Supplementary material

Contents

Chapter 1. Details about reported adverse drug reactions of ibuprofen

Table 1 Year when ADRs of ibuprofen were reported

Year	n (%)
2007	3 (3.3)
2008	4 (4.4)
2009	8 (8.8)
2010	8 (8.8)
2011	10 (11)
2012	10 (11)
2013	23 (25)
2014	25 (27)

Table 2 Institution where ADRs of ibuprofen were reported

Institution	n (%)
Pharmacy	39 (43)
Hospital	11 (12)
Family medicine practice	10 (11)
Outpatient clinic	7 (7.7)
HALMED	2 (2.2)
Specialist pediatric clinic	1 (1.1)
Medical School	1 (1.1)
Emergency medicine department	1 (1.1)
Not described	19 (21)

HALMED=The Agency for Medicinal Products and Medical Devices of Croatia.

Table 3 Person reporting ADRs of ibuprofen

Person	n (%)
Pharmacist	44 (48)
Physician	36 (40)
Other healthcare workers	7 (7.7)
Patient or another non-health worker	3 (3.3)
Not described	1 (1.1)

Table 4 ADRs of ibuprofen on skin and mucosa

Type of ADR	n (%)
Urticaria	8 (4.1)
Angioedema	7 (3.6)
Swollen eyelids	7 (3.6)
Erythema	7 (3.6)
Rash	6 (3.1)
Itch	6 (3.1)
Lip edema	5 (2.5)
Face edema	4 (2)
Swollen tongue	4 (2)
Generalized itch	4 (2)
Maculopapular rash	4 (2)
Eye itch	3 (1.5)
Hyperhidrosis	2 (1)
Hypoesthesia	2 (1)
Oral mucosal blistering	2 (1)
Dermatosis	1 (0.5)
Chapped lips	1 (0.5)
Larynx edema	1 (0.5)
Eye edema	1 (0.5)
Paresthesias	1 (0.5)
Peripheral edema	1 (0.5)
Alopecia	1 (0.5)
Purpura	1 (0.5)
Joint edema	1 (0.5)
Erythematous rash	1 (0.5)
Generalized rash	1 (0.5)

Table 5 ADRs of ibuprofen in gastrointestinal system

Type of ADR	n (%)
Nausea	6 (3.1)
Upper abdominal pain	5 (2.5)
Abdominal pain	4 (2)
Diarrhea	4 (2)
Dyspepsia	3 (1.5)
Vomiting	3 (1.5)
Hematemesis	2 (1)
Melena	2 (1)
Hemorrhagic erosive gastritis	2 (1)
Bloating	2 (1)
Esophagitis	1 (0.5)
Hunger	1 (0.5)
Hematochezia	1 (0.5)
Hemorrhagic diarrhea	1 (0.5)
Duodenal ulcer bleeding	1 (0.5)
Upper gastrointestinal bleeding	1 (0.5)
Mouth discomfort	1 (0.5)
Dry mouth	1 (0.5)

Table 6 ADRs of ibuprofen in respiratory system

Type of ADR	n (%)
Suffocation feeling	4 (2)
Dyspnea	2 (1)
Asthma	1 (0.5)
Chest pain	1 (0.5)
Bronchostenosis	1 (0.5)
Runny nose	1 (0.5)
Sneezing	1 (0.5)
Chest discomfort	1 (0.5)
Nasal congestion	1 (0.5)
Lacrimation increased	1 (0.5)

Table 7 ADRs of ibuprofen in cardiovascular system

Type of ADR	n (%)
Hypertension	3 (1.5)
Hemorrhagic shock	2 (1)
Arterial blood pressure not measurable	1 (0.5)
Absent pulse	1 (0.5)
Tachycardia	1 (0.5)

Table 8 Other ADRs of ibuprofen

Type of ADR	n (%)
Hypersensitivity	4 (2)
Vertigo	3 (1.5)
Asthenia	3 (1.5)
Blurred vision	3 (1.5)
Myalgia	2 (1)
Headache	2 (1)
Anaphylaxis	2 (1)
Photopsya	2 (1)
Tingling	2 (1)
Hallucinations	1 (0.5)
Drowsiness	1 (0.5)
Body temperature decreased	1 (0.5)
Loss of consciousness	1 (0.5)
Tinnitus	1 (0.5)
Restlessness	1 (0.5)
Sedation	1 (0.5)
Amnesia	1 (0.5)
Abnormal vision	1 (0.5)
Tremor	1 (0.5)
Muscle spasm	1 (0.5)
Amenorrhea	1 (0.5)
Throat irritation	1 (0.5)
Paralysis	1 (0.5)
Aphasia	1 (0.5)
Foreign body feeling	1 (0.5)
Feeling disconnected	1 (0.5)
Nervousness	1 (0.5)

Chapter 2. Details about reported adverse drug reactions of diclofenac sodium

Table 9 Year when ADRs of diclofenac sodium were reported

Year	n (%)
2007	3 (3.6)
2008	5 (6)
2009	7 (8.4)
2010	10 (12)
2011	11 (13)
2012	13 (16)
2013	19 (23)
2014	15 (18)

Table 10 Person reporting ADRs of diclofenac sodium

Person	n (%)
Pharmacist	38 (46)
Physician	28 (34)
Other healthcare workers	9 (11)
Patient or another non-healthcare worker	7 (8.4)
Not described	1 (1.2)

