

4

Louis A. Montgomery
6542 Hypoluxo Road, Suite 114
Lake Worth, FL 33467

August 23, 2005

Bundesinstitut für Arzneimittel und Medizinprodukte
Attn: Unit 71, Herrn Norbert Paeschke
VIA FACSIMILE: 49-(0)228-207 - 5207

Dear Herr Paeschke:

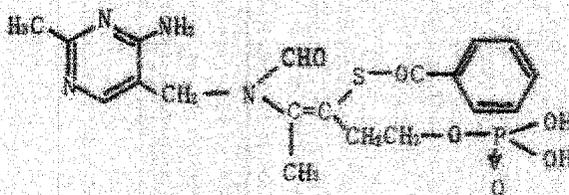
Please reference our telephone conversation earlier today.

I am assembling data from multiple sources to propose to the U.S. Food and Drug Administration (FDA) that the compound benfotiamin can reasonably be expected to be safe for human consumption.

If under the provisions of the U.S. Dietary Supplement Health and Education Act of 1994 (DSHEA 1994) the FDA determines that benfotiamin can reasonably be expected to be safe, I will be able to distribute benfotiamin as a dietary supplement in the United States.

Benfotiamin is distributed in Germany under the trade name Milgamma, in tablets of 50mg., 100mg. and 150mg., by Woerwag Pharma, GmbH, of Boeblingen. The chemical name for benfotiamine is: S-benzoylthiamine-O-monophosphate. The molecular formula and structure is depicted below:

White crystals or crystalline powder.
FORMULA: $C_{19}H_{23}N_4O_6PS$ MOLECULAR FORMULA: 466.45



MELTING POINT: about 200°C (with decomposition)

Louis A. Montgomery
6542 Hypoluxo Road, Suite 114
Lake Worth, FL 33467

The following information, if available, would be very useful to me:

1. The date benfotiamin began to be distributed in Germany.
2. The typical daily dose for benfotiamin.
3. The highest daily dose available/recommended for benfotiamin.
4. The gross number of doses sold annually in Germany.
5. Any adverse effects/events reported which could be associated with the use of benfotiamin.
6. The number of adverse effects/events as a percent of total users of benfotiamin.
7. An assessment by your institute as to the safety of benfotiamin for human use.
8. Any open source clinical data regarding the safety of benfotiamin you may be aware of and can supply or direct me to.

I of course would be pleased to reimburse your expenses for providing any or all of the requested information.

Don't hesitate to contact me if you require further explanation or clarification.

Mit Vielen Dank im Voraus,



Louis A. Montgomery



BFARM

Federal Institute for Drugs
and Medical Devices

BfArM • Kurt-Georg-Kiesinger-Allee 3 • D-53175 Bonn

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Your reference and letter of
August 23, 2005

Our reference (Please quote in your reply)
715-3811-110211/05

Telephone: +49-1888-307-
3796 Bonn
Sep. 22, 2005

Request for information on benfotiamine-containing drugs in Germany

Dear Mr Montgomery,

herewith I would like to answer your request concerning the marketing situation and other aspects of benfotiamine-containing drugs in Germany. Please apologize our delayed response – my attempt to respond to you via lou3551@aol.com has obviously failed.

ad Q1:
1978

ad Q2:
The typical daily benfotiamine-dose depends on respective indications and varies between different drugs (the below mentioned example represents typical dose recommendations):

- Prevention of Vitamin B1-deficiency: 1-2 x 50 mg dragee/week
- Treatment of Vitamin B1 deficiency: 1-3 x 50 mg dragee/day
- Treatment of polyneuropathy (caused by Vitamin B1 deficiency): up to 400 mg/day (first three weeks), afterwards up to 150 mg/day

ad Q3:

- 400 mg benfotiamine (enteral dosage forms)/day = highest daily dose of a marketed drug
- 900 mg benfotiamine (enteral dosage forms)/day = highest daily dose of a non-marketed but authorised drugs.

ad Q4:
This question cannot be answered exactly, since no respective data are available to us.



