A Brief Review of Newly Approved Respiratory, Cardiovascular, and Gastrointestinal Drugs in India

Abstract

Objective: To provide information about respiratory, cardiovascular, and gastrointestinal drugs newly approved for marketing in India.

Method: The list of drugs approved for marketing in India was obtained from the Central Drugs Standard Control Organization (CDSCO) website (http://cdsco.nic.in). Of these, the drugs used for respiratory, cardiovascular, and gastrointestinal system were selected. The details for each drug were looked up from reliable sources and the relevant data is presented in a comprehensive manner.

Results: A total of 99 drugs were approved for marketing in India till the end of May 2009 either as a new formulation or an already available drug for a new indication. Of these, 13 were respiratory drugs, 8 cardiovascular, and 8 gastrointestinal. Only 1 drug alformoterol was a new molecule introduced, the rest were either new dosage forms or approvals for new indications.

Conclusion: Though a number of new drugs are approved, their benefit over the already available preparations should be weighed before prescribing them.

Key-words: Cardiovascular; Gastrointestinal; Respiratory; Approved; India.

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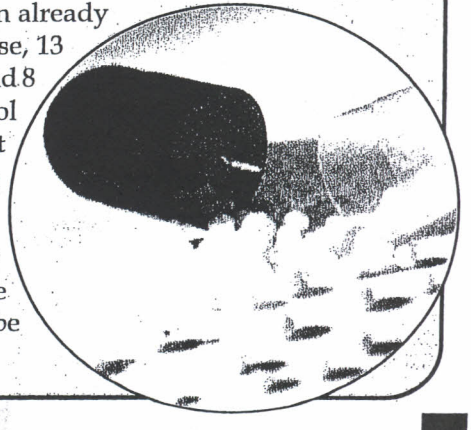
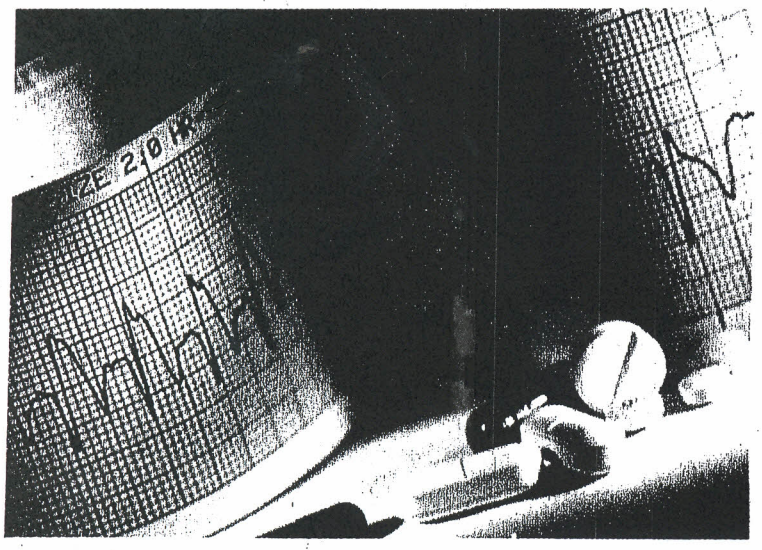




Introduction:

The number of drugs approved for marketing in India is steadily increasing. The Central Drugs Standard Control organization (CDSCO) provides a regularly updated list on its website [1] about the recently marketed drugs.

Method: The list of drugs approved for marketing in India during the first 5 months of 2009 (Jan-May) was used. The drugs used for respiratory, cardiovascular, and gastrointestinal system were selected. Details of each drug were provided regarding brief mechanism of action, indication, dosage form, dose, advantage over prior dosage form/other drugs available for the same indication, and adverse effects. The details of each drug were obtained from new edition textbooks [2,3], reputed medical journals as well as reliable sites on the net.

Results: A total of 99 drugs were approved for marketing in India till the end of May 2009 either as a new formulation or an already available drug for a new indication. Of these, 13 were respiratory drugs, 8 cardiovascular, and 8 gastrointestinal.

