

Activsubstance MAXACTIVEING_002;

Trade Name ALL

Type of Report: NORMAL

Line Listing Data Elements

- Case number
- Source Country
- Source
- Age
- Sex
- Formulation
- Dosage Frequency
- Dosage Daily Dose
- Dosage Route of Administration
- Dosage Duration
- Event Verbatim [PT]
- Event Verbatim [LLT]
- Event Verbatim Both [LLT] + [PT]
- Event Onset Date Time
- Patient Outcome
- Serious
- Listed
- Related
- Fatal
- Report Case Number
- Initial Patient
- Occurrence Country
- Initial Receipt Date
- Reference to Studio
- Prod.Name Report Inclusion
- Product Name
- Case Narrative
- Reporter Comments

Inclusion Criteria

Spontaneous	<input checked="" type="checkbox"/> Serious	<input checked="" type="checkbox"/> Non Serious	<input checked="" type="checkbox"/> Listed	<input checked="" type="checkbox"/> Non Listed	<input checked="" type="checkbox"/> Related	<input checked="" type="checkbox"/> Non Related	<input checked="" type="checkbox"/> Fatal	<input checked="" type="checkbox"/> Non Fatal
Literature	<input checked="" type="checkbox"/> Serious	<input checked="" type="checkbox"/> Non Serious	<input checked="" type="checkbox"/> Listed	<input checked="" type="checkbox"/> Non Listed	<input checked="" type="checkbox"/> Related	<input checked="" type="checkbox"/> Non Related	<input checked="" type="checkbox"/> Fatal	<input checked="" type="checkbox"/> Non Fatal
Report from study	<input checked="" type="checkbox"/> Serious	<input checked="" type="checkbox"/> Non Serious	<input checked="" type="checkbox"/> Listed	<input checked="" type="checkbox"/> Non Listed	<input checked="" type="checkbox"/> Related	<input checked="" type="checkbox"/> Non Related	<input checked="" type="checkbox"/> Fatal	<input checked="" type="checkbox"/> Non Fatal
Post Marketing Surv.	<input checked="" type="checkbox"/> Serious	<input checked="" type="checkbox"/> Non Serious	<input checked="" type="checkbox"/> Listed	<input checked="" type="checkbox"/> Non Listed	<input checked="" type="checkbox"/> Related	<input checked="" type="checkbox"/> Non Related	<input checked="" type="checkbox"/> Fatal	<input checked="" type="checkbox"/> Non Fatal
Other	<input checked="" type="checkbox"/> Serious	<input checked="" type="checkbox"/> Non Serious	<input checked="" type="checkbox"/> Listed	<input checked="" type="checkbox"/> Non Listed	<input checked="" type="checkbox"/> Related	<input checked="" type="checkbox"/> Non Related	<input checked="" type="checkbox"/> Fatal	<input checked="" type="checkbox"/> Non Fatal

Activesubstance MAXACTIVEING_002;
 Trade Name ALL
 Type of Report NORMAL

Case Number	Country Source	Age Sex	Daily Dose [Dose Frequency]	Form / Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
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Body System: Psychiatric disorders No. of cases for this body system: 1

– Sexual dysfunctions, disturbances and gender identity disorders

IT-Max Application s.r.l.-2010	ITALY Sp	44 Y Male	1 Mg [1 Mg]	Tablet / Po	01-MAR-1999 to 20-MAR-1999 20 Day	02-MAR-1999 Onset after therapy initiation: 21 Day 04-MAR-1999	[Anorgasmia] N / Y / Y [Tension headache] N / N /	unknown unknown
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Initial Receipt Date: 31-MAR-1999
 Serious/Listed/Related/Fatal: Case Serious: NO. Case Unlisted: YES.

Comments:

Body System: Nervous system disorders No. of cases for this body system: 1

– Headaches

IT-Max Application s.r.l.-2010MAX0000147 [Tension headache] (Case is listed under: Psychiatric disorders -- Sexual dysfunctions, disturbances and gender identity disorders)

Body System: Ear and labyrinth disorders No. of cases for this body system: 1

– Inner ear and VIIIth cranial nerve disorders

2010MAX0000188	ITALY Sp	65 Y Male	20 Mg [1 dosage 20 Mg 1 time per Day] 15 Mg [15 Mg]	Tablet /	01-DEC-1999 to 05-DEC-1999 5 Day	06-DEC-1999	[Vertigo] N / N / Y	recovered/resolved
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Initial Receipt Date: 31-DEC-1999
 Serious/Listed/Related/Fatal: Case Serious: NO. Case Unlisted: NO.

Comments:

Body System: Cardiac disorders No. of cases for this body system: 1

– Coronary artery disorders

Case Number	Country Source	Age Sex	Daily Dose [Dose Frequency]	Form / Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
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2010MAX0000039	ITALY Study	48 Y Male	80 Mg [2 dosages 80 Mg / Po 1 time per Day]		19-MAR-1997 to 15-JUL-1997 16 Week	15-JUL-1997 Onset after therapy initiation: 17 Week	[Myocardial infarction] Y / N / N	recovered/resolved
Initial Receipt Date:			19-AUG-1997					
Serious/Listed/Related/Fatal:			Case Serious: YES. Case Unlisted: NO.					

