



# Drug Information Bulletin

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## Editorial

Disposal of Bio-hazardous waste and drugs-that have expired / confiscated under law, pose a huge problem with respect to environmental pollution. The environment today is overloaded with myriad hazardous chemicals, drugs, excipients and biohazardous waste from different institutions pose a serious threat to the environment. It is a serious concern to the responsible citizens. Strict guidelines need to be framed and enforced with proper vigilance, so that they do not contaminate soil, water bodies / air and through these contaminate / damage human or animal bodies, crops, cattle, fishes etc. It is imperative to note that packaging materials used in the pharmaceutical industry is also another area, whose disposal poses a serious problem.

Guidelines for "Safe Disposal of unwanted pharmaceuticals in and after emergencies" have been framed by international agencies, but no such guidelines have been framed in India under any legislation. It is high time to prepare and enforce strict legislation for disposal of Pharmaceuticals and packaging materials to save the environment.

As pharmacists, we should be more conscious and cautious about disposal of drugs and other pharmaceutical and medical substances / aids, so as to reduce environmental hazards.

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## New Drug: Isavuconazonium capsules

(First approved by USFDA in 2015 in the form of Capsules for oral administration For Injection for intravenous administration under the brand name Cresemba).

INDICATIONS AND USAGE: CRESEMBA is an azole antifungal indicated for use in the treatment of:

- Invasive aspergillosis.
- Invasive mucormycosis.

DOSAGE AND ADMINISTRATION:

- CRESEMBA for injection must be administered through an in-line filter over a minimum of 1 hour.
- Loading Dose: 372 mg isavuconazonium sulfate (equivalent to 200 mg of isavuconazole) every 8 hours for 6 doses (48 hours) via oral (2 capsules) or intravenous administration (1 reconstituted vial) (2.2).
- Maintenance Dose: 372 mg isavuconazonium sulfate (equivalent to 200 mg of isavuconazole) once daily via oral (2 capsules) or intravenous administration (1 reconstituted vial) starting 12 to 24 hours after the last loading dose (2.2).
- Capsules can be taken with or without food.

OSAGE FORMS AND STRENGTHS:

- CRESEMBA capsules contain 186 mg of isavuconazonium sulfate (equivalent to 100 mg of isavuconazole) (3).
- CRESEMBA for injection is supplied in a single-dose vial as a sterile lyophilized powder containing 372 mg of isavuconazonium sulfate (equivalent to 200 mg of isavuconazole)

CONTRAINDICATIONS:

- Hypersensitivity to CRESEMBA.
- Coadministration with strong CYP3A4 inhibitors, such as ketoconazole or high-dose ritonavir.
- Coadministration with strong CYP3A4 inducers, such as rifampin, carbamazepine, St. John's wort, or long acting barbiturates.
- Use in patients with familial short QT syndrome

WARNINGS AND PRECAUTIONS:

- Hepatic Adverse Drug Reactions: Serious hepatic reactions have been reported. Evaluate liver-related laboratory tests at the start and during the course of CRESEMBA therapy (5.1).
- Infusion-related reactions were reported during intravenous administration of CRESEMBA. Discontinue the infusion if these reactions occur.
- Hypersensitivity Reactions: Serious hypersensitivity and severe skin reactions, such as anaphylaxis or Stevens Johnson syndrome, have been reported during treatment with other azole antifungal agents. Discontinue CRESEMBA for exfoliative coetaneous reactions (5.3).
- Embryo-Fetal Toxicity: Do not administer to pregnant women unless the benefit to the mother outweighs the risk to the fetus. Inform pregnant patients of the hazard.
- Drug Interactions: Review patient's concomitant medications. Several drugs may significantly alter isavuconazole concentrations. Isavuconazole may alter

concentrations of several drugs.

