



SAFE MEDICINE FOR ALL

IT TAKES ONLY

5 MINUTES

OF YOUR ATTENTION TO REPORT A SUSPECTED

ADR

(KNOWN OR UNKNOWN)

Zika virus is spread by *Aedes mosquito* and area of Active transmission is given as shaded area on world map.



ADR to any Radio-Contrast Dye

Pharma Quiz -5

Q. Pethidine

- A. 100mg is equal to 10mg morphine in effect
- B. Increases heart rate
- C. No effect on cardiac output
- D. Is preferred to morphine for analgesia

Answer- Pharma Quiz-4 (D)

SIDE EFFECTS

A **side effect** is usually regarded as an undesirable secondary effect which occurs in addition to the desired therapeutic effect of a drug or medication. Side effects may vary for each individual depending on the person's disease state, age, weight, gender, ethnicity and general health.

Side effects can occur when commencing, decreasing/increasing dosages, or ending a drug or medication regimen. Side effects may also lead to non-compliance with prescribed treatment. When side effects of a drug or medication are severe, the dosage may be adjusted or a second medication may be prescribed. Lifestyle or dietary changes may also help to minimize side effects.

MAJOR DRUG CLASS OF ADR

anti-retroviral	26
antibacterial	14
anti-tubercular	12
anti-cancer	7
anti-apileptic	6
anti-malarial	5
steroids	3
PG analogues	3
anti-psychotic	2
anesthetic agents	2
radiocontrast dye	2
iron preparation, antianginal, antiemetic. leucovorine.iv fluids	1 each

**ADVERSE DRUG REACTION MONITORING CENTER (AMC),
PDU GOVERNMENT MEDICAL COLLEGE, RAJKOT**

Department of Pharmacology, Newsletter – Vol-2 No 1 Jan 2016

Co-ordinator - Dr. Anil Singh, Professor

INACTIVE INGREDIENTS

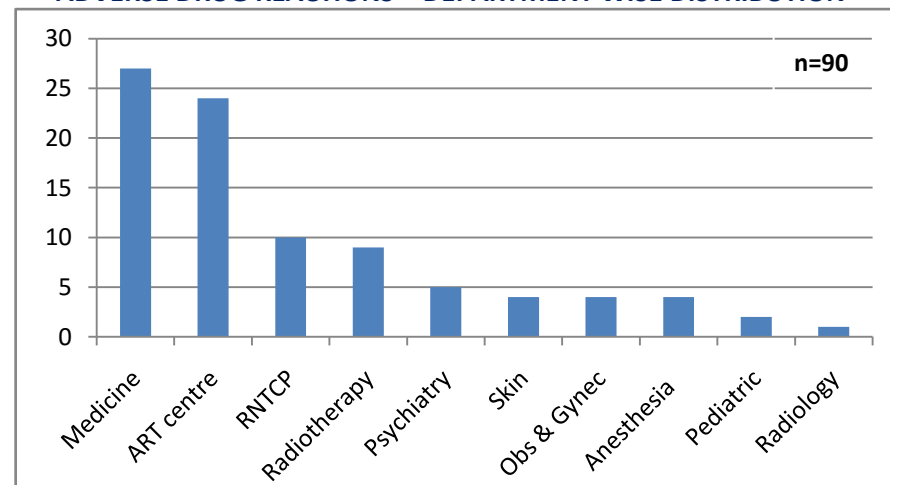
Inactive ingredients are components of a drug product that do not increase or affect the therapeutic action of the active ingredient, which is usually the active drug. Inactive ingredients are added during the manufacturing process of pharmaceutical products such as tablets, capsules, suppositories, and injections. Inactive ingredients may also be referred to as **inert ingredients** or **excipients**, and generally have no pharmacological effect. Examples of inactive ingredients include binding materials (which may be excipients), dyes, preservatives, and flavoring agents. Agents that combine with active ingredients to facilitate drug transport in the body are also considered inactive.

The FDA approves inactive ingredients that are included in pharmaceutical products. However, not all inactive ingredients are always inactive. Alcohol is one example of an ingredient that may be active or inactive based on the specific formulation of the medication. Patients may have allergic reactions or other adverse effects to inactive ingredients. If a patient has a known allergic reaction to an inactive ingredient, they should check for the ingredient in new prescription or over-the-counter medications or check with their pharmacist. Examples of inactive ingredients that are have been reported to cause reactions in some patients include: sulfites, benzoates, aspartame, saccharin, oleic acid, benzyl alcohol, lactose, soya lecithin, propylene glycol, and sorbitan trioleate. Patients who have allergic or adverse reactions to certain inactive ingredients may be able to use products that are color- or preservative-free.

