



# Drug Information Bulletin

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*Indian Pharmaceutical Association*

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**Regulatory Affairs Division (RAD), IPA**

World Tuberculosis

Day- 2018

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**Theme:**

**“Wanted Leaders for  
a TB free world”**

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## *Editorial*

It is my proud privilege to pen the editorial at a historical moment – the completion of 11 years of publication of this Drug Information Bulletin. The weekly bulletin started its journey in April 2007, brought out by the Drug Information Centre (DIC), IPA, Bengal Branch and is now a bi weekly bulletin jointly published by Drug Information Centre, IPA, Bengal Branch & Regulatory Affairs Division, IPA. As far as my knowledge, this is the first of its kind of bulletin serving its readers from all spheres of the society like-Pharmacists, Doctors, Nurses, health workers, NGOs, and general public worldwide. It has received reach accolades and great appreciation from most of the readers due to its content and its regular publication. Initially it was started to serve IPA members then receiving request from other professional stake holders, as well as request from other countries the bulletin marched ahead Presently we have readers from different countries all over the world and different strata of society.

Some hospitals and educational institutes are forwarding this bulletin among their faculty members and keeping hard copies in their libraries with our prior permission so that students can read this. A number of Drug Information Centers are reproducing this with our permission both in Govt. and private sector. A few international agencies have extended recognition like-Commonwealth Pharmacists Association (CPA), HIFA, UK etc.

This is a free service to anybody and everybody, and any person / institute interested in drug information, and we have never accepted any donation or advertisement from anybody for this publication to keep our voice unbiased.

This has been possible due to help and co operation from all of our readers and mentors. Hope this bulletin will continue its service to the society with help from all of you in future too! Greetings to all.

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# Tuberculosis Fact sheet

Reviewed January 2018

## Key facts

- Tuberculosis (TB) is one of the top 10 causes of death worldwide.
- In 2016, 10.4 million people fell ill with TB, and 1.7 million died from the disease (including 0.4 million among people with HIV). Over 95% of TB deaths occur in low- and middle-income countries.
- Seven countries account for 64% of the total, with India leading the count, followed by Indonesia, China, Philippines, Pakistan, Nigeria, and South Africa.
- In 2016, an estimated 1 million children became ill with TB and 250 000 children died of TB (including children with HIV associated TB).
- TB is a leading killer of HIV-positive people: in 2016, 40% of HIV deaths were due to TB.
- Multidrug-resistant TB (MDR-TB) remains a public health crisis and a health security threat. WHO estimates that there were 600 000 new cases with resistance to Rifampicin – the most effective first-line drug, of which 490 000 had MDR-TB. Globally, TB incidence is falling at about 2% per year. This needs to accelerate to a 4–5% annual decline to reach the 2020 milestones of the End TB Strategy.
- An estimated 53 million lives were saved through TB diagnosis and treatment between 2000 and 2016.
- Ending the TB epidemic by 2030 is among the health targets of the Sustainable Development Goals.

Source: WHO

## New Drug: Ulipristal acetate tablet

This drug was first approved by USFDA in 2010

**INDICATIONS AND USAGE:** This is a progesterone agonist/antagonist emergency contraceptive indicated for prevention of pregnancy following unprotected intercourse or a known or suspected contraceptive failure. ella is not intended for routine use as a contraceptive.

**DOSAGE AND ADMINISTRATION:** • One tablet taken orally as soon as possible, within 120 hours (5 days) after unprotected intercourse or a known



or suspected contraceptive failure (2) • The tablet can be taken with or without food.

**DOSAGE FORMS AND STRENGTHS:** • 30 mg tablet

**CONTRAINDICATIONS:** • Known or suspected pregnancy

**WARNINGS AND PRECAUTIONS:** • Ulipristal (ella) is not indicated for termination of an existing pregnancy. Exclude pregnancy before administering. (5.1) • Ectopic pregnancy: Women who become pregnant or complain of lower abdominal pain after taking ella should be evaluated for ectopic pregnancy. (5.2) • Effect on menstrual cycle: ella may alter the next expected menses. If menses is delayed beyond 1 week, pregnancy should be ruled out. (5.5) • ella does not protect against STI/HIV.

**ADVERSE REACTIONS:** The most common adverse reactions ( $\geq 5\%$ ) in the clinical trials were headache (18%), abdominal pain (12%), nausea (12%), dysmenorrhea (9%), fatigue (6%) and dizziness (5%). (6) To report SUSPECTED ADVERSE REACTIONS, contact Watson Laboratories, Inc. at 1-800-272-5525 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

**DRUG INTERACTIONS:** • Drugs or herbal products that induce certain enzymes, such as CYP3A4, may decrease the effectiveness of ella.

**USE IN SPECIFIC POPULATIONS:** • Nursing mothers: ella is not recommended for use by breastfeeding women. (8.3) • ella is not intended for use in premenarcheal (8.4) or postmenopausal women.

## Status in India:

Ulipristal Acetate 5 mg tablets is approved by CDSCO for the pro-operative treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age and intermittent treatment of moderate to severe

symptoms of uterine fibroids in adult women of reproductive age on 14.03.2018

### **Drug-Resistant TB cases In Mumbai up 36% In 3 years**

The menace of drug-resistant TB grew by 36% in the city in the last three years, shows latest data by the BMC's public health department. While 3,608 multi-drug resistant (MDR) TB patients were identified in Mumbai in 2015, the number climbed to 4,891 in 2017.