The distribution of benfotiamine-containing drugs in Germany is restricted to pharmacies. A medical prescription is not compulsory. Based on prescription data only, for example, in 2002, a total of 2.4 million defined daily dosages of one benfotiamine-containing drug (milgamma mono®) have been prescribed in Germany.

ad Q5:

Within the BfArM-database (spontaneous reports from Germany, reporting source: HCPs only) the following numbers of reports describing adverse reactions (ADRs) observed in association with use of benfotiamine-containing drugs have been identified (the reports were not differentiated with regard to the causal relationship between the drug and the reported ADRs).

Number of ADR-reports within the BfArM-database mentioning association with use of Benfotiamine-containing drugs:

- Benfotiamine-containing monotherapeutics: n = 18
- Benfotiamine-containing combination drugs: n = 92

per email

ad Q6:

No reporting rates can be calculated since no exact exposition data are available to us.

ad Q7:

With regard to benfotiamine routine pharmacovigilance has been performed using data from different sources (spontaneous ADR reports, periodic safety update reports, scientific literature); in doing so, no safety signals pertaining benfotiamine-containing drugs have been identified.

ad Q8:

Respectively, the following homepages may be of interest to you.

<http://www.clinicaltrials.gov/>

<http://www.centerwatch.com/>

<http://controlledtrials.com/>

We hope this information is of use to you. In case of further questions, please don't hesitate to contact me.

Yours sincerely
(on behalf of the BfArM)


Jörg Seebeck

04-Okt-2005 15:05

BFARM ABT 7

+49 228 207 3515 S.01/11

Von Jörg Seebeck
An: lou1355@hotmail.com
Datum: 26.09.2005 09:19:51
Betreff: benfotiamine_BfArM

Dear Mr Montgomery,

with regard to the questions outlined in your last mail, please find here the following answers:
the number of ADR reports mentioned in my letter represent the total number of reports received by the BfArM since 1978.

The second part of your "question 2" relates to the types of ADRs (hypersensitivity, etc) which have been received in association with use of benfotiamine. Please find attached a table of all reports describing cases in which benfotiamine was applied in the form of a monotherapeutic (n = 18 [and not 28 as falsely described in my previous letter]). Of these, the most important ones are those in which benfotiamine was considered by the reporter as "suspected" or "interacting" drug - these cases are indicated in the column "role" by the letters "s" or "i".

Hoping to be of assistance.
Yours sincerely

Jörg Seebeck

Jörg Seebeck MD
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Email: seebeck@bfarm.de

*Kind regards
Jörg*

Fax: 001-561-641-0838

n. ①/②

04-Okt-2005 15:05

BFARM 187 7

+49 228 207 3515 S. 02/11

Line listing mit Bewertung

| BfARM Ref. no. | Country | Source Report type | Literature | Patient Age | Sex | Weight (kg) | Pregnancy_int |
|-------------------|---------|--------------------|------------|-------------|-----|-------------|---------------|
| DE-BFARM-04011841 | Inland | Spontaneous report | | 44 Year | m | | |

| DRUG Identification Drug name | Role | Start | End | Route of Administration | Dosage Daily dose | Assessment Bewertung BfARM |
|----------------------------------|------|-------------|-------------|-------------------------|----------------------|-------------------------------|
| #1 tavanic 250 | s | 17-SEP-2004 | 20-SEP-2004 | Oral | 250 | possible |
| #2 insuman rapid | c | | | Subcutaneous | | |
| #3 zocer | c | | | Oral | 040 | |
| #4 norvasc | c | | | Oral | 010 | |
| #5 lantus | c | | | Subcutaneous | | |
| #6 beloc zok | c | | | Oral | 001 | |
| #7 atacand | c | | | Oral | 024 | |
| #8 plavix | c | | | Unknown | 001 | |
| #9 adalat | c | | | Unknown | | |
| #10 resonium a | c | | | Unknown | | |
| #11 isomol | c | | | Unknown | 002 | |
| #12 viox | c | | | Unknown | 025 | |
| #13 migamma mono | c | | | Unknown | 150 | |
| #14 renagel | c | | | Unknown | 2.4 | |
| #15 renavit | c | | | Unknown | 001 | |
| #16 furorrese | c | | | Unknown | 500 | |
| #17 danoprox | c | | | Unknown | 100 | |
| #18 motium | c | | | Oral | | |
| #19 calciumcetat nefro | c | | | Unknown | 2.5 | |
| #20 tilidolor | c | | | Unknown | | |
| #21 bitain | c | | | Unknown | | |
| #22 novalgine | c | | | Rectal | 001 | |
| #23 neuronin | c | | | Unknown | | |
| #24 pantozol | c | | | Unknown | 002 | |