Table 11 Institutions reporting ADRs of diclofenac sodium

Institution	n (%)
Pharmacy	38 (46)
Family medicine practice	16 (19)
Hospital	5 (6)
University hospital	5 (6)
Emergency medicine department	3 (3.6)
Outpatient clinic	2 (2.4)
University clinic	1 (1.2)

Table 12 Age group for which ADRs of diclofenac sodium were reported

Age group	n (%)
Adults	48 (58)
Elderly	20 (24)
Infants	4 (4.8)
Adolescents	1 (1.2)
Not described	10 (12)

Table 13 ADRs of diclofenac sodium observed on skin and mucosa

Type of ADR	n (%)
Edema	
Peripheral edema	5 (2.4)
Edema	4 (1.9)
Lip edema	3 (1.5)
Swollen tongue	3 (1.5)
Face edema	2 (1)
Eye edema	2 (1)
Angioedema	1 (0.5)
Mucosal edema	1 (0.5)
Periorbital edema	1 (0.5)
Erythema	
Erythema	8 (3.9)
Palm erythema	1(0.5)
Generalized erythema	1 (0.5)
Rash	
Generalized rash	2 (1)
Rash	2 (1)
Itchy rash	2 (1)
Macular rash	1 (0.5)
Pustulous rash	1 (0.5)
Other skin ADRs	
Urticaria	8 (3.9)
Itch	7 (0.5)
Allergic dermatitis	1 (0.5)
Skin exfoliation	1 (0.5)
Hyperhidrosis	1 (0.5)
Hematomas	1 (0.5)
Necrosis	1 (0.5)
Stomatitis	1 (0.5)
Dry skin	1 (0.5)
Dry throat	1 (0.5)

Table 14 ADRs of diclofenac sodium observed in gastrointestinal system

Type of ADR	n (%)
Nausea	6 (2.9)
Upper abdominal pain	5 (2.4)
Abdominal pain	5 (2.4)
Diarrhea	3 (1.5)
Vomiting	3 (1.5)
Dyspepsia	2 (1)
Hematemesis	2 (1)
Ageusia	1 (0.5)
Epigastric discomfort	1 (0.5)
Feces color loss	1 (0.5)
Sudden defecation	1 (0.5)
Stomach upset	1 (0.5)
Appetite disturbance	1 (0.5)
Abdominal pain	1 (0.5)
Loss of appetite	1 (0.5)
Intestinal bleeding + Hematochezia	1 + 4 (2.4)
Bleeding in gastrointestinal system	1 (0.5)
Bleeding of the upper gastrointestinal system + melena + stomach bleeding	5 + 1 + 1 (3.4)

Table 15 ADRs of diclofenac sodium in respiratory system

Type of ADR	n (%)
Suffocation feeling	7 (3.4)
Dyspnea	5 (2.4)
Chest discomfort	2 (1)
Cough	1 (0.5)
Asthma	1 (0.5)

Table 16 ADRs of diclofenac sodium in cardiovascular system

Type of ADR	n (%)
Increased blood pressure	3 (1.5)
Hypotension	2 (1)
Tachycardia	2 (1)
Extrasystole	1 (0.5)
Palpitations	1 (0.5)
Increased heart rate	1 (0.5)
Agranulocytosis	1 (0.5)
Hypertension	1 (0.5)

Table 17 ADRs of diclofenac sodium in the eye

Type of ADR	n (%)
Ocular hyperemia	3 (1.5)
Eye irritation	1 (0.5)
Painful eye	1 (0.5)
Blurred vision	1 (0.5)
Loss of vision	1 (0.5)
Dry eye	1 (0.5)

Table 18 ADRs of diclofenac sodium in the urinary system

Type of ADR	n (%)
Urinary system infection	1 (0.5)
Nephritis	1 (0.5)
Nephrotic syndrome	1 (0.5)
Oliguria	1 (0.5)
Decreased frequency of urination	1 (0.5)
Kidney failure	1 (0.5)
Blood in urine	1 (0.5)

Table 19 Other ADRs of diclofenac sodium

Type of ADR	n (%)
Vertigo	5 (2.4)
Hypersensitivity	4 (1.9)
Fever	3 (1.5)
Syncope	2 (1)
Weakness	2 (1)
Tinnitus	2 (1)
Tingling	2 (1)
Headache	2 (1)
Pain	2 (1)
Anaphylaxis	1 (0.5)
Asthenia	1 (0.5)
Depression	1 (0.5)
Flu	1 (0.5)
Loss of consciousness	1 (0.5)
Hemorrhoids	1 (0.5)
Hypoesthesia	1 (0.5)
Hypothermia	1 (0.5)
Cold sweat	1 (0.5)
Heat wave	1 (0.5)
Paresthesias	1 (0.5)
Increased body temperature	1 (0.5)
Slow response time	1 (0.5)
Inertia	1 (0.5)

Chapter 3. Details about reported adverse drug reactions of tramadol/paracetamol combination

Table 20 Year when ADRs of tramadol/paracetamol were reported

Year	n (%)
2007	0
2008	0
2009	1 (1.7)
2010	11 (19)
2011	1 (1.7)
2012	10 (17)
2013	14 (24)
2014	22 (37)

Table 21 Person reporting ADRs of tramadol/paracetamol

Person	n (%)
Pharmacist	38 (64)
Physician	18 (30)
Other healthcare workers	2 (3.4)
Patient or another non-healthcare worker	1 (1.7)

Table 22 Institutions reporting ADRs of tramadol/paracetamol

Institution	n (%)
Pharmacy	35 (59)
Family medicine practice	8 (14)
Outpatient clinic	3 (5.1)
Hospital	2 (3.4)
Specialized shop	1 (1.7)
Psychiatric clinic	1 (1.7)
Not described	8 (14)

