

RELATÓRIO DE REACÇÃO ADVERSA												

I. INFORMAÇÃO DA REACÇÃO

1. IDENT. DOENTE	1a. PAÍS	2. DATA DE NASCIMENTO			2a. IDADE	3. SEXO	3a. PESO	4-6 INICIO DA REACÇÃO			8-12 ASSINALE OS CAMPOS APLICÁVEIS À REACÇÃO ADVERSA
		Dia	Mês	Ano				Dia	Mês	Ano	
7 + 13 DESCRIÇÃO DA(S) REACÇÃO(ÕES) (incluindo testes relevantes/dados laboratoriais)										<input type="checkbox"/> MORTE <input type="checkbox"/> MOTIVOU OU PROLONGOU A HOSPITALIZAÇÃO <input type="checkbox"/> PROVOCOU INCAPACIDADE OU DEFICIÊNCIA SIGNIFICATIVA OU TEMPORÁRIA <input type="checkbox"/> PÓS EM PERIGO A VIDA <input type="checkbox"/> OUTRA	

II. INFORMAÇÃO DE MEDICAÇÃO SUSPEITA

14. MEDICAMENTO(S)/ FARMACO(S) SUSPEITO(S)		20. REACÇÃO DESAPARECEU APÓS SUSPENSÃO DA MEDICAÇÃO? <input type="checkbox"/> SIM <input type="checkbox"/> NÃO <input type="checkbox"/> NA
15. DOSE DIÁRIA	16. VIA DE ADMINISTRAÇÃO	
17. INDICAÇÃO TERAPÉUTICA		21. REACÇÃO APARECEU APÓS REINTRODUÇÃO? <input type="checkbox"/> SIM <input type="checkbox"/> NÃO <input type="checkbox"/> NA
18. DATAS DE TRATAMENTO	19. DURAÇÃO DO TRATAMENTO	

III. MEDICAÇÃO CONCOMITANTE E DADOS ADICIONAIS

22. MEDICAÇÃO CONCOMITANTE E DATAS DE ADMINISTRAÇÃO (EXCLUÍDOS AQUELES USADOS COMO TRATAMENTO)
23. OUTROS DADOS RELEVANTES

IV. INFORMAÇÕES DA AUTORIDADE REGULADORA

24a. NOME E MORADA DA AUTORIDADE	26a. Observações
24b. N.º INFARMED	
24c. DATA DE RECEPÇÃO	

Figura 1 - Modelo CIOMS de comunicação da suspeita de reacção adversa ao titular de A.I.M. e à O.M.S.

SYSTEM-ORGAN CLASSES	CODES
Skin and appendages disorders	0100
Musculo-skeletal system disorders	0200
Collagen disorders	0300
Central & peripheral nervous system disorders	0410
Autonomic nervous system disorders	0420
Vision disorders	0431
Hearing and vestibular disorders	0432
Special senses other, disorders	0433
Psychiatric disorders	0500
Gastro-intestinal system disorders	0600
Liver and biliary system disorders	0700
Metabolic and nutritional disorders	0800
Endocrine disorders	0900
Cardiovascular disorders, general	1010
Myo-, endo-, pericardial & valve disorders	1020
Heart rate and rhythm disorders	1030
Vascular (extracardiac) disorders	1040
Respiratory system disorders	1100
Red blood cell disorders	1210
White cell and RES disorders	1220
Platelet, bleeding & clotting disorders	1230
Urinary system disorders	1300
Reproductive disorders, male	1410
Reproductive disorders, female	1420
Foetal disorders	1500
Neonatal and infancy disorders	1600
Neoplasms	1700
Body as a whole – general disorders	1810
Application site disorders	1820
Resistance mechanism disorders	1830
Secondary terms - events	2000
Poison specific terms	2100

Tabela 1- World Health Organization Adverse Reaction Terminology - classes de órgãos e sistemas.

CATEGORIAS DE CODIFICAÇÃO

1	Infectious and Parasitic Diseases
2	Neoplasms
3	Endocrine, Nutritional and Metabolic Diseases, and Immunity Disorders
4	Diseases of the Blood and Blood-forming Organs
5	Mental Disorders
6	Diseases of the Nervous System and Sense Organs
7	Diseases of the Circulatory System
8	Diseases of the Respiratory System
9	Diseases of the Digestive System
10	Diseases of the Genitourinary System
11	Complications of Pregnancy, Childbirth, and the Puerperium
12	Diseases of the Skin and Subcutaneous Tissue
13	Diseases of the Musculoskeletal System and Connective Tissue
14	Congenital Anomalies
15	Certain Conditions Originating in the Perinatal Period
16	Symptoms, Signs, and Ill-defined Conditions
17	Injury and Poisoning
V	Supplementary classification of factors influencing health status and contact with health services
E	Supplementary classification of external causes of injury and poisoning

