Drug Information Bulletin

Drug Information Centre (DIC)

Indian Pharmaceutical Association

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Volume: 07 ***Number: 04*** ***5th May 2013***

Content

Editorial

Scientific studies show, that an estimated 4.8 million people suffering from moderate to severe cancer pain do not receive treatment. Similarly, about 1.4 million people suffering from moderate to severe pain at terminal stages of HIV annually, remain untreated. In India, a million people with cancer and an unknown number of people with other incurable and disabling diseases like HIV/AIDS, need opioids for pain relief and only a minute fraction (0.4%) of the population in need of opioids have access to the drugs. Major barriers to gain access to opioids are complicated regulations and problems related to attitude and knowledge among health professionals, regulators, administrators and the public regarding pain relief and opioids. As a result of collaborative efforts among the WHO, certain Palliative Care Organizations and Pain & Palliative care activists, the Government of India has taken some steps like - asking all state governments to modify the narcotic rules & regulations following a model, extended schedule K exemption to Morphine Tablets. Currently, more than 15 states and union territory in India have simplified regulations, but opioid availability for medical use has improved only in a minority of these states. Establishment of simple standard operating procedures to implement the simplified regulations, advocacy, and aggressive and improved education of professionals are essential for further improvement of the situation.

In the mean time Govt. of India has published a Draft Gazette Notification seeking opinion of the stake holders regarding amendment of NDPS Act 1985 to improve access to opoids for medical purpose. It is expected that the same will be amended with an aim to improve palliative care of millions of patients suffering from pain.

New Drug: Tapentadol

(Tapentadol Hydrochloride Tablets 50mg/75mg/100mg approved by DCGI 18.04.2011 for relief of moderate to severe acute pain in adults 18 years of age or older).
Availability in India: It is available in different Brand name manufactured by several manufacturers.

Tapentadol is a centrally-acting synthetic opioid which is structurally similar to tramadol. It is thought to bind to the mu opioid receptor and inhibit the reuptake of noradrenaline.

The immediate-release form of tapentadol is indicated for moderate to severe pain. In a trial of 603 patients, tapentadol (50, 75 or 100 mg every 4–6 hours) was compared to immediate-release oxycodone (15 mg every 4–6 hours) or placebo for acute pain after bunionectomy. Tapentadol and oxycodone were significantly better than placebo at relieving pain over the first 48 hours. The analgesic effects of tapentadol seemed to be dose-dependent with tapentadol 100 mg being comparable to oxycodone 15 mg. However, at these doses nausea and vomiting appeared to be less common with tapentadol than with oxycodone (nausea 49% vs 67%; vomiting 32% vs 42%) and somnolence seemed to be more common (21% vs 10%).1

The efficacy of immediate-release tapentadol (50 and 75 mg) was also similar to immediate-release oxycodone (10 mg) for osteoarthritis pain due to moderate to severe joint disease (in 659 patients). Again, gastrointestinal effects were less for tapentadol than oxycodone.2

A sustained-release formulation of tapentadol has also been approved in Australia for moderate chronic pain unresponsive to non-narcotic analgesia. It has been compared to controlled-release oxycodone for chronic low back pain and osteoarthritis in several trials. In a pooled analysis of three trials (2968 patients), tapentadol (100–250 mg twice daily) was not inferior to oxycodone (20–50 mg twice daily) for pain associated with osteoarthritis of the knee and low back pain over 12 weeks of maintenance treatment.3

The adverse effects of tapentadol are similar to other opioids. The most common events in the trials were nausea, dizziness, vomiting, somnolence, constipation and pruritus. These events seemed to be dose-related and some people discontinued treatment because of them.

After a single oral dose of tapentadol immediate-release, serum concentrations peak at 1.25 hours. It is extensively

metabolised, mainly by glucuronidation, and to a lesser extent by CYP2C9 and CYP2C19, so drug interactions mediated through cytochrome P450 are unlikely. Most of the metabolites are excreted in the urine and the terminal half-life is four hours.

The maximum serum concentrations of the sustained-release formulation are reached in 3–6 hours. Its half-life is approximately six hours.

Tapentadol is not recommended in people with severe renal or hepatic impairment. Caution is urged in those with moderately impaired liver function or a history of seizures.

As tapentadol increases noradrenaline, it should not be taken with monoamine oxidase inhibitors. Drugs that may contribute to serotonin toxicity should also be avoided with tapentadol. Additive central nervous system depression can occur if tapentadol is taken with other centrally-acting drugs, including alcohol.

Prescribers should be aware that tapentadol is not recommended for labour pain and there are inadequate data to support its use for cancer pain. Like other opioids, there is a risk of drug dependence.

The efficacy of tapentadol appears to be similar to oxycodone, but with less gastrointestinal adverse effects. It is not known how it will compare to other opioids such as tramadol.

References *

1. Daniels SE, Upmalis D, Okamoto A, Lange C, Häeussler J. A randomized, double-blind, phase III study comparing multiple doses of tapentadol IR, oxycodone IR, and placebo for postoperative (bunionectomy) pain. Curr Med Res Opin 2009;25:765-6.
2. Hartrick C, Van Hove I, Stegmann JU, Oh C, Upmalis D. Efficacy and tolerability of tapentadol immediate release and oxycodone HCl immediate release in patients awaiting primary joint replacement surgery for end-stage joint disease: a 10-day, phase III, randomized, double-blind, active- and placebo-controlled study. Clin Ther 2009;31:260-71.
3. Lange B, Kuperwasser B, Okamoto A, Steup A, Häufel T, Ashworth J, et al. Efficacy and safety of tapentadol extended release for chronic osteoarthritis pain and low back pain. Adv Ther 2010;27:381-99.