For respiratory ailments, 13 new formulations were introduced, 9 for systemic, 2 for inhalation, and 2 for topical use. Of the systemic formulations, 3 were a single drug while the other 6 were combinations. Only 1 drug was a new molecule introduced in India for the first time i.e. alformoterol, whereas the others were introduced as a new dosage forms. Acebrophylline syrup was later in the same year, approved for an additional indication for use in the pediatric population as well.

For cardiovascular ailments, 8 new formulations were introduced; all of which are for systemic use. Of these, 4 were single drugs while the other 4 were combinations. 6 drugs were new dosage forms whereas the other 2 were approved for a new indication. There were no new molecules introduced for the cardiovascular system.

For gastrointestinal ailments, 8 new formulations were introduced, 6 for systemic and 2 for topical use. Of all the formulations, 3 were a single drug while the other 5 were combinations. 7 drugs were new dosage forms whereas the 1 drug was approved for a new indication. There were no new molecules introduced for the gastrointestinal system.

The brief details of the drugs are presented in Table 1.

Table 1

	RESPIRATORY SYSTEM	
1.	Asthma and Chronic Obstructive Pulmonary Disease	
a.	Acebrophylline Syrup	
	Dosage form	Syrup 10mg/ml
	Indications	For the treatment of adult patients with chronic obstructive pulmonary disease (COPD) and bronchial asthma. For the treatment of children (age 6to 12years) with chronic obstructive pulmonary disease (COPD) and bronchial asthma.
	Prior dosage form available	Capsules 100 mg.
	Mechanism of Action	Inhibits enzyme phosphodiesterase4 (PDE-4, that leads to increased cyclic AMP and bronchodilation.
	Adverse Effects	Methyl xanthines have a very narrow therapeutic range causing mainly GI, CNS, and CVS toxicity.
	Advantages over previous dosage form	Ease of administration; can be administered to pediatric population.
b.	Montelucast + Levocetrizine	
	Dosage form	Montelucast 4 mg + Levocetrizine 2.5 mg tablet
	Indication	Additional lower pediatric dose.
	Prior dosage form available	Montelucast 10mg + Levocetirizine 5mg film coated tablets-for adults only.
	Mechanism of Action	Montelukast is a leukotriene D4 receptor antagonist. Levocetrizine is an H1 receptor antagonist
	Adverse Effects	Montelukast may produce headache, rashes, eosinophilia, neuropathy, and features of Churg-Strauss syndrome (vasculitis with eosinophilia). Levocetrizine has minimal anticholinergic effects.
	Dose	1 tablet once daily
	Advantages over prior dosage form	Can be administered in pediatric population, compliance will be better as compared to inhaled therapy. However, syrup would be preferred in children.
c.	Doxyphylline + Terbutaline tablet	
	Dosage form	Doxyphylline 400 mg + Terbutaline 5mg tablets
	Indications	For the treatment of asthma and chronic obstructive pulmonary disease in adult patients only.
	Prior dosage form available	Doxyphylline 400 mg tablets, terbutaline 2.5, 5 mg tablets
	Mechanism of Action	Doxyphylline inhibits enzyme phosphodiesterase 4 that leads to increased cyclic AMP & bronchodilation. Terbutaline is a beta 2 selective adrenoceptor agonist.
	Adverse Effects	Doxyphylline has a narrow therapeutic range causing mainly GI, CNS, and CVS toxicity. Terbutaline causes tremors and tachycardia.
	Dose	1 tablet twice or thrice daily
	Advantages over prior dosage form	Combination of two drugs acting through different mechanisms of action, thus showing synergestic action; better compliance.
d.	Ambroxol + Levo salbutamol + Guaiaphenesin syrup	
	Dosage form	Ambroxol 30mg + Levo salbutamol 1mg+ Guaiaphenesin 50mg /5ml syrup
	Indications	For the symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis
	Prior dosage form available	Ambroxol 15mg + salbutamol 1mg+ guaiphenesin 50mg /5ml syrup
	Mechanism of Action	Ambroxol acts as a mucolytic, salbutamol a bronchodilator and guaiphenesin as a bronchial secretion enhancer.

