Drug Information Bulletin

Drug Information Centre (DIC)
Indian Pharmaceutical Association
Bengal Branch
Tele fax: 033 24612776, E-mail: ipabengal.dic@gmail.com
Web Site: http://www.ipabengal.org
Contact: 09830136291

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Regulatory Affairs Division (RAD), IPA

India:
Covid vaccination of 12-18 years will start on 3rd Jan 2022 & Booster dose of 60+ with co morbidities will start from 10th Jan 2022

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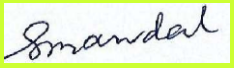
Content

Editorial

Merry Christmas and Happy New Year 2022!

I am penning down the last editorial of this bulletin for this year with a heavy heart as we lost millions of people round the globe due to the devastating COVID-19 Pandemic. This covid-19 virus affected people in almost all countries round the globe irrespective of race or religion, rich or poor. Health authorities are trying their best to manage the situation and at present the situation has improved significantly. Though a few medicines have been repurposed and approved for emergency use, incidentally, new medicines for the treatment COVID -19 are yet to be developed, and a few COVID vaccines are being developed in different countries. Recently USFDA has approved one drug for treatment of Covid without hospitalization.

Vaccination in different developed countries has been completed and some of them has already started booster dose but most of the countries in under developed or undeveloped countries are fighting for vaccinating their people because unequal distribution of vaccines. India has covered a significant portion of its population and yesterday Govt of India declared vaccination of 12-18 years of age will start from 3rd January 2021. 60+ with co morbidities will also get booster dose from 10th January 2021. Another issue is manufacturing of sufficient quantity of vaccines to make i available to each and every human being. To make this possible, we also need sufficient numbers of vaccinators, but presently such number of vaccinators is meager. Considering this fact, different global agencies and governments are engaging more cadres as vaccinators like Pharmacists. Indian government has also planned to engage pharmacists as vaccinator along with MBBS Doctors, Staff Nurses, and BDS Doctors etc. Therefore this is a challenge for the pharmacists to deliver the responsibility bestowed on them. Wishing all a safe, happy and "normal" New Year 2021!



Dr. Subhash C. Mandal
Editor
E mail: subhash.mandaldr@gmail.com
Mob. 9830136291

DGCI Nod to Covaxin for Use in Children above 12 Years

More than two months after an expert panel endorsed Covaxin for kids, the Drug Controller General of India on 24th December 2021 approved the Covid19 vaccine by Bharat Biotech for the 12-17 age group in India.

However, the country's highest drug regulator has permitted the vaccine only for adolescents and not for kids under 12, as recommended by the subject expert committee on Covid19 in October.

Earlier, the Hyderabad based vaccine maker had said that it had submitted data from clinical trials in the 2-18 years age group for Covaxin to the regulator which was thoroughly reviewed by the Central Drugs Standard Control Organization and the subject expert committee.

"This represents one of the first approvals worldwide for Covid-19 vaccines for the 2-18 age group," the company had said. "We now await further regulatory approvals from the CDSCO prior to product launch and market availability of Covaxin for Children.

Raches Ella, clinic lead of Covid vaccines at the company had also said in a tweet that Covaxin has been "reported to be safe and immunogenic" in a pediatric cohort and "the approval in children will help expedite the reopening of schools".

Now, Covaxin has become the second vaccine, after Zydus Cadila's ZyCoV D, to be permitted for under 18 population group in India even though the country is yet to clearly spell out its policy on Covid vaccination for minors.

Approved for adolescents aged 12-17 years of age in August by the DCGI, along with adults, ZyCoV D however is still to be rolled out for any population group in the country.

Meanwhile, Officials in the CDSCO said that though the amount of Covaxin recommended for minors remains the same—0.5 ml—as it is for adults and will also be administered in two doses- 28 days apart- there will be slight difference in the approach.

"It has been discussed that for adolescents, vaccines can be supplied in pre-filled syringes—instead of vaccines being taken out of vials at the time of administration," said an official.

This, officials said, was recommended in order to ensure that exactly the specified quantity of vaccines are administered in kids as the higher quantity may lead to adverse effects.

Source: The New Indian Express

Ibuprofen makers to add Adverse Reaction Stevenson Johnson Syndrome in Package Insert: CDSCO Panel

The Subject Expert Committee (SEC) functional under the Central Drugs Standard Control Organization (CDSCO) has recommended that CDSCO may request the State Drugs Controllers to direct the manufacturers of Ibuprofen to include adverse reaction Stevenson Johnson Syndrome (SJS)/Toxic Epidermal Necrolysis (TEN) in the package insert of the product.