Ref. Australian Prescriber

Palliative care centres in India

Sl. No.	State	No.
1	ANDHRAPRADESH	3
2	ASSAM	2
3	CHANDIGARH	1
4	DELHI	4
5	JHARKHAND	1
6	KARNATAKA	5
7	KERALA	193
8	MAHARASHTRA	3
9	PUNJAB	1
10	RAJASTHAN	1
11	ORISSA	1
12	TAMIL NADU	13
13	UTTAR PRADESH	2
14	WEST BENGAL	2

Ref.
http://www.painandpalliativecarethrissur.org/

Govt. of India declare some more substances as controlled substances as per sec. 2 of the NDPS Act 1985

रजिस्ट्री सं० डी० एल०-33004/99

REGD. NO. D. L.-33004/99

भारत का राजपत्र
The Gazette of India

असाधारण
EXTRAORDINARY
भाग II—खण्ड 3—उप-खण्ड (ii)
PART II—Section 3—Sub-section (ii)
प्राधिकार से प्रकाशित
PUBLISHED BY AUTHORITY

सं. 726] नई दिल्ली, मंगलवार, मार्च 26, 2013/चैत्र 5, 1935
No. 726] NEW DELHI, TUESDAY, MARCH 26, 2013/CHAITRA 5, 1935

वित्त मंत्रालय
(राजस्व विभाग)
अधिसूचना
नई दिल्ली, 26 मार्च, 2013

का.आ. 834(अ).—केन्द्रीय सरकार ने, विभिन्न स्वापक औषधियों और मन:प्रभावी पदार्थों के उत्पादन या विनिर्माण में नीचे सारणी में उपदर्शित पदार्थों के यथासंभव उपयोग के बारे में उपलब्ध जानकारी को ध्यान में रखते हुए और स्वापक औषधियों और मन:प्रभावी पदार्थ में अयुक्त दुर्व्यापार के विरुद्ध संयुक्त राष्ट्र संधि, 1988 के उपबंधों को भी कार्यान्वित करने के लिए उनको नियंत्रित पदार्थ के रूप में घोषित करने का विनिश्चिय किया है;

अत: अब, केंद्रीय सरकार, स्वापक औषधि और मन:प्रभावी पदार्थ अधिनियम, 1985 (1985 का 61) की धारा 2 के खंड (viiik) द्वारा प्रदत्त शक्तियों का प्रयोग करते हुए, उक्त खंड के प्रयोजनों के लिए नीचे सारणी में उपदर्शित पदार्थों को नियंत्रित पदार्थ के रूप में घोषित करती है, अर्थात् :-

सारणी

क्र.स	पदार्थ का वर्णन
1.	इरगोमेट्राइन और उसके लवण
2.	इरगोटेमाइन् और उसके लवण
3.	आइसासेफ्रोल
4.	लेसर्जिक अम्ल और उसके लवण
5.	3, 4-मिथाइलिनेडिआक्सीफिनाइल-2-प्रोपेनोन
6.	मिथाइल इथिल कीटोन
7.	नोरफेड्राइन (फिनाइलप्रोपेनोलामिन), उसके लवण और उसकी निर्मितियां
8.	1-फिनाइल-2-प्रोपेनोन
9.	फिनाइलएसिटिक अम्ल और उसके लवण
10.	पिपरोनाल
11.	पोटैशियम परमैगनेट
12.	सेफ्रोल और कोई आवश्यक तेल जिसमें 4 % या अधिक सेफ्रोल हो
13.	एफेड्रीन की निर्मितियां
14.	स्यूडोफिड्रीन की निर्मितियां

[फा. सं. एन-11012/3/2010-एनसी-II]
सत्य नारायण दास, अवर सचिव

1265 GI/2013

MINISTRY OF FINANCE
(Department of Revenue)
NOTIFICATION
New Delhi the 26th March, 2013

S.O. 834(E).—Whereas, the Central Government, having regard to the available information as to the possible use of substances mentioned in the Table below in the production or manufacture of various narcotic drugs and psychotropic substances, and also to implement the provisions of the United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988, decided to declare them as controlled substances ;

Now, therefore, the Central Government in exercise of the powers conferred by clause (viid) of section 2 of the Narcotic Drugs and Psychotropic Substances Act, 1985 (61 of 1985), hereby declares the substances mentioned in the Table below as controlled substance for the purposes of the said clause, namely :

TABLE

Sl. No.	Description of substance
1.	Ergometrine and its salts
2.	Ergotamine and its salts
3.	Isosafrole
4.	Lysergic acid and its salts
5.	3, 4-methylenedioxyphenyl-2-propanone
6.	Methyl ethyl ketone
7.	Norephedrine (Phenylpropanolamine), its salts and preparations thereof
8.	1--phenyl-2 propanone
9.	Phenylacetic acid and its salts
10.	Piperonal
11.	Potassium permanganate
12.	Safrole and any essential oil containing 4% or more safrole
13.	Preparations of Ephedrine
14.	Preparations of Pseudoephedrine

[F. No. N-11012/3/2010-NC-II]
SATYA NARAYANA DASH, Under Secy.

Printed by the Manager, Government of India Press, Ring Road, Mayapuri, New Delhi-110064
and Published by the Controller of Publications, Delhi-110054.