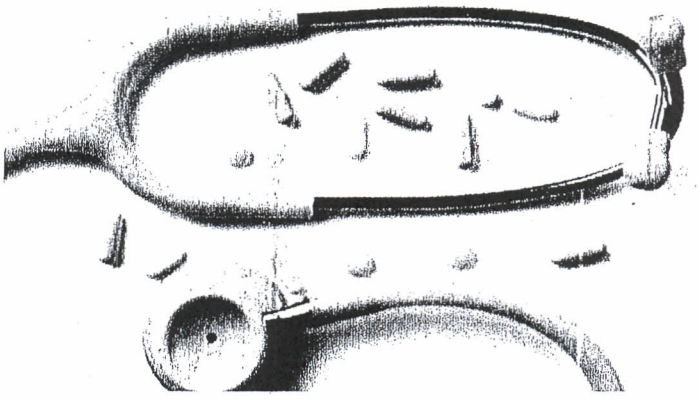
	Adverse Effects	Ambroxol can cause rhinorrhoea, lacrimation, gastric irritation, and hypersensitivity. Levosalbutamol causes beta adrenergic side effects, but less frequently than salbutamol. Urinary calculi has been reported with guaiaphenesin, it is unsafe in patients of porphyria.
	Dose	5ml three times daily
	Advantages over prior dosage form	Marginal benefit from having levosalbutamol since it may have less beta 1 stimulation instead of salbutamol, but will just add to the numerous cough syrups available.
e.	Theophylline + Montelukast Tablet	
	Dosage form	Theophylline 400mg SR + Montelukast 10mg Tablet
	Indications	For the treatment of patients with bronchial asthma.
	Prior dosage form available	Combination not available earlier
	Mechanism of Action	Theophylline inhibits enzyme phosphodiesterase 4 and blockade of adenosine receptors that leads to bronchodilation. Montelukast is a leukotriene D4 receptor antagonist.
	Adverse Effects	Theophylline has very narrow therapeutic range causing mainly GI, CNS, and CVS toxicity. Montelukast may cause headache, rashes, eosinophilia, neuropathy or features of Churg Strauss syndrome.
	Dose	1 tablet once daily
	Advantages over prior dosage form	Combination not available earlier, has the advantage of better compliance and synergistic action since bronchodilation is achieved by different mechanisms.
f.	Arformoterol	
	Dosage form	Arformoterol (as Tartrate) 15mcg / 2ml inhalation solution
	Indication	For the long term, twice daily (morning and evening) maintenance treatment of bronchoconstriction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema.
	Prior dosage form available	Not available earlier
	Mechanism of Action	Long acting selective beta 2 adrenergic bronchodilator
	Adverse Effects	Muscle tremors, palpitations, restlessness, and nervousness. Long acting beta adrenergic agonists could lead to an increase in asthma related deaths.
	Dose	15mcg / 2ml nebulization twice daily (morning and evening)
	Advantages over prior dosage form	Potency twice that of formoterol and longer half life. Cost should be considered.
g.	Ciclesonide + Formoterol + Tiotropium MDI	
	Dosage form	Ciclesonide 200mcg + Formoterol 6mcg + Tiotropium 9mcg MDI
	Indication	Indicated as third line treatment of severe cases of COPD, when monotherapy and second line therapy with two drugs do not respond adequately.
	Prior dosage form available	Ciclesonide 160mcg/320mcg + Formoterol 12mcg + Tiotropium 18mcg Dry powder inhaler
	Mechanism of Action	Ciclesonide is a corticosteroid antiinflammatory. It is a prodrug, activated by esterases in the bronchial epithelial cells; active product is tightly bound to serum protein, so it has little access to glucocorticoid receptors in other organs. Formoterol is a long acting beta 2 adrenergic agonist, and tiotropium is an anticholinergic agent.
	Adverse Effects	Ciclesonide can cause hoarseness of voice, dysphonia, sore throat and oropharyngeal candidiasis. Formoterol can cause muscle tremors, palpitations, restlessness, and nervousness. Long acting beta adrenergic agonists could lead to an increase in asthma related deaths. Tiotropium can cause side effects like dryness of mouth, scratching of trachea, cough, bad taste, and nervousness.
	Dose	1 puff daily
	Advantages over prior dosage form	Increased compliance in patients not responding to 2 drugs.