- Drug Particulates: Intravenous formulation may form insoluble particulates following reconstitution. Administer CRESEMBA through an in-line filter

ADVERSE REACTIONS: Most frequent adverse reactions: nausea, vomiting, diarrhea, headache, elevated liver chemistry tests, hypokalemia, constipation, dyspnea, cough, peripheral edema, and back pain. To report SUSPECTED ADVERSE REACTIONS, contact Astellas Pharma US, Inc. at 1-800-727-7003 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

DRUG INTERACTIONS:

- CYP3A4 inhibitors or inducers may alter the plasma concentrations of isavuconazole.
- Appropriate therapeutic drug monitoring and dose adjustment of immunosuppressants (i.e., tacrolimus, sirolimus, and cyclosporine) may be necessary when co-administered with CRESEMBA.
- Drugs with a narrow therapeutic window that are P-gp substrates, such as digoxin, may require dose adjustment when administered concomitantly with CRESEMBA

USE IN SPECIFIC POPULATIONS:

- Pregnancy: CRESEMBA should only be used if the benefits to the mother outweigh the risk to the fetus. Inform pregnant woman of risk.
- Mothers should not breast feed children while taking CRESEMBA.
- Use in patients with severe hepatic impairment only when the benefits outweigh the risks; clinical monitoring for CRESEMBA-related adverse reactions is recommended.

**Indian situation:** Isavuconazole sulfate 100mg capsules has approved by CDSCO Indicated for patients 18 years of age and older for the treatment of Invasive Aspergillosis and Invasive Mucormycosis on 14.02.2020.

### New Adverse Drug Reaction reported by PvPI and subsequent action by CDSCO

Sl. No.	Name of the Drug	Adverse Drug Reaction
1.	Chloroquine formulations	DCGI directed all manufacturers to mention <b>Stevens-Johnson Syndrome (SJS)/ Toxic Epidermal Necrolysis (TEN)</b> as an adverse drug reaction in the package insert / promotional literature of the drug
2.	Lamivudin	DCGI directed all manufacturers to mention <b>hearing loss</b> as an adverse

		drug reaction in the package insert / promotional literature of the drug
3.	Proton Pump Inhibitors	DCGI directed all manufacturers to mention <b>acute kidney injury</b> as an adverse drug reaction in the package insert / promotional literature of the drug
4.	Diclofenac Injection	DCGI directed all manufacturers to mention <b>Nicilau's Syndrome</b> as an adverse drug reaction in the package insert / promotional literature of the drug
5.	Carbamazepine	DCGI directed all manufacturers to mention Rash with Eosinophilia and symptomatic symptoms (DRESS) as an adverse drug reaction in the package insert / promotional literature of the drug

### 35 Drugs in the race to treat new Corona virus

The world is scrambling to find a vaccine to treat the new coronavirus (COVID-19) as new cases keep emerging, a survey by Genetic Engineering & Biotechnology News (GEN) has revealed that 35 active drug development programmes are currently on in North America, Europe and China.

Big pharma companies like GlaxoSmithKline and Sanofi to small biotechs such as Moderna and Gilead Sciences are in the race but the researchers worldwide feel a vaccine to treat COVID-19 is at least 12 month away.

Gilead has already begun clinical trials in China after peer-reviewed journals showed that its antiviral candidate, remdesivir, had positive results in a case involving a US patient and Chinese in vitro tests.

Global bio-pharmaceutical company Takeda said this week it has initiated development of a plasma-derived therapy for new coronavirus (COVID-19) and produce the therapy termed as "TAK-888".

Hyper immune globulins are plasma derived-therapies that have previously been shown to be effective in the treatment of severe acute viral respiratory infections and may be a treatment option for COVID-19.

As a leader in plasma-derived therapies with more than 75 years of experience in the development of plasma-derived products, Takeda has the expertise to

research, develop, and manufacture a potential therapy, referring to as "TAK-888," the company said. Researchers have also found a drug called camostat mesylate, that they believe may work to combat the novel coronavirus (COVID-19), which has claimed over 3,000 lives globally, majority of them in China, the virus's country of origin.

Camostat mesilate is a drug approved in Japan for use in pancreatic inflammation.

"We have tested SARS-CoV-2 isolated from a patient and found that camostat mesilate blocks entry of the virus into lung cells," said the study's lead author Markus Hoffmann.

According to the GEN survey, another example is Pirfenidone - an idiopathic pulmonary fibrosis drug marketed by Roche and its Genentech subsidiary as Esbriet.

The drug would be studied in patients with severe and critical COVID-19, under a planned randomized, open-label clinical trial that has been prospectively registered by Tongji Hospital of Tongji Medical College, part of Huazhong Science and Technology University.

The US National Institute of Health (NIH) has announced that it will run the first US clinical trial evaluating an experimental treatment for COVID-19, by assessing remdesivir in patients at the University of Nebraska Medical Center in Omaha, where some Americans with the disease are being cared for or are under quarantine.

