

APPENDIX B

PRESENTATION OF INDIVIDUAL CASE HISTORIES

FOR

EQUASYM / METHYLPHENIDATE

**(MEDICALLY SUBSTANTIATED CASES
- SERIOUS & NON-SERIOUS UNLISTED)**

LEGENDS

Age Units:

| | | | | | |
|----|-------------------|----|---------|----|---------|
| A | adult | D | days | NB | newborn |
| a | approximate years | Y | years | M | months |
| AD | adolescent | EL | elderly | W | weeks |
| CH | child | IN | infant | | |

Source:

| | | | | | |
|----|-------------------------|----|----------------------|--|--|
| CN | consumer | LT | literature | | |
| CT | clinical study | RG | regulatory authority | | |
| HP | healthcare professional | | | | |

Time Units:

| | | | | | |
|------|-----------------|------|------------------|-----|---------|
| AFTR | after treatment | DTRE | During treatment | min | minutes |
| CON | continues | hr | hours | M | months |
| D | days | IM | immediately | Y | years |

Outcome:

| | | | | | |
|------|-------------|------|------------------------|--|--|
| CON | continues | REC | complete recovery | | |
| FAT | fatal | RSEQ | resolved with sequelae | | |
| NBAB | normal baby | RESG | resolving | | |

Countries:

| | | | | | |
|----|---------|-----|----------------|--|--|
| IE | Eire | UK | United Kingdom | | |
| FI | Finland | USA | United States | | |
| BE | Belgium | NL | Netherlands | | |

General:

| | | | | | |
|------|----------------|--|--|--|--|
| NA | not applicable | | | | |
| NRPT | not reported | | | | |
| UNK | unknown | | | | |

CIOMS II Report

Serious and Non-serious unlisted

Body system: Investigations

| Reference No. | Country | Source | Age | Sex | Dose | Treat.dur. till onset | Outcome | Reaction description | Comments |
|---------------|------------|--------|------------|------------|------------------|--------------------------|---------|----------------------------|----------|
| [REDACTED] | [REDACTED] | RG | [REDACTED] | [REDACTED] | 20 mg (Daily) | UNK | CONT | Transaminases increased | Serious |
| [REDACTED] | [REDACTED] | HP | [REDACTED] | [REDACTED] | | UNK | UNK | LDH increased | Serious |
| [REDACTED] | [REDACTED] | | [REDACTED] | [REDACTED] | | UNK | UNK | CK increased | Serious |

Report from [REDACTED] (ref: [REDACTED] & health care professionals (physician & paediatrician). Medical history: hyperkinetic syndrome. Experienced increased GOT, GPT, LDH & CK an unknown time after commencing Equasym. Previously taking Ritalin. No comeds reported. Equasym withdrawn. Patient hospitalised for 52 days for diagnostic confirmation of transaminase increase. Reporter: events possibly related to Equasym.

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CIOMS II Report

Serious and Non-serious unlisted

Body system: Musculoskeletal and connective tissue disorders

| Reference No. | Country | Source | Age | Sex | Dose | Treat. dur. till onset | Outcome | Reaction description | Comments |
|---------------|---------|--------|-----|-----|---------|------------------------|---------|----------------------|---|
| [REDACTED] | HP | UNK | UNK | UNK | Unknown | 1D | UNK | Muscle spasms | Not Serious Report received from Geneva Pharm (report [REDACTED]) via a physician concerning two patients (age and gender unknown) (ref. [REDACTED]) with unk PMH exp. severe back spasms within a day (onset date unknown) after commencing treatment with Methylophenidate 5 mg (dates of therapy unknown). Concomitant medication unknown. Treatment and outcome is unknown. Further information requested. |
| [REDACTED] | HP | UNK | UNK | UNK | Unknown | 1D | UNK | Muscle spasms | Not Serious Report received from Geneva Pharm (report [REDACTED]) via a physician concerning two patients (age and gender unknown) (ref. [REDACTED]) with unk PMH exp. severe back spasms within a day (onset date unknown) after commencing treatment with Methylophenidate 5 mg (dates of therapy unknown). Concomitant medication unknown. Treatment and outcome is unknown. Further information requested. |

CIOMS II Report

Serious and Non-serious unlisted

Body system : Psychiatric disorders

| Reference No. | Country | Source | Age | Sex | Dose | Treat. dur. till onset | Outcome | Reaction description | Comments |
|---------------|------------|------------------|------------|------------|--|------------------------|---------|-------------------------------|-------------|
| [REDACTED] | [REDACTED] | LT | [REDACTED] | [REDACTED] | 10 mg (Twice daily) | 3W | REC | Obsessive-compulsive reaction | Not Serious |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | 3W | REC | Behavior abnormal | Not Serious |
| [REDACTED] | [REDACTED] | Spontan- eous | [REDACTED] | [REDACTED] | 20mg daily given orally | UNK | RBC | Nightmares | Not Serious |
| [REDACTED] | [REDACTED] | RG | [REDACTED] | [REDACTED] | [REDACTED] | UNK | RBC | Flu like symptoms | Not Serious |
| [REDACTED] | [REDACTED] | CT | A | [REDACTED] | 0.3 mg/kg (rounded to the nearest 2.5mg) twice daily, per oral | UNK | UNK | Anxiety | Not Serious |
| [REDACTED] | [REDACTED] | LT | [REDACTED] | [REDACTED] | [REDACTED] | UNK | UNK | Light headedness | Not Serious |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | UNK | UNK | Irritability | Not Serious |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | UNK | UNK | Dry mouth | Not Serious |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | UNK | UNK | Decreased appetite | Not Serious |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | UNK | UNK | Difficulty sleeping | Not Serious |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | UNK | UNK | Sexual function decreased | Not Serious |

Literature Report: A [REDACTED] YO [REDACTED] PMH depression, short-term memory deficit, dx early Alzheimer's, type II Diabetes, hip replacement, spinal stenosis, exp drastic change in behavior spending several hrs each day ritually performing 2 behaviors, & intensely compulsive behavior 25 days after commencing tx with methylphenidate. Concom med- donepezil trial. After 40 days methylphenidate d/c. Pt recovered over 2 months.

Published : CNS Spectrums, 2003, 8: 612 - 613

ASPP received from [REDACTED]. Concerning a [REDACTED] year old [REDACTED] medical history unknown, who experienced flu like symptoms & severe nightmares for 2 weeks whilst receiving Methylphenidate (brand unspecified). Co-suspect: Bacillus Calmette Guerin vaccination. No concomitant medications reported. Methylphenidate was continuing and the patient recovered.

One of two reports for this study. Hx: Traumatic brain injury. Concomeds: none reported. Pt was participating in study to assess effects of Methylphenidate on

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Body system : Psychiatric disorders

| Reference No. | Country Source | Age | Sex | Dose | Treat.dur. till onset | Outcome | Reaction description |
|---------------|----------------|-----|-----|------|--------------------------|---------|-------------------------|
|---------------|----------------|-----|-----|------|--------------------------|---------|-------------------------|

Comments

vital signs & AEs in adults with Hx of traumatic brain injury. Pt withdrew from study after 5 days on active drug, because of excessive adverse effects. Case linked to [REDACTED]
Published : American Journal of Physical Medicine & Rehabilitation, 2004, VOL 83, 2: 131 - 137