Table 23 ADRs of tramadol/paracetamol in gastrointestinal system

Type of ADR	n (%)
Nausea	22 (13)
Vomiting	14 (8)
Upper abdominal pain	5 (2.9)
Diarrhea	3 (1.7)
Loss of appetite	2 (1.1)
Pain in gastrointestinal system	2 (1.1)
Abdominal pain	2 (1.1)

Dyspepsia	1 (0.6)
Epigastric discomfort	1 (0.6)
Dysphagia	1 (0.6)
Bloating	2 (1.1)
Disturbed gastrointestinal motility	1 (0.6)
Vomiting attempt	1 (0.6)
Thirst	1 (0.6)

Table 24 ADRs of tramadol/paracetamol in neurological system

Type of ADR	n (%)
Vertigo	14 (8)
Ataxia	3 (1.7)
Paresthesias	2 (1.1)
Balance disorder	2 (1.1)
Tingling	2 (1.1)
Oral hypoesthesia	2 (1.1)
Tremor	1 (0.6)
Coordination disorder	1 (0.6)
Impaired memory	1 (0.6)
Amnesia	1 (0.6)
Loss of consciousness	1 (0.6)

Table 25 ADRs of tramadol/paracetamol affecting general condition of a patient

Type of ADR	n (%)
Drowsiness	8 (4.6)
Asthenia	7 (4)
Abnormal feeling	3 (1.7)
Disoriented	3 (1.7)
Tiredness	2 (1.1)
Muscle weakness	2 (1.1)
Hypersomnia	2 (1.1)
Inertia	1 (0.6)
Uneasiness	1 (0.6)
Weakness	1 (0.6)
Feeling drunk	1 (0.6)
Decreased level of consciousness	1 (0.6)

Table 26 ADRs of tramadol/paracetamol affecting mental health

Type of ADR	n (%)
Confusion	3 (1.7)
Agitation	2 (1.1)
Restlessness	2 (1.1)
Euphoria	1 (0.6)
Insomnia	1 (0.6)
Nightmares	1 (0.6)
Abnormal behavior	1 (0.6)
Irritability	1 (0.6)
Crying	1 (0.6)
Mood changes	1 (0.6)
Attention disorder	1(0.6)

Table 27 ADRs of tramadol/paracetamol affecting skin and mucosa

Type of ADR	n (%)
Hyperhidrosis	5 (2.9)
Itch	3 (1.7)
Skin burning	1 (0.6)
Maculopapular rash	1 (0.6)
Urticaria	1 (0.6)
Rash	1 (0.6)
Dry mouth	1 (0.6)

Table 28 Other ADRs of tramadol/paracetamol

Type of ADR	n (%)
Vision impairment	4 (2.3)
Headache	4 (2.3)
Dyspnea	3 (1.7)
Heat wave	2 (1.1)
Transient ischemic attack	1 (0.6)
Dysuria	1 (0.6)
Hypoacusia	1 (0.6)
Tachycardia	1 (0.6)
Chest discomfort	1 (0.6)
Weight loss	1 (0.6)
Palpitations	1 (0.6)
Pain	1 (0.6)
Dry mouth	1 (0.6)
Hiccups	1 (0.6)
Tinnitus	1 (0.6)
Urination disorder	1 (0.6)
Myalgia	1 (0.6)
Asthma	1 (0.6)
Increased systolic blood pressure	1 (0.6)

Chapter 4. Details about reported adverse drug reactions of acetylsalicylic acid (ASA)

Table 29 Year when ADRs of ASA were reported

Year	n (%)
2007	7 (12)
2008	0
2009	7 (12)
2010	5 (8.8)
2011	6 (10)
2012	10 (17)
2013	10 (17)
2014	12 (21)

Table 30 Institutions reporting ADRs of ASA

Institution	n (%)
Pharmacy	23 (40)
Hospital	11 (19)
Family medicine practice	5 (8.8)
Outpatient clinic	1 (1.7)
Dermatologic clinic	1 (1.7)
Not described	15 (26)

Table 31 ADRs of ASA reported on skin and mucosa

Type of ADR	n (%)
Urticaria	6 (5.2)
Itch	6 (5.2)
Rash	5 (4.3)
Erythema	3 (2.6)
Hematoma	3 (2.6)
Angioedema	3 (2.6)
Gum bleeding	2 (1.7)
Blisters	2 (1.7)
Aphthous stomatitis	1 (0.9)
Dermatitis	1 (0.9)
Swollen tongue	1 (0.9)
Lip edema	1 (0.9)
Generalized erythema	1 (0.9)
Generalized itch	1 (0.9)
Hyperhidrosis	1 (0.9)
Peripheral edema	1 (0.9)

Table 32 ADRs of ASA in gastrointestinal system

Type of ADR	n (%)
Gastrointestinal system bleeding	6 (5.2)
Erosive gastritis	4 (3.4)
Melena	3 (2.6)
Bleeding duodenal ulcer	2 (1.7)
Nausea	2 (1.7)
Vomiting	2 (1.7)
Gastric acid increased	1 (0.9)
Bloating	1 (0.9)
Feces color loss	1 (0.9)
Erosive esophagitis	1 (0.9)
Dysphagia	1 (0.9)
Diarrhea	1 (0.9)
Colon hematoma	1 (0.9)

Table 33 ADRs of ASA in respiratory system

Type of ADR	n (%)
Suffocation feeling	4 (3.4)
Dyspnea	3 (2.6)
Asthma	2 (1.7)
Runny nose	1 (0.9)
Chest discomfort	1 (0.9)