2.	**Allergic Rhinitis**	
a.	Loteprednol Etabonate Nasal spray	
	Dosage form	Loteprednol etabonate Nasal spray 0.1% w/v
	Indication	For prophylaxis and treatment of the nasal symptoms of seasonal allergic rhinitis.
	Prior Dosage form available	Loteprednol eye drops 0.5%
	Mechanism of Action	Topical corticoid antiinflammatory with high lipid solubility.
	Adverse Effects	Has little systemic side effect.
	Dose	1 spray up each nostril twice daily
	Advantages over other corticoid nasal sprays	No documented advantage.
b.	Fluticasone furoate Nasal spray	
	Dosage form	Fluticasone furoate Nasal spray 27.5mcg per spray
	Indication	For prophylaxis and treatment of the nasal symptoms of seasonal allergic rhinitis.
	Prior Dosage form available	Fluticasone propionate 50 mcg/spray
	Mechanism of Action	Topical corticoid antiinflammatory
	Adverse Effects	Epistaxis, ulcerations, Candida albicans infection, impaired wound healing, Rare, Cataracts and glaucoma; immunosuppression, hypothalamic-pituitary-adrenal (HPA) axis effects, including growth reduction
	Dose	The starting dosage in adults and adolescents more than 12 years is 110 mcg once daily administered as 2 sprays (27.5 mcg/spray) in each nostril. Maintenance dose is 55 mcg (1 spray in each nostril). The recommended starting dosage in children between 2 to 12 years is 55 mcg once daily administered as 1 spray (27.5 mcg/spray) in each nostril. Maintenance dose is 55 mcg once daily.
	Advantages over other corticoid nasal sprays	Recommended dose can be administered with each spray
3.	**Cough with allergic rhinitis**	
a.	Cetrizine + Ambroxol syrup	
	Dosage form	Cetrizine 5/10mg + Ambroxol 30mg per 5ml syrup
	Indication	For the symptomatic relief of productive cough associated with allergic rhinitis, when both anti-histamine and mucolytic agents are desired.
	Prior dosage form available	Cetirizine 5mg, ambroxol 60mg tablet available; Cetirizine 2.5mg, ambroxol 30mg/5ml
	Mechanism of Action	Cetirizine is an H1 antagonist. Ambroxol depolymerises mucopolysaccharides directly as well as liberating lysosomal enzymes.
	Adverse Effects	Cetirizine causes minimal somnolence and anticholinergic side effects. Ambroxol causes rhinorrhea, lacrimation, gastric irritation
	Dose	5 ml once/twice daily
	Advantages over prior dosage form	Syrup could have better compliance in adults.
b.	Cetrizine + Ambroxol Tablet	
	Dosage form	Cetrizine 10 mg + Ambroxol 75 mg SR Tablet
	Indication	For symptomatic relief of productive cough associated with allergic rhinitis, when both anti-histamine and mucolytic agents are desired.
	Prior dosage form available	Cetirizine 5mg, ambroxol 60mg tablet available; Cetirizine 2.5mg, ambroxol 30mg/5ml
	Mechanism of Action	Cetirizine is an H1 antagonist. Ambroxol depolymerises mucopolysaccharides directly as well as liberating lysosomal enzymes
	Adverse Effects	Cetirizine causes minimal somnolence and anticholinergic side effects. Ambroxol causes rhinorrhea, lacrimation, gastric irritation
	Dose	1 tablet once daily
	Advantages over prior dosage form	Contains higher dose of cetirizine and ambroxol, can be used once daily.
4.	**Cough**	
a.	Guaiphenesin ER Tablet	
	Dosage form	Guaiphenesin ER Tablet 1200mg
	Indication	For the treatment of productive cough accompanied by phlegm
	Prior dosage form available	Guaiphenesin ER Tablet (600mg)