Remdesivir showed "no adverse events" when administered to the first American confirmed to be infected with the new virus, in a case study published in The New England Journal of Medicine.

Source: IANS

### SC Holds PCI as Supreme Authority to Regulate Pharmacy Education and Approve Courses & Institutions

In a landmark judgment, a three-judge bench of the Supreme Court of India has ordered that the Pharmacy Council of India (PCI) is the supreme authority to regulate pharmacy education, and for approval of pharmacy courses and institutions in the country.

Dual regulation of pharmacy colleges needs to be ended forthwith and the AICTE Act governing the general technical education would be amended deleting 'pharmacy' from its mandate. Pharmacy education in the country should be governed by the Pharmacy Act, 1948, says the order.

The judgment says that both the Pharmacy Act and the PCI, the statutory body constituted under it, will prevail as far as the recognition of degrees and diplomas of pharmacy education is concerned. The norms and regulations set by the PCI and other specified authorities under the Pharmacy Act needs to be followed by any institution imparting education for degrees and diplomas in pharmacy.

The court was considering a bunch of petitions on the difficulties faced by pharmacy institutions in the country due to dual regulations by PCI and the technical education regulator, All India Council for Technical Education (AICTE).

The order issued on March 5 is applicable to all petitions filed in the Supreme Court and also to those cases transferred to the top court from various high courts. “As common question of law and facts arise in this group of cases, all these cases are being decided together by this common judgment and order”, says the court order.

The highest court in the country has found that since the Pharmacy Act is a special act in the field of pharmacy it will prevail as far as the recognition of degrees and diplomas of pharmacy education is concerned. Similarly, since the Pharmacy Council of India is constituted under the provisions of the pharmacy act which consists of experts in the field of pharmacy and related subjects, it will prevail.

The court has directed those institutions which have increased their intake capacity as approved by AICTE and that increase has been not approved by PCI to apply afresh with the PCI within a period of four months for increasing the intake capacity for the next academic year. Further, cases for increase in intake capacity and/or applications for recognition and/or applications for approval of the course or evening shift should be considered by the PCI in accordance with the Pharmacy Act, 1948 and rules and regulations framed therein and the norms prescribed by the PCI. Hearing the arguments of the PCI, the three member court has observed that considering the statutory scheme under the pharmacy act, the word

“pharmacy” needs to be dropped from the definition of “technical education” under Section 2 (g) of the AICTE Act. Similarly, it deserves to be held as one inapplicable in relation to the regulatory measures for prescribing minimum standards for education in the field of pharmacy.

The All India Council for Technical Education has argued that the word, ‘pharmacy’ is there in the definition of ‘technical education’ in Section 2 (g) of the AICTE Act, the council is solely based on it.

PCI has argued that considering the statutory scheme contained in the Pharmacy Act, which is a complete code by itself dealing with the subject of pharmacy, the jurisdiction for regulating the standards of education in the subject of pharmacy and subsequent professional conduct of pharmacists vests entirely on PCI and AICTE does not have any jurisdiction or power in this behalf. Under pharmacy act, the council has been constituted as a body empowered to regulate the education and profession of Pharmacy in India. It is empowered to determine and enforce the qualifications required for a person to practice as Pharmacist in India, including approving courses of study and institutions which may offer such courses of study to enable one to practice the profession of a pharmacist. PCI is supposed to prescribe the minimum standards of education and approve courses of study for pharmacists.

The court has taken note of the decisions of the joint meeting held by ministry of health and family welfare and by the ministry of HRD on dual recognition of pharmacy colleges. It was found that both the Pharmacy Act, 1948 and the AICTE Act, 1987, contain the provisions regarding pharmacy education leading to duplication of regulations and considerable confusion at the field level. So it was unanimously agreed that this dual regulation should be ended forthwith and the AICTE Act governing the general technical education would be amended deleting ‘pharmacy’ from its mandate and the pharmacy education would thereafter be governed by the Pharmacy Act, 1948, says the order.

Source: Pharmabiz

## DISCLAIMER:

The Newsletter intends to provide updated and reliable information on medicines and other related issues in an attempt to equip healthcare professionals to take informed decision in recommending medicines to the patients. However, they are encouraged to validate the contents. None of the people associated with the publication of the Newsletter nor the organization shall be responsible for any liability for any damage incurred as a result of use of contents of this publication. The brand names of medicines, if mentioned, are for illustration only and the Newsletter does not endorse them.