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Review Article

A Review of Adverse Effects of Banned Drugs in India

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ABSTRACT

A Number of drugs that are banned in the Indian market. The most potable feature is that use of these drugs is regularly using lung term implication for our Physical health. Some of the common ones that we easily available and people Ne frequently without doctor's prescription are D- cold, Nimesulide and Analgin The decision to ban drugs based on the risk versus benefit ratio evaluated through post-marketing surveillance and the Adverse Drug Reaction Reporting System. Pharmaceutical negligence among doctors can lead to hazardous effects on the general health of a patient. Some drugs may cause adverse effects only within comb nod with particular drugs in such cases, only the fixed dose combination is banned and not the individual drugs. The drugs which am found unsafe in post marketing surveillance are banned by regulatory authorities. Banned drugs still available in developing countries like India due to lack of Law enforcement physician awareness and drug control authorizes fails to inform all hospital of the status of medicine India is a major hub of banned drug. Many of the banned drugs are available as over the counter drugs and people consume them unaware and cause damage to one self. Government should be ordered to damage theme cheap drugs in proper manner. And are, India's pharmacovigilance, effort has to be scaled up rapidly. People should say top selling banned drugs. Mefenamic acid is a fenamate nonsteroidal anti-inflammatory (NSAID) drug that belongs to the anthranilic acid derivative family, which is used for several years for pain management. Mefenamic acid is a cyclooxygenase (cox-1 and cox-2) inhibitor and blocks the production of intracellular prostaglandins that are important in pain and inflammatory pathways. Like most NSAID, Mefenamic acid is generally well tolerated but side effects an include headache, dizziness, nausea, diarrhea, abdominal discomfort, heartburn, peripheral edema and hypersensitivity reactions. Other analgesics and NSAID's avoid concomitant use of two or more NSAID as this may increase the risk of adverse effects. Drug reaction with eosinophilia and systemic symptoms (DRESS) syndrome is a potentially life-threatening adverse drug-induced reaction with an estimated mortality of 10%.

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INTRODUCTION

Drug is an agent used for the diagnosis, mitigation, treatment, cure or prevention of disease in human or animals. The government of India is in the process of developing a regulatory regime designed to ensure the quality, safety and performance of medical devices. A drug in usually prescribed to a patient for it' positive effect but may rise to several adverse effect. Pharmacist don't hesitate to sell these drugs because doctors continuously prescribe the despite knowing their implication and side effect on the patient. In promoting healthy lifestyle, the prevention of diseases important but equally important is treatment of such diseases with safe drugs. A number of single drags as well as fixer close combinations have been banned for manufacture, marketing and Distribution in India. These adverse effects are detected through a process or despite knowing their implication and side effect on the patient. In promoting healthy lifestyle, the prevention of diseases important but equally important treatment of such diseases with safe drugs. A number of single drugs as well at fixed close combinations have been banned for manufacture, marketing and distribution in India. These adverse effects are detected through a process regular monitoring after the drug is released into the market called pharmacovigilance. Many spurious drugs that have been banned, withdrawers marketed under restrictions in other countries, continue to be sold in India. When drugs are found to be unsafe in post marketing surveillance conducted, the developed countries immediately impose h through regulatory bodies on the manufacture and sale of drug The pharmacist should hold public information campaigns and educate consumers and play an important role in eliminating the market for Banned drugs. In most countries of the world medicine as well classified, including the category of OTC wire, such a specific category does sot exit in India Besides, the categorization of medicine India is also not very transparent.

Chlorpheniramine maleate

Chlorpheniramine Maleate (CPM), also known as chlorophenamine, is a potent alkyl amine first generation H1 antihistamine that has been used since the 1950s. And patented in 1948[1]. Chlorpheniramine maleate (CPM) is a classic, first- generation antihistamine commonly used for urticaria, rhinitis, and conjunctivitis. CPM belongs to the chemical group called alkyl amines. Like the other antihistamines, it inhibits H1 receptors in a non-selective way, antagonizing the effects of histamine [2]. In addition, Chlorpheniramine maleate has been proved. To have an antidepressant property. The bioavailability of chlorpheniramine maleate is 0.4 and its half time is about 30 hours. Chlorpheniramine maleate is freely soluble in water and has a pKa=9.2 Chlorpheniramine maleate does not exist in such dosage form [3].

