

Activsubstance MAXACTIVEING_002;

Trade Name ALL

SUMMARY TABULATION IN PRINCIPAL LINE LISTING

Body System	Spontaneous		Regulatory		Literature		Total		Studies		Others		Grand Total	
High Level Group Term	Spontaneous	Non-serious	Serious	Non-serious	Serious	Non-serious	Serious	Non-serious	Serious	Non-serious	Serious	Non-serious	Serious	Non-serious
Low Level Term	Spontaneous	Non-serious	Serious	Non-serious	Serious	Non-serious	Serious	Non-serious	Serious	Non-serious	Serious	Non-serious	Serious	Non-serious
Psychiatric disorders														
<i>Sexual dysfunctions, disturbances and gender identity disorders</i>														
Anorgasmia *	0	1	0	0	0	0	0	1	0	0	0	0	0	1
Total HLGT:	0	1	0	0	0	0	0	1	0	0	0	0	0	1
Total Body System:	0	1	0	0	0	0	0	1	0	0	0	0	0	1
Ear and labyrinth disorders														
<i>Inner ear and VIIIth cranial nerve disorders</i>														
Vertigo	0	1	0	0	0	0	0	1	0	0	0	0	0	1
Total HLGT:	0	1	0	0	0	0	0	1	0	0	0	0	0	1
Total Body System:	0	1	0	0	0	0	0	1	0	0	0	0	0	1
Cardiac disorders														
<i>Cardiac arrhythmias</i>														
Arrhythmia *	1	0	0	0	0	0	1	0	0	0	0	0	1	0
Total HLGT:	1	0	0	0	0	0	1	0	0	0	0	0	1	0
<i>Coronary artery disorders</i>														
Myocardial infarction	0	0	0	0	0	0	0	0	1	0	0	0	1	0
Total HLGT:	0	0	0	0	0	0	0	0	1	0	0	0	1	0
Total Body System:	1	0	0	0	0	0	1	0	1	0	0	0	2	0
Vascular disorders														
<i>Vascular haemorrhagic disorders</i>														
Allergic purpura *	0	1	0	0	0	0	0	1	0	0	0	0	0	1
Total HLGT:	0	1	0	0	0	0	0	1	0	0	0	0	0	1
Total Body System:	0	1	0	0	0	0	0	1	0	0	0	0	0	1

SUMMARY TABULATION IN PRINCIPAL LINE LISTING

Body System	Spontaneous		Regulatory		Literature		Total		Studies		Others		Grand Total	
High Level Group Term	Spontaneous	Non-serious	Regulatory	Non-serious	Literature	Non-serious	Total	Non-serious	Studies	Non-serious	Others	Non-serious	Grand Total	Non-serious
Low Level Term	Spontaneous	Non-serious	Regulatory	Non-serious	Literature	Non-serious	Total	Non-serious	Studies	Non-serious	Others	Non-serious	Grand Total	Non-serious
Respiratory, thoracic and mediastinal disorders														
<i>Bronchial disorders (excl neoplasms)</i>														
Asthmatic attack *	0	0	0	0	0	0	0	0	2	0	0	0	2	0
Asthma aggravated	0	0	0	0	0	0	0	0	1	0	0	0	1	0
Exacerbation of asthma *	0	0	0	0	0	0	0	0	1	0	0	0	1	0
Allergic asthma *	0	0	0	0	0	0	0	0	1	0	0	0	1	0
Total HLGTT:	0	0	0	0	0	0	0	0	5	0	0	0	5	0
Total Body System:	0	0	0	0	0	0	0	0	5	0	0	0	5	0
Skin and subcutaneous tissue disorders														
<i>Skin vascular abnormalities</i>														
Ecchymosis *	0	1	0	0	0	0	0	1	0	0	0	0	0	1
Total HLGTT:	0	1	0	0	0	0	0	1	0	0	0	0	0	1
Total Body System:	0	1	0	0	0	0	0	1	0	0	0	0	0	1
Musculoskeletal and connective tissue disorders														
<i>Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)</i>														
Slipped disc *	0	0	0	0	0	0	0	0	1	0	0	0	1	0
Total HLGTT:	0	0	0	0	0	0	0	0	1	0	0	0	1	0
<i>Musculoskeletal and connective tissue disorders NEC</i>														
Lumbago *	0	0	0	0	0	0	0	0	0	1	0	0	0	1
Total HLGTT:	0	0	0	0	0	0	0	0	0	1	0	0	0	1
Total Body System:	0	0	0	0	0	0	0	0	1	1	0	0	1	1
Grand Total:	1	4	0	0	0	0	1	4	7	1	0	0	8	5
Total Number of Cases:	1	3	0	0	0	0	1	3	7	1	0	0	8	4

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CUMULATIVE TABULATION OF SERIOUS UNLISTED

Body System	Total received before 31-DEC-1994	Number received betw een 01-JAN-1995 And 31-DEC-2000	Total received
High Level Group Term			
Low Level Term			
Cardiac disorders			
<i>Cardiac arrhythmias</i>			
Arrhythmia	0	1	1
Total HLGT:	0	1	1
Total Body System:	0	1	1
Respiratory, thoracic and mediastinal disorders			
<i>Bronchial disorders (excl neoplasms)</i>			
Allergic asthma	0	1	1
Exacerbation of asthma	0	1	1
Asthmatic attack	0	2	2
Total HLGT:	0	4	4
Total Body System:	0	4	4
Musculoskeletal and connective tissue disorders			
<i>Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)</i>			
Slipped disc	0	1	1
Total HLGT:	0	1	1
Total Body System:	0	1	1
Grand Total:	0	6	6
Total Number of Cases:	0	6	6

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SUMMARY TABULATION OF NON-SERIOUS LISTED

Body System	High Level Group Term	Low Level Term	Count
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Ear and labyrinth disorders			
<i>Inner ear and VIIIth cranial nerve disorders</i>			
		Vertigo	1
	Total HLGT:		1
	Total Body System:		1
	<u>Grand Total:</u>		1
Total Number of Cases:			1

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SUMMARY TABULATION OF SPONTANEOUS NON-MEDICALLY CONFIRMED

Body System

High Level Group Term

Low Level Term

Serious

Non-serious

Grand Total

Psychiatric disorders

Sexual dysfunctions, disturbances and gender identity disorders

Anorgasmia

0

1

1

Total HLGT:

0

1

1

Total Body System:

0

1

1

Ear and labyrinth disorders

Inner ear and VIIIth cranial nerve disorders

Vertigo

0

1

1

Total HLGT:

0

1

1

Total Body System:

0

1

1

Grand Total:

0

2

2

Total Number of Cases:

0

2

2

End of summary Reporting