| Seriousness | REACTION | Onset | Outcome |
|--------------------------------|----------------------------------|-------------|---------|
| Serious : Seriousness criteria | Reaction MedDRA | | |
| Yes | Marked restlessness Confusion | 19-SEP-2004 | Unknown |
| | | 19-SEP-2004 | Unknown |

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23.09.2005 13:30:04

Line listing mit Bewertung

Serie 2 von 10

04-Okt-2005 15:06

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| BIARM Ref. no. | Country | Source Report type | Literature | Patient Age | Sex | Weight (kg) | Pregnancy_int |
|-------------------|---------|--------------------|------------|-------------|-----|-------------|---------------|
| DE-BFARM-04003161 | Inland | Report from study | | 56 Year | f | 51 | |

| DRUG Identification Drug name | Role | Start | End | Route of Administration | Dosage Daily dose | Assessment Bewertung BIARM |
|-------------------------------|------|-------------|-------------|---------------------------------------|-------------------|----------------------------|
| #1 lonafarnib | s | 16-APR-2003 | | Oral | 200 | possible |
| #2 phenprocoumon | c | JUL-2003 | | Oral | | |
| #3 hydromorphone | c | JUL-2003 | | Oral | 008 | |
| #4 carboplatin | s | 16-APR-2003 | 30-JUL-2003 | Intravenous (not otherwise specified) | | possible |
| #5 benfotiamine | c | 29-JUL-2003 | | Oral | 300 | |
| #6 paclitaxel | s | 16-APR-2003 | 30-JUL-2003 | Intravenous (not otherwise specified) | | possible |

| Seriousness Serious : Seriousness criteria | REACTION Reaction MedDRA | Onset | Outcome |
|--|---------------------------------|-------------|--------------------|
| Yes hospitalization | Anaemia Weakness generalized | 08-AUG-2003 | recovered/resolved |
| | | 08-AUG-2003 | recovered/resolved |

| BIARM Ref. no. | Country | Source Report type | Literature | Patient Age | Sex | Weight (kg) | Pregnancy_int |
|-------------------|---------|--------------------|------------|-------------|-----|-------------|---------------|
| DE-BFARM-04003105 | Inland | Spontaneous report | | 58 Year | m | | |

| DRUG Identification Drug name | Role | Start | End | Route of Administration | Dosage Daily dose | Assessment Bewertung BIARM |
|-------------------------------|------|----------|-----|-------------------------|-------------------|----------------------------|
| #1 extraneal | s | MAY-2001 | | intraperitoneal | 002 | possible |
| #2 unal 200 | c | | | Unknown | | |
| #3 ass 100 | c | | | Unknown | | |
| #4 silberne | c | | | Unknown | | |
| #5 physioneal 1.36% | c | | | Unknown | | |
| #6 rocalrol | c | | | Unknown | | |
| #7 melolazone | c | | | Unknown | | |
| #8 benfotiamine | c | | | Unknown | | |
| #9 iantus | c | | | Unknown | | |

| Seriousness Serious : Seriousness criteria | REACTION Reaction MedDRA | Onset | Outcome |
|--|--------------------------|----------|--------------------|
| Yes hospitalization | Peritonitis | MAY-2001 | recovered/resolved |

