implant and explant dates are unknown)	
Accessories / associated devices (if applicable)	
Notified Body (NB) ID-number 0344/DEKRA	

7 Incident Information

Date the incident occurred

2019-06-25

Incident description narrative

Patient with mammaca in 1980, and radiation therapie. Has know for some weeks a wound at the breast.

According to the nurse, the patient had two times a sort of allergic reaction after they used the prontosan. The prontosan was deliverd by Mathot, they are the delivery at home, batchnumber is unknown.

The nurse also tried (after the first time) a gauze with prontosan for several hours on the skin without a reaction, they find it rather strange also.

SPECIAL REMARKS:

11 or 18/6/2019 First time with the use of prontosan she was afterwards not feeling well, no big problems. The patient mentioned not feeling well and a bit itchy around the wound.
The nurse also tried some prontosan on a gauze and attached this for some hours to the skin, this was without any problems or reaction.

25/6/2019
The second time (they don't know why there is a gap in the use of the prontosan for 2 weeks).

The patient did get in about half an hour (after the use of prontosan), again itchy, was not feeling well and she got a swollen

mouth and became like a shock. She was transported to the hospital (Alrijne) and stayed there for 2 days. There is no information about the treatment there (most likely observation, infusion). Wound has been treated with aquacel Ag before the prontosan and they still use it now
User facility report reference number, if applicable
Manufacturer's awareness date 2019-07-05

Number of patients involved (if known)	**Number of medical devices involved (if known)**
1	1

Medical device current location/disposition (if known) No sample available.

Operator of the medical device at the time of incident (select one)

- (•) Healthcare Professional
- ( ) Patient
- ( ) Other

Usage of the medical device (select from list below)

- (•) initial use
- ( ) reuse of a single use medical device
- ( ) reuse of a reusable medical device
- ( ) re-serviced/refurbished
- ( ) other
- ( ) problem noted prior use

8 Patient information

Patient outcome
Patient recovered fully without sequelae.

Remedial action taken by the healthcare facility relevant to the care of the patient
Unknown. Most likely observation, infusion.

Gender, if applicable
(•) Female ( ) Male

Age of the patient at the time of incident, if applicable	**units** (•) Years ( ) months ( ) days
Weight in kilograms, if applicable	

9 Healthcare facility information

new

Name of the healthcare facility Activite Thuiszorg (Home care service)	
Contact person within the facility Dhr. Ben Evers	
Address Postbus 149	
Postcode 2350 AC	**City** Leiderdorp
Phone 06 46892881	**Fax**
E-mail benevers@gmail.com	**Country** NL - Netherlands

10 Manufacturer's preliminary comments (Initial/Follow-up report)

Manufacturer's preliminary analysis

This report has been identified as B. Braun Medical AG internal report number 400437996.

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 2018 for Prontosan Wound Irrigation Solution were over 4.4 million. No negative trend can be observed.

Initial corrective actions/preventive actions implemented by the manufacturer

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.

Expected date of next report

11 Results of manufacturers final investigation (Final report)

The manufacturer's device analysis results

No sample was forwarded to B. Braun Medical AG, Sempach. Therefore, no analytical testing is possible.

Remedial action/corrective action/preventive action / Field Safety Corrective Action

Allergic and anaphylactic reactions are known side effects, as stated in the IfU. Since there is no trend, no further actions will be taken.

Time schedule for the implementation of the identified actions

No actions defined.

Final comments from the manufacturer

The rate of allergic and anaphylactic reactions is continously monitored and in case of negative trend further actions have to be implemented.

Further investigations

None.

Is the manufacturer aware of similar incidents with this type of medical device with a similar root cause?

◉ Yes ○ No

Number of similar incidents

25

If yes, state in which countries and the report reference numbers of the incidents.

Germany - BfArm 2443/09 and 2448/09 and 4394/09
Denmark - LMST 20111 00586
Denmark - SST 20144040452
Sweden- Läkemedelsverket Ref no: 6.6.2-2014-38149

Sweden- Läkemedelsverket Ref no: 6.6.2-2014-52572
Spain- PS/CV/AG/26537 (Literature case)
Netherlands- NL - Health Care Inspectorate: Reg. number: 1013686
Italy-Incidente 400271165
Switzerland-Incidence 400279591, Vk 20151221_18
Norway - NO -Incidence 400289152
Portugal-Infarmed Case no - 1713/2016 (Literature case), 400324889
Norway - NO- Incidence REF: 17/4252, 400330046
Australia-AU-Incidence TGA 45911, 400344664
China-CN-Incidence CFDA 131311800201702326, 400344718
Netherland-NL-Incidence IGZ: IT2002226, 400356184
Czech Republic-CZ-SUKL: sukls265875/2017, 400363450
Sweden-SE-Incidence MPA (MoH): 6.6.2-2018-13625, 400376081
Sweden-SE-Incidence MPA (MoH): 6.6.2-2018-15837, 400377710
UK - MHRA (MoH): 2018/007/017/601/005, 400394358
UK - MHRA (MOH): 2018/009/028/601/003, 400403450
Sweden-SE-Incidence MPA (MoH): 6.6.2-2018-83189, 400407527
Sweden-SE-Incidence MPA (MoH): 6.6.2-2019-58959, 400435406
Sweden-SE-Incidence MPA (MoH): 6.6.2-2019-58740, 400435522

For final reports only. The medical device has been distributed to the following countries:

within the EEA and Switzerland and Turkey

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

Candidate Countries

☐ HR

☐ All EEA, candidate countries and Switzerland and Turkey

Others:

AR, CL, CO, PE, MX, PY, ZA, EC, MY, MT, SV, NA, LU, MQ, SY, MV, PH, SG, RO, HK, TW, TH, ID, IL, VN

12 Comments

Submission of this report does not, in itself, 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.

Signature theijech

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

print | check | send XML-data by E-Mail