Mefenamic Acid

Mefenamic acid is also known as anthranilic acid it is a weak organic acid. It was initially released as early as 1962 for pharmaceutical purposes and was largely marketed then by Parke, Davis and company (NS, USA) in most countries under the names of Ponsten and Ponstel. (1) Meftal is a commonly used non-steroidal anti-inflammatory drug (NSAID) The primary component of Meftal is Mefenamic acid, a pain- relieving medication employed to a mitigate muscle and joint discomfort as well as menstrual pain (Menstrual cramps and Rheumatoid Arthritis) (2) The side effect liable with these drugs are gastric irritation, abdominal pain, bleeding, nausea, diarrhea, heartburn, peripheral edema and hypersensitivity reaction. (3) The short half-life of Mefenamic acid

is 2 hr conventially it is available in tablets, capsules and suspensions because of short half-life oral dose required to frequent administration of drug required to maintain desired steady state level (4) Mefenamic acid is a commonly used NSAID that is a cycloxygenase-1 and 2 inhibitors with anti-inflammatory properties. It was found to exert neuroprotective effects and improve cognitive impairment in vitro and in vivo Alzheimer's disease models and also neuroprotective activities against (5) NSAID have produced a variety of distinct renal syndromes which include acute ischemic renal insufficiency and acute interstitial nephritis caused by hemodynamic effect which is direct result of cox inhibition (6)

Mechanism of action Chlorpheniramine Maleate

Chlorpheniramine helps control the symptoms of cold or allergies but will Not treat the cause of the symptoms or speed recovery. Chlorpheniramine is in a class of medications called Antihistamine. It works by blocking the action of histamine, a substance in the body that causes allergic basically it is Histamine H1 Receptor Antagonist.

Mefenamic acid

The mechanism of action of Mefenamic acid like that of other NSAIDs, is not completely understood but involves inhibition of cyclooxygenase (COX-1 and COX- 2). Mefenamic acid is a potent inhibitor of prostaglandin synthesis in vitro. Mefenamic acid concentrations reached during therapy have produced in vivo Effects. Prostaglandins sensitize afferent nerves and potentiate the action of Bradykinin in inducing pain in animal models. Prostaglandins are mediators of Information. Because Mefenamic acid is an inhibitor of prostaglandin synthesis, it's mode of action may be due to a decrease of prostaglandins in peripheral tissues.

How Chlorpheniramine Maleate works

Chlorpheniramine Maleate is an antiallergic medication. When your body is exposed to an allergen (pollen, animal dander, house dust etc.), it produces a chemical called histamine. This causes watery eyes, runny or blocked nose, sneezing, skin rashes, itching etc. Chlorpheniramine Maleate works by blocking the action of histamine, thereby relieving these symptoms.

How Mefenamic acid works

Meftal-spas Tablet contains Dicyclomine and Mefenamic acid, which are two different medicines. Dicyclomine is an anticholinergic that relaxes the muscles of the stomach and intestines. It relieves cramps, pain, bloating, and discomfort by stopping sudden muscle contractions (spasms). Mefenamic acid is a non-steroidal anti-inflammatory medication (NSAID) that acts by inhibiting the release of chemical messengers that trigger pain and inflammation in the abdomen. (swelling) They work well together.

Pharmacokinetics properties Chlorophenamine maleate

Chlorpheniramine has a serum half-life of approximately 20 hours in adults, and elimination from the body is primarily by metabolism to monodactyl and Dide methyl compounds. The half-life is increased in the presence of renal. Dysfunction and decrease in children.

Mefenamic acid Absorption: -

Mefenamic acid is rapidly absorbed after oral administration. In two 500-mg single oral dose studies, the mean extent of absorption was 30.5 mcg/hr/mL (17%CV).

Distribution: -

Mefenamic acid has been reported as being greater than 90% bound to albumin. The relationship of unbound fraction to drug concentration has not been studied. The apparent volume of distribution estimated 500-mg oral dose of Mefenamic acid was 1.06L/kg.

Metabolism: -

Mefenamic acid is metabolized by cytochrome P450 enzyme CYP269 to 3- hydroxymethyl Mefenamic acid (Metabolite-1). Further oxidation to a 3- carboxymefenamic acid (Metabolite-2) may occur the activities of these metabolites has not been studied. The metabolites may undergo glucuronidation and Mefenamic acid is also glucuronidated directly. A peak plasma level approximating 20 mcg/ml was observed at 3 hours for the hydroxy metabolite and it's glucuronide after a single 1-gram dose similarly, a peak plasma level of 8 mcg/ml was observed at 6-8 hours for the carboxy metabolite and its glucuronide.

