Drug Information Bulletin

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Content

Editorial

Lifestyle diseases are caused due to daily human habits and activities. Basically Lifestyle disease is associated with lifestyle of a person and includes atherosclerosis, heart disease, stroke, obesity, diabetes mellitus, and diseases associated with smoking, alcohol and drug abuse. Changes in daily habits and regular physical activity help to prevent many of the diseases like obesity, heart disease, hypertension, diabetes, colon cancer, and premature mortality. Globally 14.2 million people between 30-69 years of age die prematurely each year from lifestyle diseases, as they have emerged as the biggest killers compare to infectious diseases. Various studies indicate that 80% of deaths due to NCDs occur in low- and middle-income countries. A recent estimate of the Indian population has showed increasing prevalence of life-style diseases and one out of every four persons are at risk of dying from diabetes, cardio-vascular diseases or cancer at an early age. WHO pegs the percentage of global deaths due to NCDs at 68 percent. Cardiovascular disease, diabetes, cancer, and chronic respiratory disease account for 87% of all deaths, originate from untoward outcomes of the 21st Century life style such as unhealthy diet, lack of physical activity, high consumption of tobacco and alcohol along with psycho-social stress. Some of these diseases need to be taken seriously or its consequences will make life miserable, and result in premature and painful death. Skipping breakfast, unhealthy eating habits, having supersized meals, and inactivity or reduced physical activity is a major cause of obesity and a number of complications.

Recently Indian Pharmaceutical Association has written to the Ministry of Health, Government of India for engaging pharmacists to manage non communicable diseases through the national health programme. Hope policy makers on health of India will utilize the potential of pharmacists in this matter.

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New Drug: Vortioxetine for major depression

Approved indication: major depression

Brintellix (Lundbeck)

5 mg, 10 mg, 15 mg and 20 mg film-coated tablets

Most antidepressants are presumed to work by increasing the synaptic availability of serotonin or noradrenaline. Based on non-clinical studies, the manufacturers of vortioxetine say it has a multimodal mechanism of action. They claim that it selectively inhibits reuptake of serotonin (5-HT) via the serotonin transporter and acts as an agonist or antagonist at various serotonin receptors (5-HT_{1A}, 5-HT_{1B}, 5-HT_3, 5-HT_{1D} and 5-HT_7).

Numerous short-term clinical trials (6–8 weeks) have compared the efficacy of vortioxetine to placebo with variable results.[1-6] Not all of the studies have been published in full. One randomised trial found that daily vortioxetine at doses of 15 mg or 20 mg was significantly more effective than placebo at lowering scores on a depression rating scale.[1] In other trials, doses of 1 mg, 5 mg and 10 mg also lowered depression scores more than placebo.[2,3] In a trial enrolling people aged 65 years and over, vortioxetine 5 mg was better than placebo.[4] However, in two other trials of younger people (mean age 42–43 years) the 5 mg dose was no better than placebo.[5,6]

In a longer term relapse trial, 396 patients who responded to 12 weeks of vortioxetine 5 mg or 10 mg were randomised to continue treatment or receive placebo. After a total of 24 weeks, fewer patients in the vortioxetine arm than in the placebo arm had relapsed (13% vs 26%, p=0.0013).[7]

Nausea was the most common adverse event with vortioxetine. Its incidence was dose-related, occurring in 32% of patients who received the 15 mg or 20 mg dose. Other common events included diarrhoea, dizziness, constipation and vomiting.

In an analysis of seven placebo-controlled trials, sexual dysfunction was reported by up to a third of men and women taking the 15 mg or 20 mg dose. Sexual problems were also reported in up to 20% of people taking the placebo. As these events are often under-reported, doctors should ask the patients about these possible effects.

Following multiple oral doses, maximum plasma concentrations are reached after 7–8 hours. Bioavailability is 75% and vortioxetine's mean terminal half-life is about 66 hours. Vortioxetine is mainly metabolised by cytochrome P450 (CYP) 2D6 and metabolites are eliminated in the faeces (59%) and urine (26%).

The recommended starting dose of vortioxetine is 10 mg per day. However, because exposure is increased in people over 65 years old, the recommended starting dose is 5 mg per day in this age group.

Dose reduction should be considered if co-administration of strong CYP2D6 inhibitors (e.g. bupropion, fluoxetine) is necessary. Conversely, the vortioxetine dose may need to be increased if strong CYP2D6 inducers (e.g. rifampicin, carbamazepine) are used.