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23.09.2004 11:00 04

Line listing mit Bewertung

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| BIARM Ref. no. | Country | Source Report type | Literature | Patient Age | Sex | Weight (kg) | Pregnancy_int |
|-------------------|---------|-----------------------|------------|----------------|-----|-------------|---------------|
| DE-BFARM-02003111 | Inland | Report from study | | 70 Year | f | 68 | |

| DRUG Identification | | | | Role | Start | End | Route of Administration | Dosage Daily dose | Assessment Bewertung BIARM |
|---------------------|-----------------|---|-------------|-------------|-------|-----|-------------------------|----------------------|-------------------------------|
| #1 | mitigamina mono | s | 30-JAN-2002 | 26-FEB-2002 | Oral | | 600 | possible | |

| Seriousness | | REACTION | | Onset | Outcome |
|-------------|----------------------|-------------------------------|--------|-------------|--------------------|
| Serious | Seriousness criteria | Reaction | MedDRA | | |
| Yes | hospitalization | Cerebral vascular disturbance | | 19-FEB-2002 | recovered/resolved |
| | | Syncope | | 26-FEB-2002 | recovered/resolved |

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04-Okt-2005 15:06

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Line listing mit Bewertung

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| BEARM Ref. no. | Country | Source Report type | Literature | Patient Age | Sex | Weight (kg) | Pregnancy_Int |
|-------------------|---------|--------------------|------------|-------------|-----|-------------|---------------|
| DE-BFARM-01008602 | Inland | Spontaneous report | | 66 Year | m | | |

| DRUG Identification | | | | Role | Start | End | Route of Administration | Dosage Daily dose | Assessment Bewertung BEARM |
|---------------------|--------------------------|--|--|------|----------|-------------|-------------------------|-------------------|----------------------------|
| #1 | zocor 40 mg | | | s | JUL-2001 | 06-NOV-2001 | Oral | 001 | possible |
| #2 | sandimmun | | | c | | | Oral | 050 | |
| #3 | lendormin | | | c | | | Oral | 001 | |
| #4 | imurek | | | c | | | Oral | 100 | |
| #5 | captopril | | | c | | | Oral | 100 | |
| #6 | furiose | | | c | | | Oral | 080 | |
| #7 | pyridoxine hydrochloride | | | c | | | Oral | 200 | |
| #8 | sandimmun 100 mg | | | c | | | Oral | 002 | |
| #9 | insulin human | | | c | | | Unknown | 032 | |
| #10 | benfotiamine | | | c | | | Oral | 200 | |
| #11 | prednisolone | | | c | | | Unknown | 005 | |
| #12 | aspirin | | | c | | | Oral | 100 | |
| #13 | diamox | | | c | | | Oral | | |

| Seriousness Serious ; Seriousness criteria | REACTION Reaction MedDRA | Onset | Outcome |
|--|-------------------------------------|-------------|--------------------|
| Yes hospitalization | Rhabdomyolysis | 06-NOV-2001 | recovered/resolved |
| | Creatine kinase increased | 06-NOV-2001 | recovered/resolved |
| | CPK increased | 06-NOV-2001 | recovered/resolved |
| | Myoglobin urine | 06-NOV-2001 | recovered/resolved |
| | Alanine aminotransferase increase | 06-NOV-2001 | recovered/resolved |
| | Strength loss of | 06-NOV-2001 | recovered/resolved |
| | Aspartate aminotransferase increase | 06-NOV-2001 | recovered/resolved |
| | BUN increased | 06-NOV-2001 | recovered/resolved |

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23.08.2005 17:30:04

Line listing mit Bewertung

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| BIARM Ref. no. | Country | Source Report type | Literature | Patient Age | Sex | Weight (kg) | Pregnancy_int |
|-------------------|---------|--------------------|------------|-------------|-----|-------------|---------------|
| DE-BFARM-01003601 | Inland | Spontaneous report | | 66 Year | m | 97 | |

| DRUG Identification | | | | Dosage | Assessment |
|----------------------|------|-------------|-------------|------------|-----------------|
| Drug name | Role | Start | End | Daily dose | Bewertung BIARM |
| #1 milgamma mono 150 | s | 02-APR-2001 | 04-APR-2001 | 001 | possible |
| #2 marcumar | c | | | Unknown | |
| #3 siolor 850 | c | | | 002 | |
| #4 glibendamid 3,5mg | c | | | 002 | |

| Seriousness | | REACTION | | Onset | Outcome |
|-------------|----------------------|----------|--------|-------------|--------------------|
| Serious | Seriousness criteria | Reaction | MedDRA | | |
| | | Erythema | | 04-APR-2001 | recovered/resolved |
| | | Itching | | 04-APR-2001 | recovered/resolved |