Comments:

Body System: Vascular disorders	No. of cases for this body system: 1
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- Vascular haemorrhagic disorders

2010MAX0000197	ITALY Sp	78 Y Female	20 ##### [1 dosage 20 Mg 1 time per Day]	Tablet / Po	01-FEB-2000 to 01-MAR-2000 30 Day	01-MAR-2000 Onset after therapy initiation: 30 Day 01-MAR-2000 Onset after therapy initiation: 30 Day	[Henoch-Schonlein purpura] N / Y / Y [Ecchymosis] N / Y / Y	not recovered/not resolved not recovered/not resolved
Initial Receipt Date:			01-MAR-2000					
Serious/Listed/Related/Fatal:			Case Serious: NO. Case Unlisted: YES.					

Comments:

Body System: Respiratory, thoracic and mediastinal disorders	No. of cases for this body system: 5
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- Bronchial disorders (excl neoplasms)

IT-Max Application s.r.l.-7890	ITALY Study	24 Y Male	80 Mg [2 dosages 80 Mg / Po 1 time per Day]		26-MAR-1997 to 07-OCT-1997 27 Week	13-OCT-1997 Onset after therapy initiation: 29 Week	[Asthma] Y / Y / N	recovered/resolved
Initial Receipt Date:			14-OCT-1997					
Serious/Listed/Related/Fatal:			Case Serious: YES. Case Unlisted: YES.					

Comments:

2010MAX0000005	ITALY Study	20 Y	160 Mg	/ Po	13-JUN-1996 to Unknow n	14-DEC-1996 Onset after therapy	[Asthma] Y / / N	recovered/resolved
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Case Number	Country Source	Age Sex	Daily Dose [Dose Frequency]	Form / Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
		Female				initiation: 26 Week		
		Initial Receipt Date:	06-FEB-1997					
		Serious/Listed/Related/Fatal:	Case Serious: YES. Case Unlisted: NO.					
Comments:								
2010MAX0000006	ITALY Study	20 Y Female	160 Mg	/ Po	13-JUN-1996 to 12-FEB-1997 8 Month	12-FEB-1997 Onset after therapy initiation: 8 Month	[Asthma] Y / / N	not recovered/not resolved
		Initial Receipt Date:	20-FEB-1997					
		Serious/Listed/Related/Fatal:	Case Serious: YES. Case Unlisted: NO.					
Comments:								
2010MAX0000014	ITALY Study	42 Y Female	160 Mg	/ Po	26-JUN-1996 to 05-FEB-1997 7 Month	06-FEB-1997 Onset after therapy initiation: 7 Month	[Asthma] Y / N / N	recovered/resolved
		Initial Receipt Date:	12-MAY-1997					
		Serious/Listed/Related/Fatal:	Case Serious: YES. Case Unlisted: NO.					
Comments:								
2010MAX0000023	ITALY Study	69 Y Male	160 Mg [1 dosage 160 Mg 1 time per Day]	/ Po	24-MAY-1996 to Unknow n	04-MAY-1997 Onset after therapy initiation: 11 Month	[Asthma] Y / Y / N	not recovered/not resolved
		Initial Receipt Date:	06-MAY-1997					
		Serious/Listed/Related/Fatal:	Case Serious: YES. Case Unlisted: YES.					
Comments:								
Body System: Gastrointestinal disorders							No. of cases for this body system: 1	
- Tongue conditions								
2010MAX0000199	ITALY Sp	57 Y Male	20 Mg [1 dosage 20 Mg 1 time per Day]	Tablet / Po	07-JUN-1999 to 09-JUL-1999 33 Day	01-JUL-1999 Onset after therapy	[Dysgeusia] N / Y /	fatal

Case Number	Country Source	Age Sex	Daily Dose [Dose Frequency]	Form / Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
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initiation: 25 Day

Initial Receipt Date: 10-OCT-2010

Serious/Listed/Related/Fatal: Case Serious: YES. Case Unlisted: YES.

Comments:

Body System: Skin and subcutaneous tissue disorders	No. of cases for this body system: 1
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– Skin vascular abnormalities

2010MAX0000197 [Ecchymosis] (Case is listed under: Vascular disorders -- Vascular haemorrhagic disorders)

Body System: Musculoskeletal and connective tissue disorders	No. of cases for this body system: 2
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– Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)

2010MAX0000009	ITALY	43 Y		/ Po	07-JAN-1997 to Unknow n	24-JAN-1997	[Intervertebral disc protrusion]	not recovered/hot resolved
	Study	Female				Onset after therapy initiation: 17 Day	Y / / N	
						24-JAN-1997	[Back pain]	recovered/resolved
						Onset after therapy initiation: 17 Day	N / / N	

Initial Receipt Date: 10-MAR-1997

Serious/Listed/Related/Fatal: Case Serious: YES. Case Unlisted: NO.

Comments:

– Musculoskeletal and connective tissue disorders NEC

2010MAX0000009 [Back pain] (Case is listed under: Musculoskeletal and connective tissue disorders -- Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders))

Total number of cases entries printed: 14

Total number of cases: 11

Error(s) legend.	
Case:	
IT-Max Application s.r.l.-	Missing dosage unit(s)
2010MAX0000197	