	Mechanism of Action	Guaiphenesin as a bronchial secretion enhancer.
	Adverse Effects	Urinary calculi have been reported with guaiphenesin, it is unsafe in patients of porphyria.
	Dose	1 tablet once daily
	Advantages over prior dosage form	Better compliance since greater strength
5.	**Apnea of prematurity**	
a.	Caffeine Injection	
	Dosage form	Caffeine(as Citrate) 10mg / ml Injection
	Indication	For the short term treatment of apnea of prematurity of infants between 28 and < 33 weeks gestational age
	Prior dosage form available	Caffeine tablets available in combination for other indications.
	Mechanism of Action	Methyl xanthine, stimulates respiration and reduces the duration and frequency of apnea. Exact mechanism not known.
	Adverse Effects	Restlessness, jitteriness, faster heart beat, increased urination. Possibility of necrotizing enterocolitis.
	Dose	Loading dose 20 ml/kg Intravenous over 30 minutes, Maintenance dose 5 ml/kg Intravenous over 10 minutes every 24 hours beginning 24 hours after loading dose.
	Advantages over prior dosage form	Efficacy similar to theophylline that is used for this purpose.
	CARDIOVASCULAR SYSTEM	
1.	**Antianginal**	
a.	Ranolazine	
	Dosage form	1000mg ER Tabs
	Indication	For angina pectoris in patients who have not responded to other antianginals and should be given as an adjunct to standard therapy
	Prior dosage form available	500 mg tablets
	Mechanism of Action	It blocks the late sodium current that facilitates calcium entry, and also partially inhibits the fatty acid oxidation pathway in myocardium.
	Adverse Effects	Palpitation, tinnitus, vertigo, dizziness, dry mouth, constipation, peripheral edema, dose related QT prolongation may occur.
	Dose	500 mg twice daily, upto 1000 mg twice daily.
	Advantages over prior dosage form	Better compliance, since the dose can be upto 1000 mg twice daily. Enteric coated may reduce gastric irritation
2.	**Antihypertensives**	
a.	Losartan + Hydrochlorothiazide tablet	
	Dosage form	Losartan 100mg+ HCTZ 25 mg tablet
	Indication	For the treatment of mild to moderate hypertension, heart failure, post myocardial infarction patients and in chronic renal failure.
	Prior dosage form available	Losartan 100mg+ HCTZ 25 mg tablet (Same approved on 10.11.08)
	Mechanism of Action	Losartan blocks angiotensin (AT1) receptor. HCTZ inhibits sodium chloride reabsorption from luminal side of distal convoluted tubule by blocking Na^+/Cl^- transporter.
	Adverse Effects	Losartan can cause hypotension, hyperkalemia, angioedema, headache, and dizziness. It is contraindicated in pregnancy. HCTZ causes hypokalemic metabolic alkalosis, hyperuricemia, impaired carbohydrate tolerance, hyperlipidemia and hyponatremia.
	Dose	Losartan(25-100mg)+HCTZ(25-100mg) per day.
	Advantages over prior dosage form	Nil
b.	Telmisartan + Amlodipine tablet	
	Dosage form	Telmisartan 80mg + Amlodipine 5mg tablet
	Indication	Mild to moderate hypertension, heart failure, post myocardial infarction, and chronic kidney disease.
	Prior dosage form available	Telmisartan 40mg + Amlodipine (as Besylate) 5mg tablet
	Mechanism of Action	Telmisartan blocks angiotensin (AT_1) receptor. Amlodipine is a calcium channel blocker.
	Adverse Effects	Telmisartan can cause hypotension, hyperkalemia, angioedema, headache, dizziness, upper gastrointestinal side effects. It is contraindicated in pregnancy. Amlodipine causes ankle edema, flushing, headache, skin rashes and fatigue.
	Dose	1 tablet once a day.
	Advantages over prior dosage form	Oral bioavailablity is dose dependent. By increasing the dose the bioavailablity can also be increased, so may be useful in patients not responding to 40 mg.
c.	Quinapril + Hydrochlorothiazidetablet	
	Dosage form	Quinapril 20mg + HCTZ 25mg film coated tablet
	Indication	For the treatment of mild to moderate hypertension in adult patients (in whom combination therapy is appropriate) who have been stabilized on the individual components given in the same proportion
	Prior dosage form available	Quinapril 20mg + hydrochlorothiazide 12.5mg
	Mechanism of Action	Quinapril is an angiotensin converting enzyme (ACE) inhibitor. HCTZ inhibits sodium chloride reabsorption from luminal side of DCT by blocking Na^+/Cl^- transporter.
	Adverse Effects	Quinapril can cause cough, hypotension, hyperkalemia, angioedema, headache, dizziness, upper gastrointestinal side effects, It is contraindicated in pregnancy. HCTZ causes hypokalemic metabolic alkalosis, hyperuricemia, impaired carbohydrate tolerance, hyperlipidemia and hyponatremia.
	Dose	1 tablet once a day.
	Advantages over prior dosage form	Film coating helps to overcome acid lability and gastric irritation. It can have longer duration of action. Useful in patients needing higher dose of hydrochlorothiazide.
d.	Metoprolol + Chlorthalidone	
	Dosage form	Each film coated bilayered tablet contains Metoprolol 25mg/50mg + Chlorthalidone 6.25 mg /12.5mg
	Indication	For the treatment of patients with mild to moderate essential hypertension
	Prior dosage form available	Same combination not available earlier.
	Mechanism of Action	Metoprolol is a cardioselective beta blocker whereas chlorthalidone is a long acting thiazide like diuretic.
	Adverse Effects	Metoprolol can cause fatigue, cold extremity, headache, depression, dizziness, sleep disturbance and bradycardia. Chlorthalidone causes hypokalemic metabolic alkalosis, hyperuricemia, impaired carbohydrate tolerance, hyperlipidemia and hyponatremia
	Dose	1 tablet twice a day to four times a day.
	Advantages over prior dosage form	Film coated lower dose can produce the same response as that of prior higher dosage form.
e.	Perindopril arginine film coated tablet	
	Dosage form	Perindopril arginine 2.5mg/5mg/10mg film coated tablet
	Indication	For the treatment of arterial hypertension, congestive heart failure and coronary artery disease.
	Prior dosage form available	Perindopril 2, 4, 8 mg
	Mechanism of Action	Perindopril is an ACE inhibitor
	Adverse Effects	Perindopril can cause cough, hypotension, hyperkalemia, angioedema, headache, dizziness, upper gastrointestinal side effects. It is contraindicated in pregnancy.
	Dose	Start with 2.5 mg daily, increase gradually.
	Advantages over prior dosage form	Perindopril arginine is more stable as compared to other salts which increases shelf life from 2 to 3 years. This salt can be distributed to climatic zones III and IV without specific package. Film coated lower dose can produce the same response as that of prior higher dosage form
3.	**Myocardial Infarction**	
a.	Amlodipine Tablets 5mg/10mg (additional indication)	