Excretion: -

Approximately fifty-two percent of a Mefenamic acid is dose is excreted into the urine primarily as glucuronides of Mefenamic acid (6%),3-hydroxymefenamic acid (25%) and 3-carboxymefenamic acid (21%) The fecal route of elimination accounts for up to 20% of the dose, mainly in the form of unconjugated 3-carboxymefenamic acid. The elimination half-life of Mefenamic acid is approximately two hours.

Duration of action Chlorophenamine maleate

Chlorpheniramine maleate is 4 mg every 4-6 hours (as conventional formulation) or 8-12 mg (as extended-release tablet) twice daily in the morning and evening.

Mefenamic acid

Short biological half-life of Mefenamic acid is 2hr usually four times a day.

Contraindications: - Chlorophenamine maleate

Hypersensitivity to chlorpheniramine or any component of the formulation, narrow-angle glaucoma, bladder neck obstruction, symptomatic prostate hypertrophy, during acute asthmatic attacks, stenosing peptic ulcer, pyloroduodenal obstruction.

Mefenamic acid

Methotrexate-Neutropenia, Renal dysfunction, Aspirin- GI bleeding, Ulceration, Cyclosporine-Increase cyclosporine's nephrotoxicity, Other NSAIDs- GI bleeding, Ulceration.

Adverse Effect: - Chlorophenamine maleate

1. Drowsiness
2. Dizziness
3. Confusion
4. Constipation
5. Anxiety
6. nausea
7. Blurred vision
8. Restlessness
9. decreased coordination
10. Dry mouth
11. Shallow mouth
12. Hallucinations
13. Irritability, problems with memory or concentration
14. Tinnitus and trouble urinating.

Mefenamic acid

1. Gastrointestinal system: Meftal spas can cause stomach ulcers associated with black or sticky Stools, stomach pain and blood vomiting.

2. Cardiovascular system: Meftal spas can cause symptoms like angina (chest pain), shortness of Breath and slurred speech.
3. Skin: It may cause skin reactions such as reddening or blistering of the skin
4. Hepatic (liver): It may cause yellowish discoloration of the skin or whitening of the eye It may cause flu-like symptoms.

Drug Interactions: Chlorophenamine maleate
CNS Depressants

1. MAO inhibitors
2. Tricyclic Antidepressants.
3. Phenothiazines: Increased toxicity.
4. Azole Antifungals, Ciprofloxacin, Clarithromycin, Diclofenac, Doxycycline, Erythromycin, Imatinib, Isoniazid, Nefazodone, Nicardipine, Propofol Protease Inhibitor
5. Quinidine and Verapamil- May increase the levels/effects of chlorpheniramine.

Mefenamic acid

1. Dicyclomine + Mefenamic ACID may have interaction with pain killers (aspirin) Diuretics (furosemide)
2. Anti-psychotic (lithium, quinidine, phenothiazine) Anti-rheumatoid (methotrexate)
3. Blood thinner (warfarin)
4. Cardiac glycoside (digoxin)
5. Anti-diabetic (glibenclamide, gliclazide, glimepiride)
6. Antibiotic (gentamycin, tobramycin, amikacin, cyclosporine)
7. Antiplatelet (clopidogrel)

Chlorophenamine maleate

CPM was approved by the FDA in 1981 with an indication for hay fever, rhinitis, urticaria, and asthma [40]. There are, however, other emerging indications that warrant further exploration. In this section, we discuss various FDA-approved clinical applications of CPM and other potential applications currently being studied.

Used in the treatment of Asthma:

Help to dry secretion in the upper and lower respiratory tracts.

Chronic Idiopathic Urticaria:

It Inhibits H1 receptors in a non- selective way, antagonizing the effect of histamine.

Motion Sickness:

Given that most treatments for motion sickness have sedative effects, CPM was also studied as a possible treatment for motion sickness. In a placebo-controlled, double-blind, dose-ranging trial, researchers concluded that a significant sedative effect was found in patients given high doses of CPM.

Depression, panic Disorder:

Chlorpheniramine inhibits the reuptake of serotonin (5-HT), the anxiolytic-like effect of chlorpheniramine may be produced by an increase in serotonergic function it well tolerated antidepressant.

Plasma Cell Gingivitis:

It is rare condition characterized by disseminated infiltration of plasma cells into the subepithelial connective tissue., This is typically seen as diffuse erythema and edematous swelling of the gingiva with a sharp demarcation along the mucogingival border.