Because of the risk of serotonin syndrome, concomitant use of monoamine oxidase inhibitors is contraindicated during vortioxetine treatment and for 14 days after it is stopped. Consult the product information if switching a patient between a monoamine oxidase inhibitor and vortioxetine, as washout periods are needed. Serotonin toxicity can also occur with other serotonergic medicines such as sumatriptan, tramadol and St John's wort. Prescribers should be vigilant for symptoms if these drugs are taken concurrently. As with other antidepressants, vortioxetine may increase the risk of suicide or mania in some patients.

Vortioxetine is a pregnancy category B3 drug. Although there is no human data, animal studies found that vortioxetine reduced fetal weight and delayed ossification. In rats, survival of pups was lower in mothers receiving vortioxetine.

Vortioxetine offers another option for people with major depression. However, the nausea and sexual adverse effects are common and may put some patients off. In general, vortioxetine reduced symptoms of depression and prevented relapse. However, it was not clear from the trials how vortioxetine's purported multimodal mechanism of action contributes to its antidepressant effect. The efficacy and tolerability of vortioxetine in comparison with other antidepressants is not currently known.

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Source: Australian Prescriber

Status in India: Vortioxetine Hydrochloride 5mg/10 mg/15mg/20mg film coated tablets has been approved by CDSCO for the treatment of major depressive disorder in adult on 14.05.2018

Patient with Parkinson's gets experimental stem cell-based treatment

Researchers have placed 2.4 million dopamine precursor cells derived from induced pluripotent stem cells into the brain of a patient with Parkinson's disease, the first of seven people to undergo the experimental treatment. "The patient is doing well, and there have been no major adverse reactions so far," said researcher Jun Takahashi of Kyoto University in Japan, where the precursor cells were developed.

Ref.: Nature

FSSAI not to allow use of terms like Natural and Traditional on labels

Food businesses in India will not be able to use words or phrases such as natural, fresh, original, traditional, authentic, genuine and real on food labels except under specific conditions detailed as per a notification issued by FSSAI vide F. No. 1-94/FSSAI/SP(Claims and Advertisements)/2017 dtd. 19.11.2018.

The regulations — Food Safety and Standards (Advertising and Claims) Regulations, 2018, — will pertain to claims and advertisements by Food Business Operators (FBOs) in respect

of their food products. The regulations will come into force from July 1, 2019.

According to the regulations, such restrictions are primarily aimed at limiting an open-ended use of these words/phrases by food businesses on frivolous grounds.

Further it states that the FBOs need to put a disclaimer when the trademark, brand name or fancy name containing adjectives such as "natural," "fresh," "pure," "original," "traditional," "authentic," "genuine," "real," and so on, appearing in the labelling, presentation or advertising of a food is such that it is likely to mislead consumer as to the nature of the food.

In such cases a disclaimer in not less than 3mm size shall be given at appropriate place on the label stating that – "*This is only a brand name or trademark and does not represent its true nature."

As regards to the advertisements in respect of a food product that undermines the importance of healthy lifestyles or portrays the food product as a complete replacement of normal meal, they are not permitted.

Food businesses are also prohibited to advertise or make claim undermining the products of other manufacturers so as to promote their own food products or influence consumer behaviour.

The apex regulator says that these regulations shall come into force on the date of their publication in the Official Gazette and FBOs shall comply with all the provisions of these regulations by July 1, 2019.

"These regulations are aimed at establishing fairness in claims and advertisements of food products and make food businesses accountable for such claims /advertisements so as to protect consumer interests" says the statement by FSSAI.

It is pertinent to mention here that many claims by the FBOs prove in contravention to view of the mismatch the FSSAI has prescribed norms in various schedules of these regulations with related criteria, which shall guide the FBOs while dealing with claims and advertisements.

Several of the claims are permitted to be made by FBOs without the need for seeking prior approval from the food regulator and only those claims which are not standardised under these regulations may require approval from the food authority and should be supported with sound scientific basis, according to FSSAI.

Also, the regulations offer a detailed procedure for approval of claims and food businesses may seek prior approval from FSSAI for reduction of disease risk claims other than those specified in these regulations.

These regulations contain several sections detailing definitions; general principles for claims and advertisements; criteria for nutrition claims (including nutrient content or nutrient comparative claims), non-addition claims (including non-addition of sugars and sodium salts), health claims (reduction of disease risk), claims related to dietary guidelines or healthy diets, and conditional claims; claims that are specifically prohibited; and procedures for approval of claims and redressal of non-compliances under these regulations.

Any person, including a third party, who advertises or is a party to the publication of any misleading advertisement not complying with these regulations would be penalised with a fine extending up to Rs 10 lakh, as per Section 53 of the Food Safety and Standards Act, 2006.

Notification is available at: https://www.fssai.gov.in/home/fss-legislation/notifications/gazette-notification.html