	Dosage form	Amlodipine Tablets 5mg/10mg
	Indication	To reduce of fatal coronary heart disease and non-fatal myocardial infarction, and to reduce the risk of stroke. To reduce the risk of coronary revascularization procedures and the need for hospitalization due to angina in patients with coronary artery disease. (additional indication)
	Prior dosage form available	Amlodipine Tablets 5mg/10mg
	Mechanism of Action	Amlodipine is a calcium channel blocker.
	Adverse Effects	Headache and edema.
	Dose	1 tablet once a day.
	Advantages	Additional indication.
	Carvedilol (additional indication)	
	Dosage form	Carvedilol Tablets 3.125/6.25/12.5/25mg
	Indication	To reduce cardiovascular mortality in clinically stable patients who have survived the acute phase of a myocardial infarction and have a left ventricular ejection fraction of = 40% (with or without symptomatic heart failure) (additional indication).
	Prior dosage form available	Carvedilol Tablets 3.125/6.25/12.5/25mg
	Mechanism of Action	Carvedilol is a beta, alpha, calcium channel blocker and has antioxidant properties.
	Adverse Effects	Postural hypotension, bradycardia, failure of ejaculation, and other alpha and beta side effects.
	Dose	Start with 3.125 mg BD, increase upto 25 mg BD
	Advantages over prior dosage form	Additional indication
	GASTROINTESTINAL SYSTEM	
1.	**Antiulcer**	
b.	Omeprazole + Sodium Bicarbonate + Magnesium Hydroxide sachet	
	Dosage form	Omeprazole 20/40mg + Sodium Bicarbonate 600mg+ Magnesium Hydroxide 700mg sachet
	Indication	Peptic ulcer disease, non ulcer dyspepsia, GERD.
	Prior dosage form available	Omeprazole 20mg/40mg + Sodium bicarbonate 1680mg per sachet powder for oral suspension
	Mechanism of Action	Omeprazole is a proton pump inhibitor, irreversibly inactivates H+/K+ ATPase. Sodium bicarbonate reacts rapidly with hydrochloric acid to produce carbon dioxide and sodium chloride. Magnesium hydroxide reacts slowly with hydrochloric acid to form magnesium chloride and water.
	Adverse Effects	Omeprazole causes headache, nausea, diarrhea, , muscle and joint pain, dizziness, and skin rashes. Sodium bicarbonate causes belching, gastric distention and metabolic alkalosis. Unabsorbed magnesium hydroxide causes diarrhea.
	Dose	1 sachet once daily
	Advantages over prior dosage form	Magnesium hydroxide has delayed onset of action in neutralizing the acid but incidence of diarrhea may increase.
2.	**Constipation**	
a.	Liquid Paraffin + Milk of Magnesia + Sodium Picosulphate	
	Dosage form	Liquid Paraffin1.25ml + Milk of Magnesia 3.75ml + Sodium Picosulphate 3.33mg per 5ml
	Indication	For symptomatic treatment of constipation in adults
	Prior dosage form available	Milk of Magnesia 3.75ml + Liquid paraffin 1.25ml + Sodium Picosulfate 3.33mg per 5 ml
	Mechanism of Action	Liquid paraffin acts as a lubricant. Milk of magnesia is an osmotic purgative. Sodium Picosulphate is a stimulant laxative.
	Adverse Effects	Liquid paraffin cause anal seepage and irritation, systemic absorption may leads to foreign body granulomatous reaction. Milk of magnesia causes dose dependent diarrhea and hypermagnesemia in patients of renal impairment. Sodium Picosulfate causes colic and cramps.