Malaria:

The efficacy of this combination of chloroquine and chlorpheniramine confirmed previous reports of enhanced activity and it was effective in the management of mild to moderate chloroquine resistant malaria

Influenza A and B:

The antihistamine drugs carbinoxamine maleate and chlorpheniramine maleate exhibit potent antiviral activity against a broad spectrum of influenza virus.

Common Cold:

By blocking another natural substance made by your body (acetylcholine), it helps dry up some body fluids to relieve symptoms such as watery eyes and runny nose. However, antihistamine-analgesic-decongestant combinations have some general Benefits in adults and older children, but there is no evidence of effectiveness in young children.

COVID-19:

The antihistamines, including CPM, have been proposed as one of the drugs for the treatment of COVID-19. It has been studied that in patients have minimal to moderate morbidity and mortality risk from COVID-19, the use of CPM nasal spray is associated with significantly improve symptoms and a 50% reduction in the clinical course of the disease.

Premedication for Anticancer Drugs:

In order to prevent possible infusion reactions associated with administering anticancer drugs, often patients are pre-medicated with glucocorticosteroids and antihistamines. Chlorpheniramine inhibits the synthesis of ornithine decarboxylase and the proliferation of human breast cancer cell lines.

Mefenamic acid

Menstrual Cramps:

Helpful against muscle cramps in women caused due to painful periods (dysmenorrhea).

Abdominal Pain:

Relax the muscles of stomach and prevents stomach contractions, thus providing relief from pain in abdomen area.

Peptic Ulcer:

Patients who have Peptic ulcer should avoid taking medicine due to an increased risk of side effects.

Hypersensitivity:

Avoid medication if you are hypersensitive or allergic to any of its ingredient.

Cardiovascular disease:

It should be avoided if a patient has any severe cardiovascular disease or has undergone Coronary Artery Bypass Surgery (CABG).

Pregnancy:

Women who are pregnant or planning for a baby should not use Meftal Spas.

Other Allergic Conditions:

If a patient suffers from any allergic disorder like urticaria or asthma, then medicine should not be consumed. Instead, some other safer substitute of this medication should be considered.

Reasons for banning drugs: - Chlorophenamine maleate

India's drug regulator has banned the use of chlorpheniramine maleate with combination of phenylephrine for children aged under four. If too many medicines, especially combination medicine are giving too much it could suppress cough but predispose the children more infections. It causes sedation, irritability, respiratory depression and behavioural changes in child. If this combination is given frequently, more than recommended dosage, it can have potential side effects that can be harmful to child's health. Cases of overdose or poisoning with chlorpheniramine have been reported, with toxicity manifesting itself mainly as central nervous system (CNS) depression followed by euphoria, which can lead to seizures and convulsions, and finally produce life-threatening exhaustive CNS depression. It causes the risk like Drowsiness, dizziness, constipation, stomach upset, blurred vision, or dry mouth/nose/throat. It can make you extremely drowsy and worsen some medical condition. Due to those reasons chlorpheniramine maleate was banned in India.

Meftal Spas

On December 7, the Indian Pharmacopoeia Commission (IPC) issued a drug safety alert about Meftal, a commonly used non- steroidal anti-inflammatory drug (NSAID), saying that its constituent, Mefenamic acid, triggers Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) syndrome, a severe allergic reaction.(DRESS syndrome is a severe allergic reaction linked to certain medications, with symptoms such as skin rash, fever, and lymphadenopathy appearing between two and eight weeks after drug intake. Drug reaction with eosinophilia and systemic symptoms (DRESS) syndrome is a rare, potentially life-threatening adverse drug reaction with cutaneous manifestations and internal organ involvement that occurs in both adults and children)

Conclusion Chlorpheniramine maleate

Drugs are designed to be life savers. Due to reporting of harmful adverse effects some drugs are banned. A ban is needed to protect the public's health and quality of health care. CPM is one of the oldest first-generation H1 antihistamines. It gives extensive clinical profile; it has been found to have a wide array of medicinal properties and can be used for various indications. Although it is widely used mainly for treat common colds and aforementioned allergic condition s, It can be used for other clinical indications. The repurposing of CPM for other clinical Indications, such as COVID-19, needs to be further explored through more extensive studies.

Mefenamic acid

The Meftal Spas concerns necessitate balancing its effectiveness and potential risks. Meftal Spas or any other drug, consuming medicines as per prescribed guidelines mitigates the risk of potential side effects.

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