Table 34 Other reported ADRs of ASA

Type of ADR	n (%)
Injury	4 (3.4)
Nose bleeding	4 (3.4)
Eye bleeding	3 (2.6)
Vertigo	3 (2.6)
Headache	2 (1.7)
Hypersensitivity	2 (1.7)
Anaphylactic shock	1 (0.9)
Anemia	1 (0.9)
Asthenia	1 (0.9)
Pain	1 (0.9)
Kidney pain	1 (0.9)
Disoriented	1 (0.9)
Blood in urine	1 (0.9)
Hemorrhagic diathesis	1 (0.9)
Sneezing	1 (0.9)
Off-label use	1 (0.9)
Hemorrhoid bleeding	1 (0.9)

Heat wave	1 (0.9)
Vision impairment	1 (0.9)
Increased blood pressure	1 (0.9)
Gait disorder	1 (0.9)
Syncope	1 (0.9)
Tachycardia	1 (0.9)
Stiffness	1 (0.9)
Fatigue	1 (0.9)
Vaginal bleeding	1 (0.9)

Chapter 5. Details about reported adverse drug reactions of tramadol

Table 35 Year when ADRs of tramadol were reported

Year	n (%)
2007	9 (16)
2008	7 (13)
2009	7 (13)
2010	5 (9.1)
2011	10 (18)
2012	6 (11)
2013	7 (13)
2014	4 (7.3)

Table 36 Persons reporting ADRs of tramadol

Person	n (%)
Healthcare worker	36 (65)
Others	2 (3.6)
Pharmaceutical company	1 (1.8)
Not described	16 (29)

Table 37 Institutions reporting ADRs of tramadol

Institution	n (%)
Family medicine practice	23 (42)
Pharmacy	21 (38)
Hospital	3 (5.4)
Outpatient clinic	3 (5.4)
Not described	5 (9.1)

Table 38 ADRs of tramadol reported in gastrointestinal system

Type of ADR	n (%)
Nausea	19 (11)
Vomiting	15 (8.9)
Diarrhea	3 (1.8)
Constipation	3 (1.8)
Bloating	3 (1.8)
Upper abdominal pain	2 (1.2)
Loss of appetite	2 (1.2)
Dyspepsia	1 (0.6)
Dysgeusia	1 (0.6)
Abdominal discomfort	1 (0.6)
Hematochezia	1 (0.6)

Table 39 ADRs of tramadol reported on skin and mucosa

Type of ADR	n (%)
Erythema	7 (4.1)
Hyperhidrosis	4 (2.4)
Itch	2 (1.2)
Urticaria	2 (1.2)
Dry mouth	2 (1.2)
Rash	2 (1.2)
Burning skin	1 (0.6)
Maculopapular rash	1 (0.6)
Hematoma	1 (0.6)

Table 40 ADRs of tramadol in nervous system

Type of ADR	n (%)
Vertigo	10 (5.9)
Paresthesias	1 (0.6)
Hypoesthesia	1 (0.6)
Hypomimia	1 (0.6)
Coordination disorder	1 (0.6)
Dyskinesia	1 (0.6)
Musculoskeletal rigidity	1 (0.6)
Slow response time	1 (0.6)
Ataxia	1 (0.6)
Gait disorder	1 (0.6)
Epilepsy	1 (0.6)
Inability to walk	1 (0.6)
Loss of consciousness	1 (0.6)
Amnesia	1 (0.6)
Fever	1 (0.6)
Hypothermia	1 (0.6)

Table 41 ADRs of tramadol reported in cardiovascular system

Type of ADR	n (%)
Palpitations	4 (2.4)
Hypertension	1 (0.6)
Bradycardia	1 (0.6)
Increased blood pressure	1 (0.6)
Fluctuating blood pressure	1 (0.6)
Hypotension	1 (0.6)

Table 42 ADRs of tramadol affecting general condition of a patient

Type of ADR	n (%)
Lightheadedness	13 (7.7)
Asthenia	9 (5.3)
Drowsiness	5 (2.9)
Insomnia	4 (2.4)
Fatigue	2 (1.2)
Abnormal feeling	1 (0.6)

Table 43 ADRs of tramadol affecting psychological condition of a patient

Type of ADR	n (%)
Hypomania	1 (0.6)
Sleeping attacks	1 (0.6)
Confusion	1 (0.6)

Table 44 Other reported ADRs of tramadol

Type of ADR	n (%)
Dysuria	2 (1.9)
Headache	2 (1.9)
Hiccups	2 (1.9)
Urinary retention	2 (1.9)
Increased level of a drug	1 (0.6)
Brain edema	1 (0.6)
Syncope	1 (0.6)
Tinnitus	1 (0.6)
Strained muscle	1 (0.6)
Erectile dysfunction	1 (0.6)
Pulmonary edema	1 (0.6)
Musculoskeletal pain	1 (0.6)
Dyspnea	1 (0.6)
Toxicity	1 (0.6)
Uneasy feeling in the head	1 (0.6)
Urinary hesitation	1 (0.6)
Contusion	1 (0.6)
Paleness	1 (0.6)
Heat wave	1 (0.6)

Chapter 6: Details about reported adverse drug reactions of ketoprofen

Table 45 Year when ADRs of ketoprofen were reported

Year	n (%)
2007	3 (6.1)
2008	3 (6.1)
2009	3 (6.1)
2010	7 (14)
2011	7 (14)
2012	9 (18)
2013	8 (16)
2014	9 (18)

Table 46 Persons reporting ADRs of ketoprofen

Person	n (%)
Pharmacist	23 (47)
Physician	21 (43)
Patient or non-healthcare worker	3 (6.1)
Other healthcare workers	1 (2)
Not described	1 (2)

Table 47 Institutions reporting ADRs of ketoprofen

Institution	n (%)
Pharmacy	21 (43)
Family medicine practice	8 (16)
Hospital	5 (10)
Outpatient clinic	4 (8.2)
Medical school clinic	1 (2)
HALMED	1 (2)
Not described	9 (18)

HALMED=The Agency for Medicinal Products and Medical Devices of Croatia.