Tabela 2 - *The International Classification of Diseases. Ninth Revision. Clinical Modification. - ICD.9.CM*

CLASSIFICAÇÃO ATC

1º Nível

2º Nível

A	ALIMENTARY TRACT AND METABOLISM
A01	Stomatological preparations
A02	Antacids, drugs for treatment of peptic ulcer and flatulence
A03	Antispasmodic and anticholinergic agents and propulsives
A04	Antiemetics and antinauseants
A05	Bile and liver therapy
A06	Laxatives
A07	Antidiarrheals, intestinal anti-inflammatory/anti-infective agents
A08	Antiobesity preparations, excl. diet products
A09	Digestives, incl. enzymes
A10	Drugs used in diabetes
A11	Vitamins
A12	Mineral supplements
A13	Tonics
A14	Anabolic agents for systemic use
A15	Appetite stimulants
A16	Other alimentary tract and metabolism products
B	BLOOD AND BLOOD FORMING ORGANS
B01	Antithrombotic agents
B02	Antithemorrhagics
B03	Antianemic preparations
B05	Plasma substitutes and perfusion solutions
B06	Other haematological agents
C	CARDIOVASCULAR SYSTEM
C01	Cardiac therapy
C02	Antihypertensives
C03	Diuretics
C04	Peripheral vasodilators
C05	Vasoprotectives
C07	Beta blocking agents
C08	Calcium channel blockers
C09	Agents acting on the renin-angiotensin system
C10	Serum lipid reducing agents

D	DERMATOLOGICALS
D01	Antifungals for dermatological use
D02	Emollients and protectives
D03	Preparations for treatment of wounds and ulcers
D04	Antipruritics, incl. antihistamines, anesthetics, etc.
D05	Antipsoriatics
D06	Antibiotics and chemotherapeutics for dermatological use
D07	Corticosteroids, dermatological preparations
D08	Antiseptics and disinfectants
D09	Medicated dressings
D10	Anti-acne preparations
D11	Other dermatological preparations
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G	GENITO URINARY SYSTEM AND SEX HORMONES
G01	Gynecological anti-infectives and antiseptics
G02	Other gynecologicals
G03	Sex hormones and modulators of the genital system
G04	Urologicals
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H	SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES
H01	Pituitary, hypothalamic hormones and analogues
H02	Corticosteroids for systemic use
H03	Thyroid therapy
H04	Pancreatic hormones
H05	Calcium homeostasis
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J	GENERAL ANTI-INFECTIVES FOR SYSTEMIC USE
J01	Antibacterials for systemic use
J02	Antimycotics for systemic use
J04	Antimycobacterials
J05	Antivirals for systemic use
J06	Immune sera and immunoglobulins
J07	Vaccines
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L	ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS
L01	Antineoplastic agents
L02	Endocrine therapy
L03	Immunomodulating agents
L04	Immunosuppressive agents
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M	MUSCULO-SKELETAL SYSTEM
M01	Anti-inflammatory and anti-rheumatic
M02	Topical products for joint and muscular pain
M03	Muscle relaxants

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- M03** Muscle relaxants
 - M04** Antigout preparations
 - M05** Drugs for treatment of bone diseases
 - M09** Other drugs for disorders of the musculo-skeletal system

N NERVOUS SYSTEM

- N01** Anesthetics
- N02** Analgesics
- N03** Antiepileptics
- N04** Anti-Parkinson drugs
- N05** Psycholeptics
- N06** Psychoanaleptics
- N07** Other nervous system drugs

P ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS

- P01** Antiprotozoals
- P02** Anthelmintics
- P03** Ectoparasiticides, incl. scabicides, insecticides and repellents

R RESPIRATORY SYSTEM

- R01** Nasal preparations
- R02** Throat preparations
- R03** Anti-asthmatics
- R05** Cough and cold preparations
- R06** Antihistamines for systemic use
- R07** Other respiratory system products

S SENSORY ORGANS

- S01** Ophthalmologicals
- S02** Otologicals
- S03** Ophthalmological and otological preparations

V VARIOUS

- V01** Allergens
 - V03** All other therapeutic products
 - V04** Diagnostic agents
 - V06** General nutrients
 - V07** All other non-therapeutic products
 - V08** Contrast media
 - V09** Diagnostic radiopharmaceuticals
 - V10** Therapeutic radiopharmaceuticals
 - V20** Surgical dressings
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