

APPENDIX C

PRESENTATION OF INDIVIDUAL CASE HISTORIES

FOR

EQUASYM / METHYLPHENIDATE

(MEDICALLY UNSUBSTANTIATED CASES

&

MEDICALLY SUBSTANTIATED NON-SERIOUS LISTED CASES)

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

Medically unsubstantiated and Non-serious unlisted

Body system : Nervous system disorders

Reference No.	Country Source	Age	Sex	Dose	Treat.dur. till onset	Outcome	Reaction description	Comments
[REDACTED]	RG	[REDACTED]	[REDACTED]	30 mg (Daily)	468D	CONT	Athetosis	Not Serious
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	468D	CONT	Tic	Not Serious

An ASPP received from the [REDACTED] ([REDACTED]) concerning pt w medical hx: ADHD, tinea, traumatic haematoma, otitis media serous, upper respiratory tract infection, eczema, asthma, cough, impetigo, viral infection & groin pain who developed AE's 468 days after commencing tx w Methylphenidate (brand unspecif.). Pt also tx acetaminophen. Reporter provided no serious criteria. Outcome: pt not recovered.

CIOMS II Report

Medically unsubstantiated and Non-serious unlisted

Reference No.	Country	Source	Age	Sex	Dose	Treat.dur. till onset	Outcome	Reaction description	Comments
[REDACTED]	[REDACTED]	CN	[REDACTED]	[REDACTED]	Unk (Twice daily intermit-tently)	IM	CONT	Hair loss	Not Serious
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	IM	CONT	Itchy scalp	Not Serious
[REDACTED]	[REDACTED]	RG	[REDACTED]	[REDACTED]	Unknown	5AMNT	CONT	Hair loss	Consumer Report: [REDACTED] pt. PMH unspc thyroid problems exp hair falling out immed after commencing methylphenidate tx (Apr 2002). Also scalp itching. Concom med- Synthroid. Rx methylphenidate- inc motivation & as stimulant (not per package insert). Used on & off 8 wks. Immed exp hair loss & falling out since. Hair is thin. Unspec lab tests done including thyroid tests & have "all come up negative". No tx. Con't.
[REDACTED]	[REDACTED]	HP	[REDACTED]	[REDACTED]	10 mg (Once)	UNK	REC	Rash	Not Serious
[REDACTED]	[REDACTED]	HP	UNK	[REDACTED]	Unk (Unknown)	UNK	UNK	Rash	Not Serious

ASPP from [REDACTED] ([REDACTED]). Med hx: attention deficit/hyperactivity disorder, impulsive disorder & asthma. Pt had sudden hair loss approx 5m after commencing Methylphenidate. Co-suspect: Concerta XL (methylphenidate). Commeds: Ventolin (salbutamol), paracetamol & beclomethasone. Action taken with Methylphenidate was unknown. Outcome: continues. Reporter considered event non serious.

HCP: [REDACTED] YO [REDACTED] pt w/med hx of ADD developed a rash after 1 dose of methylphenidate. Concom med unk. Methylphenidate discontinued after 1 dose and rash resolved by the next day. The reporter did not have access to further information as the patient was discharged from the facility the next day. Rash did not lengthen hospitalization. No further information is expected.

HCP Report: [REDACTED] pt, PMH of allergies to dyes dev a rash an unk number of days after commencing tx with methylphenidate (Therapy dates unk). Concom med unk. pt's physician inquired about the inactive ingredients in methylphenidate

CIOMS II Report

Medically unsubstantiated and Non-serious unlisted

Body system : Skin and subcutaneous tissue disorders

Reference No.	Country	Source	Age	Sex	Dose	Treat.dur. till onset	Outcome	Reaction description	Comments
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IR 10mg tab as pt was having a reaction later identified as a rash. No further information expected- reporter at time of f/u could not recall physician's name.

Not Serious

Report from a physician. Medical history: ADHD. Patient developed AE 46 days after commencing Equasym (batch number B511112). Patient initially received 2 x 2.5 mg daily, this increased to 3 x 2.5mg daily. No con meds reported. Pt developed diffuse hair loss since Jan 2004 which had not previously been seen before. No tx given & drug withdrawn. AE ongoing. Reporter: probably related.

Not Serious

A report was received from a hospital pharmacist concerning a patient (demography and medical history unknown) who experienced hair loss (date not specified) after commencing treatment with Equasym (strength, dose and therapy dates unknown). No concomitant medication was reported. Action taken with Equasym and the outcome of the event is unknown. Further information has been requested.

Spontan-
eous

Hair loss

CONT

46D

5mg daily increasing to 7.5mg daily

HP

Spontan-
eous

Hair loss

UNK

UNK

UNK Unknown

HP

CIOMS II Report

Medically unsubstantiated and Non-serious unlisted

Body system: Vascular disorders

Reference No.	Country Source	Age	Sex	Dose	Treat.dur. till onset	Outcome	Reaction description	Comments
[REDACTED]	RG	[REDACTED]	[REDACTED]	Unknown	UNK	UNK	Hypertension	Not Serious
[REDACTED]	CT	A	[REDACTED]	0.3mg/kg (rounded to the nearest 2.5mg) twice daily, oral	UNK	UNK	Hypertension	Not Serious
[REDACTED]	LT							Literature report on the effect of Methyphenidate in adults with traumatic brain injury. This is one of two reports. [REDACTED] patient with nonpenetrating traumatic brain injury, developed hypertension after commencing Methyphenidate (brand unspecified). Comment: placebo. Patient asked to leave study after 2nd week because of AE, the which may have been exacerbated by the Methyphenidate. Case linked to [REDACTED]

ASPP received from [REDACTED] ([REDACTED]). Medical history and concomitant medications were unknown. Patient experienced AE whilst receiving treatment with Methyphenidate (brand unspecified). Action taken with Methyphenidate and the outcome of the event were unknown.

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