The fiercer variant, called extensively drug resistant (XDR) TB, has increased by 21% in the same period: from 556 patients in 2015 to 670 patients in 2017. The BMC data sheet attributed the increased numbers to two factors: Better notification by both public and private sector doctors in the city; and an increase in diagnostic facilities to facilitate easy detection of cases. This is borne out by the 18% increase in the number of standard TB cases in three years, said BMC officials.

"More private sector doctors are notifying us, leading to a sudden increase in numbers," said a civic doctor.

State officials say Mumbai not only accounts for nearly 70% of Maharashtra's MDR TB cases, but also has the highest default rate.

"While there are many factors contributing to this, migration is perhaps one of the biggest. It is common for migrant labourers to take medicines for 2-3 months, then take a break and start again. The adherence issue is huge and one of the main challenges we are trying to address through counsellors and by building a better doctor-patient relationship," said Dr Sanjeev Kamble, state TB officer.

Despite the detection of over a lakh fresh TB cases every year, Dr Kamble said the elimination goal of 2025 is not an "impossible one" for the state. But experts differ and say eliminating TB is still a distant dream.

"Better diagnostics have no doubt helped, but the increase is mainly due to the disease spreading rampantly in our overcrowded city," said former

head of pulmonary medicine at civic-run KEM Hospital and TB specialist Dr Ashok Mahasur.

"The earlier government-run TB-control programmes created resistance among the community and we have still not been able to control the after-effects."

Until six years ago, TB patients were asked to complete their medicines for six months before being tested for resistance. In this period, resistance worsened in some patients. In 2012, the centre introduced special anti-TB control measures for Mumbai, leading to an increase in GeneXpert machines and easy availability of higher antibiotics.

Dr Yatin Dholakia of the NGO Maharashtra State AntiTB Association said, "Despite the steps introduced six years back, we are still on the slow track. We still do not offer individualized treatment (where patients are given drugs that work for them as against a standard box of medicines). Active case finding (house-to-house search for TB cases) needs to be carried out more often." He said there is a high component of "silent disease" in Mumbai.

"It wouldn't be surprising if Mumbai's TB burden increases a bit more." In terms of measures, Kamble said doctors will be granted Rs 500 for notifying every new case and an equal sum on completion of treatment. "The treatment of MDR TB spans over two years and it's imperative that doctors share a bond with patients and motivate them to complete treatment," he said.

Source: ET Healthworld

### **Inform Govt. about TB Patient, earn Rs.1,000 from April 1 2018: Govt. of Karnataka**

If you know of any tuberculosis patient and tip off the district TB officer beginning April 1, you will get an incentive of ₹ 1,000, thanks to a state government initiative.

The informer could be the patient himself/herself, a family member, neighbour, the chemist dispensing medicine or the doctor incharge of the treatment.

Not just that. According to Dr Ramachandra Bairy, joint director (tuberculosis), health and family welfare department, the government would also start a scheme to stabilize the nutritional intake of the TB patient by offering ₹ 500 per month as nutritional aid till the time he/she is declared TB-free.

“The scheme will be rolled out from April 1. The government would then track the patient’s treatment protocol. With these initiatives, we aim to increase the number of identified TB cases to 1 lakh per year,” said Dr Bairy.

In 2017, Karnataka identified 68,000 active TB cases during a door-to-door survey of suspected patients.

A Government of India notification has mandated chemists to register details of patients to whom they sell TB drugs and notify the state government. The state health and family welfare department is holding talks with the chemists’ association and a training programme will be conducted shortly.

“This is not a tough task for us, as the prescription will contain the patient’s details. We will have to maintain a register of sale of TB-related drugs and update the government about the patient, his or her age, drugs sold and details of the dosage along with the name of the doctor who prescribed the drug,” said MK Mayanna, president, Bruhat Bengaluru Chemists and Druggists’ Association.

Doctors have hailed the move to involve druggists in combating TB menace. “Unlike other medicines, these drugs can’t be sold over the counter without prescription. This kind of mechanism is required for eradicating TB by 2025,” said Dr K S Satish, TB specialist and pulmonologist.

However, he rued that the issue of TB patients approaching alternative therapists and quacks, who do not follow the treatment protocol, has gone unaddressed. “TB drugs have to be

prescribed based on the body weight of the person after required tests are done. Treatment protocol is flouted by alternative therapists and quacks, who put patients at risk,” he added.

Source: ET Healthworld

### **Duodenoscope makers warned by FDA on post market surveillance requirements**

Duodenoscope manufacturers Olympus, Pentax and Fujifilm received letters from the FDA for not complying with requirements involving the conduct of postmarket surveillance studies to evaluate the effectiveness of device reprocessing. The agency has set deadlines for the completion of the sample and culturing studies, as well as the human factors studies, and expects to receive a plan from the companies on achieving study milestones by March 24.

Ref. Medical Device & Diagnostic Industry online

### **Forthcoming Events:**

#### **Refresher course for registered Pharmacist**

#### **Organized by:**

IPA, Bengal Branch

#### **Supported by:**

Pharmacy Council of India (PCI)

#### **Schedule:**

25.03.2018: CMOH Meeting Hall, Tamluk

30.03.2018: Barasat Dist Hospital

01.04.2018: Suri Sadar Hospital

08.04.2018: Paschim Medinipur MCH Lecture Hall

14.04.2018: IPA Auditorium, Kolkata

21.04.2018: IPA Auditorium, Kolkata

21.04.2018: Purulia

28.04.2018: NBMCH, Siliguri

29.04.2018: Institute of Pharmacy, Jalpaiguri

05.05.2018: Hooghly

05.05.2018: Baruipur

12.05.2018: Malda

19.05.2018: Coochbehar

26.05.2018: Assansol

### **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.