Table 48 ADRs of ketoprofen on skin and mucosa

Type of ADR	n (%)
Erythema	11 (8.7)
Itch	7 (5.5)
Rash	6 (4.8)
Urticaria	5 (4)
Swollen eyelids	4 (3.2)
Lip edema	4 (3.2)
Angioedema	3 (2.4)
Blister	2 (1.6)
Dermatitis at the application point	1 (0.8)
Face edema	1 (0.8)
Edema at the application point	1 (0.8)
Photosensitivity	1 (0.8)
Papules at the application point	1 (0.8)
Peripheral edema	1 (0.8)
Purpura	1 (0.8)
Dry tongue	1 (0.8)
Blisters at the application point	1 (0.8)
Larynx edema	1 (0.8)
Dermatitis bullosa	1 (0.8)
Hematoma	1 (0.8)

Table 49 ADRs of ketoprofen in gastrointestinal system

Type of ADR	n (%)
Upper abdominal pain	5 (4)
Abdominal pain	3 (2.4)
Diarrhea	2 (1.6)
Dyspepsia	2 (1.6)
Nausea	2 (1.6)
Gastritis	2 (1.6)
Hematochezia	2 (1.6)
Vomiting	1 (0.8)
Rectal bleeding	1 (0.8)
Bloating	1 (0.8)
Dysphagia	1 (0.8)
Bleeding from gastrointestinal system	1 (0.8)
Feces color loss	1 (0.8)
Hematemesis	1 (0.8)
Duodenal ulcer	1 (0.8)
Hemorrhagic enterocolitis	1 (0.8)
Constipation	1 (0.8)

Table 50 ADRs of ketoprofen in cardiovascular system

Type of ADR	n (%)
Palpitations	2 (1.6)
Anemia	2 (1.6)
Angina pectoris	1 (0.8)
Hypertension	1 (0.8)
Myocardial infarction	1 (0.8)
Lower blood pressure	1 (0.8)

Table 51 Other reported ADRs of ketoprofen

Type of ADR	n (%)
Overdose	3 (2.4)
Hypersensitivity	3 (2.4)
Dyspnea	3 (2.4)
Pain at the location of infusion	2 (1.6)
Drowsiness	1 (0.8)
Aphonia	1 (0.8)
Tubulointerstitial nephritis	1 (0.8)
Acute kidney failure	1 (0.8)
Eye edema	1 (0.8)
Arthralgia	1 (0.8)
Asphyxia	1 (0.8)
Osteoarthritis	1 (0.8)
Paresthesias	1 (0.8)
Syncope	1 (0.8)
Throat squeezing	1 (0.8)
Eye itch	1 (0.8)
Headache	1 (0.8)
Chest pain	1 (0.8)
Insomnia	1 (0.8)
Heat wave	1 (0.8)
Loss of control in legs	1 (0.8)
Lightheadedness	1 (0.8)
Suffocation feeling	1 (0.8)
Cyst	1 (0.8)
Weakness	1 (0.8)
Spinal pain	1 (0.8)
Conjunctivitis	1 (0.8)
Off-label use	1 (0.8)

Chapter 7: Details about reported adverse drug reactions of fentanyl

Table 52.Year when ADRs of fentanyl were reported

Year	n (%)
2007	4 (9.1)
2008	2 (4.5)
2009	32 (73)
2010	0
2011	2 (4.5)
2012	3 (6.8)
2013	0
2014	1 (2.3)

Table 53 Persons reporting ADRs of fentanyl

Person	n (%)
Not described	35 (79)
Physician	5 (11)
Pharmacist	3 (6.8)
Other healthcare workers	1 (2.3)

Table 54 Institutions reporting ADRs of fentanyl

Institution	n (%)
Not described	36 (82)
Pharmacy	3 (6.8)
Family medicine practice	2 (4.5)
Hospital	1 (2.3)
Takeda Pharmaceuticals Croatia (company importing medications)	1 (2.3)
HALMED	1 (2.3)

HALMED=The Agency for Medicinal Products and Medical Devices of Croatia.

Table 55 ADRs of fentanyl in gastrointestinal system

Type of ADR	n (%)
Vomiting	3 (4)
Nausea	3 (4)
Melena	1 (1.3)
Loss of appetite	1 (1.3)
Upper abdominal pain	1 (1.3)

Table 56 ADRs of fentanyl affecting mental health of a patient

Type of ADR	n (%)
Psychomotor hyperactivity	1 (1.3)
Hypomania	1 (1.3)
Hallucinations	1 (1.3)
Aggression	1 (1.3)
Mania	1 (1.3)
Abnormal behavior	1 (1.3)
Agitation	1 (1.3)

Table 57 ADRs of fentanyl affecting general condition of a patient

Type of ADR	n (%)
Lightheadedness	2 (2.7)
Inertia	1 (1.3)
Weight loss	1 (1.3)
Worsening of a primary disease	1 (1.3)
Drowsiness	1 (1.3)
Asthenia	1 (1.3)
Dehydration	1 (1.3)
Disorientation	1 (1.3)
Insomnia	1 (1.3)