	Dose	15 ml at bedtime
	Advantages over prior dosage form	Same combination available before the year 2009.
b.	Lactulose + Ispaghula husk	
	Dosage form	Each 15 gm sachet contains: Lactulose 10 gm + Ispaghula husk 3.50 gm granules
	Indication	For the treatment of chronic idiopathic constipation in adult patients only
	Prior dosage form available	Lactulose 10g/15 ml liquid, Isphagula husk 3.5 g/5.4 g powder
	Mechanism of Action	Lactulose acts as an osmotic purgative while Isphagula is a bulk laxative.
	Adverse Effects	Lactulose can cause flatulence, nausea, and cramps. Isphagula can cause flatulence.
	Dose	1 sachet daily
	Advantages over prior dosage form	Since the two drugs have different mechanisms of action, combination has additive effect.
3.	**Ulcerative colitis**	
a.	Mesalamine PR Tablets	
	Dosage form	Mesalamine PR Tablets 1.2gm
	Indication	For the induction of remission in patients with active, mild to moderate ulcerative colitis
	Prior dosage form available	Mesalamine 500 mg P.R.tablets.
	Mechanism of Action	It reduces inflammation by scavenging free radicals and inhibiting prostaglandins and leucotriene production
	Adverse Effects	Diarrhea, salicylates sensitivity, interstitial nephritis.
	Dose	1 tablet P.R. once a day
	Advantages over prior dosage form	Once daily administration may improve compliance.
4.	**Antiemetic**	
a.	Palonosetron Hydrochloride (Addl. Strength)	
	Dosage form	Palonosetron Hydrochloride 0.075mg IV Inj (Addl. Strength)
	Indication	For treatment of Post Operative Nausea & vomiting
	Prior dosage form available	Palonesetron Injection 0.25mg/5ml
	Mechanism of Action	Serotonin 5-HT3 receptor antagonist
	Adverse Effects	Headache, QT prolongation, constipation or diarrhea, dizziness, fatigue, abdominal pain, and insomnia.
	Dose	Adults-single 0.25 mg I.V. dose administered over 30 seconds. 0.075mg IV dose can also be used.
	Advantages over prior dosage form	Lower dose.
b.	Palonosetron Injection (Additional Indication)	
	Dosage form	Palonosetron Injection 0.25mg/5ml (Additional Indication)
	Indication	For treatment of Post Operative Nausea & vomiting
	Prior dosage form available	same
	Mechanism of Action	Serotonin 5-HT3 receptor antagonist
	Adverse Effects	Headache, QT prolongation, constipation or diarrhea, dizziness, fatigue, abdominal pain, and insomnia
	Dose	Adults - single 0.25 mg I.V. dose administered over 30 seconds.
	Advantages over prior dosage form	Nil
5.	**Anal fissures**	
a.	Nifedipine + Lidocaine cream	
	Dosage form	Nifedipine 0.3% + Lidocaine1.5% cream
	Indication	For the treatment of anal fissures
	Prior Dosage form available	This combination was not available earlier.
	Mechanism of Action	Nifedipine causes smooth muscle relaxation, while Lidocaine has anesthetic effect.
	Adverse Effects	Lidocaine if absorbed into systemic circulation, may produce dizziness, paraesthesia and drowsiness. Nifedipine can cause hypotension.
	Dose	Apply twice daily.
	Advantages over prior dosage form	Additional effect of combination.
6.	**Parasitic Infections**	
a.	Albendazole + Ivermectin	
	Dosage form	Albendazole 400 mg + Ivermectin 6 mg tablet.