| BIARM Ref. no. | Country | Source Report type | Literature | Patient Age | Sex | Weight (kg) | Pregnancy_int |
|-------------------|---------|--------------------|------------|-------------|-----|-------------|---------------|
| DE-BFARM-98901069 | Inland | Report from study | | 60 Year | f | | |

| DRUG Identification | | | | Dosage | Assessment |
|---------------------|------|-------|-----|------------|-----------------|
| Drug name | Role | Start | End | Daily dose | Bewertung BIARM |
| #1 benfotiamin | s | | | Oral | possible |

| Seriousness | | REACTION | | Onset | Outcome |
|-------------|----------------------|----------------------------------|--------|-------------|---------|
| Serious | Seriousness criteria | Reaction | MedDRA | | |
| | | Hemia NOS | | 22-MAR-1989 | Unknown |
| | | Aggravation of existing disorder | | 22-MAR-1989 | Unknown |

| BIARM Ref. no. | Country | Source Report type | Literature | Patient Age | Sex | Weight (kg) | Pregnancy_int |
|-------------------|---------|--------------------|------------|-------------|-----|-------------|---------------|
| DE-BFARM-96003251 | Inland | Report from study | | 21 Year | f | | |

| DRUG Identification | | | | Dosage | Assessment |
|---------------------|------|-------|-----|------------|-----------------|
| Drug name | Role | Start | End | Daily dose | Bewertung BIARM |
| #1 benfotiamin | s | | | Oral | possible |

| Seriousness | | REACTION | | Onset | Outcome |
|-------------|----------------------|----------|--------|-------------|---------|
| Serious | Seriousness criteria | Reaction | MedDRA | | |
| | | Headache | | 30-JAN-1996 | Unknown |

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04-Okt-2005 15:06

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| BfArM Ref. no. | Country | Source Report type | Literature | Patient Age | Sex | Weight (kg) | Pregnancy_int |
|-------------------|---------|-----------------------|------------|----------------|-----|-------------|---------------|
| DE-BFARM-06003250 | Inland | Report from study | | 36 Year | f | | |

| DRUG Identification Drug name | Role | Start | End | Route of Administration | Dosage Daily dose | Assessment Bewertung BfArM |
|----------------------------------|------|-------|-----|-------------------------|----------------------|-------------------------------|
| #1 benfotiamin | s | | | Oral | | possible |

| Seriousness Serious | Seriousness criteria | REACTION Reaction MedDRA | Onset | Outcome |
|------------------------|----------------------|-----------------------------|-------------|---------|
| | | Headache | 16-JAN-1996 | Unknown |

| BfArM Ref. no. | Country | Source Report type | Literature | Patient Age | Sex | Weight (kg) | Pregnancy_int |
|-------------------|---------|-----------------------|------------|----------------|-----|-------------|---------------|
| DE-BFARM-06003249 | Inland | Report from study | | 30 Year | m | | |

| DRUG Identification Drug name | Role | Start | End | Route of Administration | Dosage Daily dose | Assessment Bewertung BfArM |
|----------------------------------|------|-------|-----|-------------------------|----------------------|-------------------------------|
| #1 benfotiamin | s | | | Oral | | possible |

| Seriousness Serious | Seriousness criteria | REACTION Reaction MedDRA | Onset | Outcome |
|------------------------|----------------------|-----------------------------|-------------|---------|
| | | Headache | 16-JAN-1996 | Unknown |

| BfArM Ref. no. | Country | Source Report type | Literature | Patient Age | Sex | Weight (kg) | Pregnancy_int |
|-------------------|---------|-----------------------|------------|----------------|-----|-------------|---------------|
| DE-BFARM-06003248 | Inland | Report from study | | 20 Year | f | | |

| DRUG Identification Drug name | Role | Start | End | Route of Administration | Dosage Daily dose | Assessment Bewertung BfArM |
|----------------------------------|------|-------|-----|-------------------------|----------------------|-------------------------------|
| #1 benfotiamin | s | | | Oral | | possible |

| Seriousness Serious | Seriousness criteria | REACTION Reaction MedDRA | Onset | Outcome |
|------------------------|----------------------|-----------------------------|-------------|---------|
| | | Headache | 16-JAN-1996 | Unknown |