Table 58 Other reported ADRs of fentanyl

Type of ADR	n (%)
Peripheral edema	4 (5.4)
Hematoma	2 (2.7)
Syncope	1 (1.3)
Cachexia	1 (1.3)
Toxicity	1 (1.3)
Bradycardia	1 (1.3)
Hypotension	1 (1.3)
AV block	1 (1.3)

Chapter 8: Details about reported adverse drug reactions of paracetamol

Table 59 Year when ADRs of paracetamol were reported

Year	n (%)
2007	7 (26)
2008	0
2009	0

2010	7 (26)
2011	3 (11)
2012	2 (7.4)
2013	4 (15)
2014	4 (15)

Table 60 Persons reporting ADRs of paracetamol

Person	n (%)
Pharmacist	15 (56)
Physician	10 (37)
Patient or non-healthcare worker	1 (3.7)
Not described	1 (3.7)

Table 61 Institutions reporting ADRs of paracetamol

Institution	n (%)
Pharmacy	13 (48)
Emergency medicine department	2 (7.4)
Hospital	2 (7.4)
Family medicine practice	2 (7.4)
Pediatric clinic	1 (3.7)
Not described	7 (26)

Table 62 ADRs of paracetamol reported on skin and mucosa

Type of ADR	n (%)
Rash	8 (13)
Urticaria	6 (9.7)
Generalized rash	3 (4.8)
Erythema	3 (4.8)
Itch	3 (4.8)
Face edema	2 (3.2)
Swollen eyelids	2 (3.2)
Eyelid erythema	1 (1.6)
Generalized erythema	1 (1.6)
Maculopapular rash	1 (1.6)
Generalized pustular rash	1 (1.6)
Generalized itch	1 (1.6)
Macular rash	1 (1.6)
Abnormal result of skin biopsy	1 (1.6)
Skin color loss	1 (1.6)
Larynx edema	1 (1.6)
Skin burning	1 (1.6)
Skin disorder	1 (1.6)

Table 63 ADRs of paracetamol reported in gastrointestinal system

Type of ADR	n (%)
Nausea	3 (4.8)
Dyspepsia	2 (3.2)
Dysphagia	1 (1.6)
Diarrhea	1 (1.6)
Upper abdominal pain	1 (1.6)
Vomiting urge	1 (1.6)
Abdominal pain	1 (1.6)

Table 64 Other reported ADRs of paracetamol

Type of ADR	n (%)
Oral paresthesia	2 (3.2)
Lymphadenopathy	1 (1.6)
Hypersensitivity	1 (1.6)
Increased lacrimation	1 (1.6)
Leukocytosis	1 (1.6)
Ineffective medication	1 (1.6)
Paresthesias	1 (1.6)
Liver damage	1 (1.6)
Death	1 (1.6)
Overdose	1 (1.6)
Pain	1 (1.6)
Suffocation feeling	1 (1.6)
Hallucinations	1 (1.6)

Chapter 9: Details about reported adverse drug reactions of dexketoprofen trometamol (DKT)

Table 65 Institutions reporting ADRs of DKT

Institution	n (%)
Family medicine practice	3 (11)
Pharmacy	2 (7.7)
Hospital	1 (3.8)
Outpatient clinic	1 (3.8)
Not described	19 (73)

Table 66 ADRs of DKT reported in gastrointestinal system

Type of ADR	n (%)
Upper abdominal pain	7 (15)
Nausea	5 (11)
Abdominal pain	1 (2.2)
Gastric ulcer bleeding	1 (2.2)
Vomiting	1 (2.2)
Hematemesis	1 (2.2)

Table 67 ADRs of DKT reported in skin and mucosa

Type of ADR	n (%)
Erythema	3 (6.7)
Face edema	2 (4.4)
Lip edema	2 (4.4)
Peripheral edema	1 (2.2)
Larynx edema	1 (2.2)
Angioedema	1 (2.2)
Joint edema	1 (2.2)
Generalized itch	1 (2.2)
Urticaria	1 (2.2)
Burning of a skin	1 (2.2)
Hematoma	1 (2.2)

Table 68 ADRs of DKT in respiratory system

Type of ADR	n (%)
Cough	2 (4.4)
Asthma	1 (2.2)
Chest discomfort	1 (2.2)
Epistaxis	1 (2.2)
Dyspnea	1 (2.2)

Chapter 10: Details about reported adverse drug reactions of meloxicam

Table 69 Year when ADRs of meloxicam were reported

Year	n (%)
2007	0
2008	4 (21)
2009	4 (21)
2010	0
2011	1 (5.3)
2012	3 (16)
2013	2 (10)
2014	5 (26)

Table 70 Institutions reporting ADRs of meloxicam

Institution	n (%)
Family medicine practice	6 (32)
Pharmacy	5 (26)
Outpatient clinic	4 (21)
Hospital	3 (16)
Not described	1 (5.3)

Table 71 ADRs of meloxicam reported on skin and mucosa

Type of ADR	n (%)
Erythema	3 (6.5)
Itch	2 (4.3)
Lip edema	2 (4.3)
Hyperkeratosis	1 (2.2)
Hyperhidrosis	1 (2.2)
Itchy rash	1 (2.2)
Dry lips	1 (2.2)
Swollen eyelids	1 (2.2)
Maculopapular rash	1 (2.2)
Skin burning	1 (2.2)