Indication	For the treatment of intestinal helminthes and suppression of microfilaraemia especially with bancrofti infections.
Prior dosage form available	Same
Mechanism of Action	Albendazole binds to beta-tubulin and inhibits its polymerization. It blocks glucose uptake and depletes glycogen stores. Intracellular microtubules are gradually lost. Ivermectin causes tonic paralysis in nematodes.
Adverse Effects	Albendazole can cause gastrointestinal side effects. It is contraindicated in pregnancy. Ivermectin can cause pruritis, giddiness, nausea, abdominal pain, constipation, lethargy, transcient ECG changes, and reaction due to degenerative products of microfilariae.
Dose	1 tablet anually for 5 to 6 years.
Advantages over prior dosage form	Additional indication



Conclusion: The review aims at providing brief information about some of the drugs newly approved for marketing in India, but it also brings out some interesting facts. From the 29 new approvals, only 1 drug is a new molecule used for the first time. However, even this drug, alformoterol is a R,R-enantiomer of formoterol which was previously available. A number of drugs are new dosage forms. These new forms can prove advantageous in some cases e.g. if a combination is available instead of two individual drugs, or if the new formulation covers an additional population e.g. Acebrophylline syrup can now be used in pediatric population. However, some of the dosage forms have minimal alteration of dose, which may not prove beneficial but will only add to the list of drugs. Also, since the cost of the newer formulations could be more than the older drugs, care should be taken to use these drugs only when really needed.

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