ADVERSE DRUG REACTION REPORT – Oct to Dec 2015

ADR	No.
GIT(vomiting, diarrhoea, gastritis, jaundice)	31
CNS(tingling, numbness, muscular weakness, tremor, neuropathy)	16
Cutaneous(maculopapular rash, fixed drug eruption, toxic epidermal necrosis,hyperpigmentation, SJ syndrome)	7
Cough	6
(Bleeding, pancytopenia)	5
Allergic reaction(anaphylactic reaction)	4
Postpartal Haemorrhage	3
Alopecia	2
Hepatotoxicity(hyperbilirubinemia)	2
Edema of legs	2
Oral cavity	2
Renal	2
Fever	2
Hearing loss	2
Injection site reaction	1
Bradycardia	1
Joint pain	1
Foetal distress	1

ADVERSE DRUG REACTIONS – DEPARTMENT WISE DISTRIBUTION



Active surveillance of - Slurred Speech due to Sodium Valproate

FOLLOWING IS LIST OF APPROVED DRUG BY CDSCO(DCGI) FROM 01-01-2015 to 31-12-2015 for use in INDIA

With Dose, Formulation and Indication

S.No	Name Of Drug	Indication	Date of issue
1	Sofosbuvir Tablet 400 mg	"In combination with other medicinal products for the treatment of chronic Hepatitis C (CHC) in adults".	13.01.2015
2	Bedaquiline Tablet 100 mg	"In adults (\geq 18 years), as part of Combination therapy of pulmonary tuberculosis due to multi-drug resistant Mycobacterium tuberculosis when an effective treatment regimen cannot Otherwise be provided".	14.01.2015
3	Lixisenatide pre-filled solution for injection 10 μ g/20 μ g	For the treatment of adults with type 2 diabetes mellitus to achieve glycaemic control in patients who are not controlled on existing therapy: In combination with the following oral antidiabetics: -Metformin, a sulphonyl urea, or a combination of these agents. In combination with a basal insulin: alone, in combination with metformin, or in combination with sulphonyl urea.	15.01.2015
4	Dapagliflozin Tablet 5mg/10mg	"In adult aged 18 years and older with Type-II diabetic mellitus to improve glycemic control: As mono-therapy when diet and exercise alone do not provide adequate glycemic control in patients for whom use of metformin is considered inappropriate due to intolerance. As add-on combination therapy in combination therapy in combination with other glucose- lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycemic control"	25.02.2015
5	Pasireotide solution for injection 0.3mg/0.6mg/0.9mg	"For the treatment of adult patients with Cushing's disease for whom pituitary surgery is not an option or has not been Curative"	18.03.2015
6	Emphagliflozin Tablet 10mg/10mg	"As an adjunct to diet and exercise to improve glycemic Control in adults with Type 2 diabetes Mellitus."	07.05.2015
7	Gadobutrol solution for injection	"In adult, adolescence and children aged 2 years and older for: 1.contrast enhancement in cranial and spinal magnetic resonance imaging (MRI). 2. Contrast enhancement MRI of other body regions: liver kidneys. 3. Contrast enhancement in Magnetic Resonance Angiography (CE-MRA) 4.For MRI of the breast to assess the presence and extent of malignant breast	07.05.2015
8	Teneligliptin Tablet 20mg	For the treatment of Type 2 Diabetes Mellitus as a Monotherapy adjunct to diet and Exercise	18.05.2015
9	Ceritinib 150 mg Hard Gelatin Capsules	"For the treatment of patients with Anaplastic lymphoma Kinase (ALK)-positive metastatic non- small cell lung cancer (NSCLC) who have progressed on or are intolerant to crizotinib"	13.01.2015
10	Vilazodone Hydrochloride 20mg/40mg and Bulk	"For the treatment of Major depressive disorders in adults"	19.08.15

S.No	Name Of Drug	Indication	Date of issue
11	Gemigliptin 50mg tablets	" As an adjunct to the diet & exercise to improve glycemic control in adults with type-2 diabetes mellitus, as an monotherapy or in combination with metformin in patients with inadequate glycemic control on metformin alone"	21.08.15
12	Atosiban Acetate Injection 6.75mg/0.9ml and Bulk	"Indicated to delay imminent pre-term birth in pregnant adult women with: -regular uterine contractions of at least 30Seconds duration at the rate of ≥ 4 per 30minutes -a cervical dilation of 1 to 3 cm (0-3 for nulliparas) and effacement of $\geq 50\%$ - a gestational age from 24 until 33 Completed weeks a normal foetal heart rate"	16.09.15
13	Ibrutinib Hard gelatin Capsule 140mg	"For the treatment of adult patients with:- -mantle cell lymphoma (MCL) who have received at least one prior therapy. -Chronic Lymphocytic leukemia (CLL) who have received at least one prior therapy. - Chronic lymphocytic leukemia with 17p deletion"	07.10.2015
14	Ledipasvir (90mg)+ Sofosbuvir (400mg) Tablet	" For the treatment of chronic hepatitis C (CHC) Genotype 1 infection in adults"	08.12.2015
15	Ledipasvir Bulk		08.12.2015
16	Daclatasvir Dihydrochloride bulk & Tablet 30mg/60mg	"For use with Sofosbuvir for the treatment of patient with chronic hepatitis C virus (HCV) genotype 3 infection"	14.12.2015
17	Enzalutamide 40 mg soft Capsule	"For the treatment of adults with metastatic castration resistant prostate cancer whose disease has progressed on or after Docetaxel therapy	18. 12 .2015

The list is provided to inform all Faculty and Residents to enable them to identify the drug and remind that any ADR due to above drugs are mandatory to be reported to PVPi.

All ADR can be reported only if Treating Physician, Nursing Staff, Pharmacist or Consumer is identifying and reporting.