Table 72 ADRs of meloxicam in gastrointestinal system

Type of ADR	n (%)
Constipation	4 (8.7)
Hematochezia	2 (4.3)
Abdominal pain	1 (2.2)
Feces color loss	1 (2.2)
Nausea	1 (2.2)
Bloating	1 (2.2)

Table 73 Other ADRs of meloxicam

Type of ADR	n (%)
Chest discomfort	2 (4.3)
Eye edema	2 (4.3)
Paresthesias	2 (4.3)
Increased blood pressure	2 (4.3)
Memory impairment	2 (4.3)
Headache	2 (4.3)
Tingling	2 (4.3)
Off-label use	2 (4.3)
Tachycardia	1 (2.2)
Thrombocytopenia	1 (2.2)

Overdose	1 (2.2)
Eye discomfort	1 (2.2)
Oral paresthesia	1 (2.2)
Dyspnea	1 (2.2)

Chapter 11: Details about reported adverse drug reactions of a combination of Caffeine/paracetamol/propyphenazone/codeine phosphate sesquihydrate (CPPC)

Table 74 Year when ADRs of CPPC combination were reported

Year	n (%)
2007	1 (7.7)
2008	1 (7.7)
2009	0
2010	2 (15)
2011	5 (38)
2012	2 (15)
2013	1 (7.7)
2014	1 (7.7)

Table 75 Institutions reporting ADRs of CPPC combination

Institution	n (%)
Pharmacy	5 (38)
Hospital	2 (15)
HALMED	2 (15)
Family medicine practice	2 (15)
Specialized shop	1 (7.7)
Emergency medicine department	1 (7.7)

HALMED=The Agency for Medicinal Products and Medical Devices of Croatia.

Table 76 ADRs of CPPC combination reported on skin and mucosa

Type of ADR	n (%)
Itch	5 (16)
Urticaria	2 (6.2)
Erythema	2 (6.2)
Angioedema	2 (6.2)
Lip edema	2 (6.2)
Maculopapular rash	1 (3.1)
Eye edema	1 (3.1)
Tongue itch	1 (3.1)
Generalized itch	1 (3.1)
Burning of skin	1 (3.1)
Allergic dermatitis	1 (3.1)
Localized edema	1 (3.1)

Table 77 Other reported ADRs of CPPC combination

Type of ADR	n (%)
Addiction	2 (6.2)
Misuse	2 (6.2)
Hypersensitivity	1 (3.1)
Gastroesophageal reflux	1 (3.1)
Hypertension	1 (3.1)
Anaphylaxis	1 (3.1)
Headache	1 (3.1)
Dyspnea	1 (3.1)
Suffocation feeling	1 (3.1)
Sneezing	1 (3.1)

Chapter 12: Details about reported adverse drug reactions of diclofenac potassium

Table 78 Year when ADRs of diclofenac potassium were reported

Year	n (%)
2007	1 (8.3)
2008	1 (8.3)
2009	3 (25)
2010	4 (33)
2011	3 (25)

Table 79 Institutions reporting ADRs of diclofenac potassium

Institution	n (%)
Pharmacy	8 (67)
Hospital	3 (25)
Family medicine practice	1 (8.3)

Table 80 ADRs of diclofenac potassium reported in skin and mucosa

Type of ADR	n (%)
Rash	4 (13)
Itch	4 (13)
Erythema	3 (9.7)
Urticaria	2 (6.4)
Swollen tongue	1 (3.2)
Face edema	1 (3.2)
Stevens-Johnson's syndrome	1 (3.2)

Table 81 ADRs of diclofenac potassium reported in gastrointestinal system

Type of ADR	n (%)
Hematochezia	2 (6.4)
Dysphagia	1 (3.2)
Diarrhea	1 (3.2)
Dyspepsia	1 (3.2)
Gastric ulcer	1 (3.2)
Upper abdominal pain	1 (3.2)

Table 82 Other reported ADRs of diclofenac potassium

Type of ADR	n (%)
Lightheadedness	1 (3.2)
Oral paresthesia	1 (3.2)
Dyspnea	1 (3.2)
Blood in urine	1 (3.2)
Asphyxia	1 (3.2)
Syncope	1 (3.2)
Anaphylaxis	1 (3.2)
Loss of consciousness	1 (3.2)

Chapter 13: Details about reported adverse drug reactions of piroxicam

Table 83 Year when ADRs of piroxicam were reported

Year	n (%)
2007	2 (18)
2008	0
2009	2 (18)
2010	3 (27)
2011	1 (9)
2012	1 (9)
2013	1 (9)
2014	1 (9)

Table 84 Institutions reporting ADRs of piroxicam

Institution	n (%)
Pharmacy	6 (45)
General hospital clinic	2 (18)
Hospital	2 (18)
Outpatient clinic	1 (9)

Table 85 ADRs of piroxicam in gastrointestinal system

Type of ADR	n (%)
Dyspepsia	1 (3.1)
Diarrhea	1 (3.1)
Abdominal pain	1 (3.1)
Duodenal ulcer	1 (3.1)
Gastric ulcer	1 (3.1)
Gastrointestinal tract disturbance	1 (3.1)
Erosive gastritis	1 (3.1)
Upper abdominal pain	1 (3.1)
Melena	1 (3.1)

Table 86 ADRs of piroxicam reported on skin and mucosa

Type of ADR	n (%)
Erythema	3 (9.4)
Swollen eyelids	2 (6.2)
Skin hardening	1 (3.1)
Urticaria	1 (3.1)
Toxic epidermal necrolysis	1 (3.1)