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23.09.2005 15:39:04

Line Listing mit Bewertung

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| BfArM Ref. no. | Country | Source Report type | Literature | Patient Age | Sex | Weight (kg) | Pregnancy_int |
|-------------------|---------|--------------------|------------|-------------|-----|-------------|---------------|
| DE-BFARM-96003247 | Inland | Report from study | | 28 Year | m | | |

| DRUG Identification Drug name | Role | Start | End | Route of Administration | Dosage Daily dose | Assessment Bewertung BfArM |
|-------------------------------|------|-------|-----|-------------------------|-------------------|----------------------------|
| #1 benfotiamin | s | | | Oral | | possible |

| Seriousness Serious : Seriousness criteria | REACTION Reaction MedDRA | Onset | Outcome |
|--|--------------------------|-------------|---------|
| | Headache | 31-JAN-1996 | Unknown |

| BfArM Ref. no. | Country | Source Report type | Literature | Patient Age | Sex | Weight (kg) | Pregnancy_int |
|-------------------|---------|--------------------|------------|-------------|-----|-------------|---------------|
| DE-BFARM-96003246 | Inland | Report from study | | 23 Year | f | | |

| DRUG Identification Drug name | Role | Start | End | Route of Administration | Dosage Daily dose | Assessment Bewertung BfArM |
|-------------------------------|------|-------|-----|-------------------------|-------------------|----------------------------|
| #1 benfotiamin | s | | | Oral | | possible |

| Seriousness Serious : Seriousness criteria | REACTION Reaction MedDRA | Onset | Outcome |
|--|--------------------------|-------------|---------|
| | Headache | 17-JAN-1996 | Unknown |

| BfArM Ref. no. | Country | Source Report type | Literature | Patient Age | Sex | Weight (kg) | Pregnancy_int |
|-------------------|---------|--------------------|------------|-------------|-----|-------------|---------------|
| DE-BFARM-96003245 | Inland | Report from study | | 26 Year | f | | |

| DRUG Identification Drug name | Role | Start | End | Route of Administration | Dosage Daily dose | Assessment Bewertung BfArM |
|-------------------------------|------|-------|-----|-------------------------|-------------------|----------------------------|
| #1 benfotiamin | s | | | Oral | | possible |

| Seriousness Serious : Seriousness criteria | REACTION Reaction MedDRA | Onset | Outcome |
|--|--------------------------|-------------|---------|
| | Headache | 31-JAN-1996 | Unknown |

8

04-OCT-2005 15:06

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P. 8

| BIARM Ref. no. | Country | Source Report type | Literature | Patient Age | Sex | Weight (kg) | Pregnancy_int |
|-------------------|---------|-----------------------|------------|----------------|-----|-------------|---------------|
| DE-BFARM-92006791 | Ierland | Spontaneous report | | 50 Year | m | 72 | |

| DRUG Identification | | | | Dosage | Assessment |
|----------------------|------|-------------|-------------|------------|-----------------|
| Drug name | Role | Start | End | Daily dose | Bewertung BIARM |
| #1 katadolon kapseln | s | 22-MAY-1991 | 22-MAY-1991 | | possible |
| #2 benfotiamine | c | 17-APR-1991 | | 003 | |
| #3 doxepin | c | 25-AUG-1989 | | 025 | |

| Seriousness | | REACTION | | Onset | Outcome |
|-------------|----------------------|---------------------|--------|-------------|--------------------|
| Serious | Seriousness criteria | Reaction | MedDRA | | |
| | | Urticaria | | 22-MAY-1991 | recovered/resolved |
| | | Rash maculo-papular | | 22-MAY-1991 | recovered/resolved |

| BIARM Ref. no. | Country | Source Report type | Literature | Patient Age | Sex | Weight (kg) | Pregnancy_int |
|-------------------|---------|-----------------------|------------|----------------|-----|-------------|---------------|
| DE-BFARM-92005052 | Ierland | Spontaneous report | | 72 Year | | 98 | |

| DRUG Identification | | | | Dosage | Assessment |
|---------------------|------|-------------|-------------|------------|-----------------|
| Drug name | Role | Start | End | Daily dose | Bewertung BIARM |
| #1 tensobon | s | MAY-1992 | 22-JUN-1992 | 063 | possible |
| #2 accupro | s | 23-JUN-1992 | 06-JUL-1992 | 013 | possible |
| #3 insulin | c | | | 070 | |
| #4 triazolam | c | | | | |
| #5 benfotiamin | c | | | 100 | |

| Seriousness | | REACTION | | Onset | Outcome |
|-------------|----------------------|----------|--------|----------|--------------------|
| Serious | Seriousness criteria | Reaction | MedDRA | | |
| Yes | | Cough | | JUN-1992 | recovered/resolved |

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23.09.2005 15:30:04

Line Listing of Events

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| BfARM Ref. no. | Country | Source Report type | Literature | Patient Age | Sex | Weight (kg) | Pregnancy_int |
|-------------------|---------|--------------------|------------|-------------|-----|-------------|---------------|
| DE-BFARM-92003142 | Ireland | Report from study | | 51 Year | m | 57 | |

| DRUG Identification | Role | Start | End | Route of Administration | Dosage Daily dose | Assessment Bewertung BfARM |
|---------------------|------|-------------|-------------|-------------------------|-------------------|----------------------------|
| #1 pankreatin | c | 25-SEP-1991 | | Oral | 600 | |
| #2 delix 1,25 | s | 09-OCT-1991 | 12-OCT-1991 | Oral | 1.3 | possible |
| #3 delix 2,5 | s | 13-OCT-1991 | 16-OCT-1991 | Oral | 2.5 | possible |
| #4 bufedil forte | c | 23-SEP-1991 | | Oral | 600 | |
| #5 cyanocobalamin | c | 23-SEP-1991 | | Unknown | 750 | |
| #6 benfotiamine | c | 23-SEP-1991 | | Oral | 150 | |

| Seriousness | REACTION | Onset | Outcome |
|-------------------------------|-----------------|-------------|---------|
| Serious: Seriousness criteria | Reaction MedDRA | | |
| Yes | Hyperkalaemia | 14-OCT-1991 | Unknown |

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04-OCT-2005 15:05

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| BFARM Ref. no. | Country | Source Report type | Literature | Patient Age | Sex | Weight (kg) | Pregnancy_int |
|-------------------|---------|--------------------|------------|-------------|-----|-------------|---------------|
| DE-BFARM-01010278 | Inland | Spontaneous report | | 64 Year | F | 60 | |

| DRUG identification | Role | Start | End | Route of Administration | Dosage Daily dose | Assessment Bewertung BfArM |
|---------------------|------|-------------|-------------|---------------------------------------|-------------------|----------------------------|
| #1 zofran | i | 16-SEP-1991 | 16-SEP-1991 | Intravenous (not otherwise specified) | | |
| #2 metoclopramide | i | | | Unknown | | |
| #3 prednisolon | c | | | Unknown | 010 | |
| #4 prazosin | c | | | Unknown | 002 | |
| #5 allopurinol | c | | | Oral | 300 | |
| #6 talinolol | c | | | Unknown | 100 | |
| #7 benfotiamine | c | | | Oral | 100 | |
| #8 indometacin | c | | | Unknown | 200 | |
| #9 glibenclamide | c | | | Unknown | | |
| #10 daunorubicin | c | 16-SEP-1991 | 16-SEP-1991 | Intravenous (not otherwise specified) | | |
| #11 cytarabine | c | 16-SEP-1991 | 16-SEP-1991 | Intravenous (not otherwise specified) | | |
| #12 lidocaine | c | 16-SEP-1991 | 16-SEP-1991 | Unknown | | |
| #13 cyanocobalamin | c | | | Oral | 050 | |

| Seriousness Serious / Seriousness criteria | REACTION Reaction MedDRA | Onset | Outcome |
|--|--------------------------|-------------|--------------------|
| Yes lifethreatening | Cardiac arrest | 16-SEP-1991 | recovered/resolved |
| | Respiratory depression | 16-SEP-1991 | recovered/resolved |