Table 87 Other reported ADRs of piroxicam

Type of ADR	n (%)
Tinnitus	2 (6.2)
Dyspnea	2 (6.2)
Blurred vision	1 (3.1)
Palpitations	1 (3.1)
Changed consciousness	1 (3.1)
Tachypnea	1 (3.1)
Headache	1 (3.1)
Vertigo	1 (3.1)
Hemorrhagic anemia	1 (3.1)
Chest discomfort	1 (3.1)

Chapter 14: Details about reported adverse drug reactions of buprenorphine

Table 88 Reported ADRs of buprenorphine

Type of ADR	n (%)
Nausea	4 (17)
Vomiting	4 (17)
Itch	2 (8.3)
Erythema	2 (8.3)
Headache	2 (8.3)
Hypersensitivity	2 (8.3)
Fatigue	1 (4.2)
Hiccups	1 (4.2)
Gait disorder	1 (4.2)
Constipation	1 (4.2)
Inertia	1 (4.2)
Irritation	1 (4.2)

Chapter 15: Details about reported adverse drug reactions of a combination of acetylsalicylic acid and clopidogrel hydrogen sulfate

Table 89 Year when ADRs of combination of acetylsalicylic acid and clopidogrel hydrogen sulfate were reported

Type of ADR	n (%)
2010	3 (30)
2011	4 (40)
2012	0
2013	1 (10)
2014	2 (20)

Table 90 Blood clotting and bleeding ADRs reported for combination of acetylsalicylic acid and clopidogrel hydrogen sulfate

Type of ADR	n (%)
Subdural bleeding	2 (8.3)
Duodenal ulcer bleeding	2 (8.3)
Deep vein thrombosis	1 (4.2)
Hematochezia	1 (4.2)
Hematoma	1 (4.2)
Blood in urine	1 (4.2)
Hemoptysis	1 (4.2)
Thrombocytopenia	1 (4.2)
Hemorrhagic shock	1 (4.2)

Table 91 Other ADRs reported for combination of acetylsalicylic acid and clopidogrel hydrogen sulfate

Type of ADR	n (%)
Acute myocardial infarction	1 (4.2)
Heart failure	1 (4.2)
Chest pain	1 (4.2)
Syncope	1 (4.2)
Gastritis	1 (4.2)
Urinary incontinence	1 (4.2)
Contusion	1 (4.2)
Instability	1 (4.2)
Weakness	1 (4.2)
Confusion	1 (4.2)

Chapter 16: Details about reported adverse drug reactions of a combination of acetylsalicylic acid/ ascorbic acid

Table 92 Type of ADRs reported for combination of acetylsalicylic acid/ascorbic acid

Type of ADR	n (%)
Abdominal pain	1 (4.2)
Swollen eyelids	1 (4.2)
Lip edema	1 (4.2)
Throat edema	1 (4.2)
Erythematous rash	1 (4.2)
Photosensitivity	1 (4.2)
Generalized erythema	1 (4.2)
Generalized itch	1 (4.2)
Itchy rash	1 (4.2)
Blisters	1 (4.2)
Eye edema	1 (4.2)
Oral paresthesia	1 (4.2)
Hypersensitivity	1 (4.2)

Chapter 17: Details about reported adverse drug reactions of fentanyl citrate

Table 94 Type of ADRs reported for fentanyl citrate

Type of ADR	n (%)
Suicide	2 (12)
Agitation	1 (6.2)
Aggression	1 (6.2)
Hypomania	1 (6.2)
Psychomotor hyperactivity	1 (6.2)
Incompliance	1 (6.2)
Intentional overdose	1 (6.2)
Asthenia	1 (6.2)
Insomnia	1 (6.2)
Vertigo	1 (6.2)
Muscle rigor	1 (6.2)
Vomiting	1 (6.2)
Nausea	1 (6.2)
Bronchospasm	1 (6.2)
Respiratory failure	1 (6.2)

Chapter 18: Details about reported adverse drug reactions of etoricoxib

Table 95 Type of ADRs reported for etoricoxib

Type of ADR	n (%)
Bloating	2 (18)
Dysgeusia	1 (9.1)
Abdominal pain	1 (9.1)
Edema	1 (9.1)
Rash	1 (9.1)
Dry mouth	1 (9.1)
Restlessness	1 (9.1)
Hallucinations	1 (9.1)
Parosmia	1 (9.1)
Fluctuating blood pressure	1 (9.1)

Chapter 19: Details about reported adverse drug reactions of metamizole sodium

Table 96 Type of ADRs reported for metamizole sodium

Type of ADR	n (%)
Edema at the place of application	1 (20)
Erythema at the place of application	1 (20)
Urticaria	1 (20)
Allergic itch	1 (20)
Agranulocytosis	1 (20)
Leukopenia	1 (20)
Decreased blood pressure	1 (20)
Paresthesia at the place of application	1 (20)
Pain at the place of application	1 (20)
Weakness	1 (20)
Hypersensitivity	1 (20)
Off-label use	1 (20)
Nausea	1 (20)

Chapter 20: Details about reported adverse drug reactions of a combination of paracetamol, acetylsalicylic acid and pseudoephedrine hydrochloride

Table 97 Type of ADRs reported for a combination of paracetamol, acetylsalicylic acid and pseudoephedrine hydrochloride

Type of ADR	n (%)
Itch	3 (33)
Face edema	1 (11)
Erythema	1 (11)
Urticaria	1 (11)
Generalized Rash	1 (11)
Rash	1 (11)