This came in line with the recommendation of signal review panel, Pharmacovigilance Programme of India (PvPI), Indian Pharmacopoeia Commission (IPC) which was placed before the committee.

Sold under top brand names such as Abbott's Brufen and Cipla's Ibugesic, Ibuprofen is a non-steroidal anti-inflammatory drug (NSAID) and non-selective COX inhibitor used to treat mild-moderate pain, fever, and inflammation.

Ibuprofen has multiple actions in different inflammatory pathways involved in acute and chronic inflammation. The main effects reported in ibuprofen are related to the control of pain, fever and acute

inflammation by the inhibition of the synthesis of prostanoids by COX-1 and COX-2. Pain relief is attributed to peripheral affected regions and central nervous system effects in the pain transmission mediated by the dorsal horn and higher spinothalamic tract.

Stevens-Johnson syndrome/toxic epidermal necrolysis (SJS/TEN) is a severe skin reaction most often triggered by particular medications.

Fever and flu-like symptoms are common signs of SJS/TEN. The skin blisters and peels within a few days, producing very painful raw areas called erosions that resemble a severe hot-water burn. Skin erosions commonly begin on the face and chest and extend to other regions of the body. The illness also destroys mucous membranes, such as the lining of the mouth and the airways, in the majority of people who are affected, which can make swallowing and breathing difficult.
At recent SEC meeting for Analgesic & Rheumatology, the recommendation of signal review panel, PVPI, IPC was placed before the committee regarding the adverse reaction related to non-steroidal anti-inflammatory drug (NSAID), Ibuprofen.
Source: Medical Dialogue

Remdesivir Risk of sinus bradycardia

The PRAC has recommended a change to the product information for remdesivir (Veklury®) to include sinus bradycardia as an adverse drug reaction. Remdesivir is indicated to treat COVID-19 in adults and adolescents with pneumonia requiring supplemental oxygen. The PRAC reviewed available data on rare reported cases of bradycardia in patients treated with remdesivir as well as data from clinical trials and the scientific literature.

The PRAC concluded that a causal relationship between the use of remdesivir and the event is reasonably possible and recommended the revision of the product information. The majority of the events of sinus bradycardia resolved a few days after the treatment with remdesivir was discontinued.
Reference: EMA, 11 June 2021

Remdesivir to be used in patients with moderate to severe COVID-19: Health Ministry

The Centre on 24th December 2021 said Remdesivir drug should only be used in patients with 'moderate to severe' COVID-19 and those with no renal or hepatic dysfunction within 10 days of the onset of any symptom. It also warned against use of the drug in patients who are not on oxygen support or in home settings. According to the clinical guidance issued by the Union health ministry for management of the infection in adult patients, Remdesivir has been asked to be "used in patients with moderate to severe COVID-19 and those with no renal or hepatic dysfunction within 10 days of onset of any symptom".

The Tocilizumab drug may be considered for use in the presence of severe disease (preferably within 24 to 48 hours of onset of severe disease/ICU admission), according to the guidelines. Tocilizumab can be used in case of significantly raised inflammatory markers (CRP &/or IL-6), condition not improving despite use of steroids and no active bacterial/fungal/tubercular infection. The ministry also said that those above 60 years of age, with cardiovascular disease, hypertension, diabetes and other immunocompromised states are at high risk for severe disease and mortality.

According to the guidelines, coronavirus patients have been classified into those affected by mild, moderate and severe disease. For mild disease, home isolation and care is recommended, while admission in a ward is recommended for those battling moderate disease and ICU has been recommended for patients with severe COVID-19, they added.
Source: The Financial Express

List of Indian Pharmacopoeial Reference Standards and Impurities

List of Indian Pharmacopoeial Reference Standards	List of Impurities
Amphotericin B New	Will be lauched Soon
L-Histidine New	Will be lauched Soon
L-Isoleucine New	Will be lauched Soon
L-Phenylalanine New	Will be lauched Soon
L-Leucine New	Will be lauched Soon
Luliconazole New	Will be lauched Soon
Citicoline sodium New	Citicoline Impurity B New
Benzhexol Hydrochloride	3-Piperidylpropiophenone HCl New
Betaxolol Hydrochloride	Betaxolol Impurity A New
Bezafibrate	Bezafibrate Impurity A New
Bisacodyly	Bisacodyl Impurity E New
Carbimazole	Carbimazole Impurity A New
Clobetasol Propionate	Clobetasol Impurity J New
Desoxycortone Acetate	Desoxycortone Acetate Impurity (Betamethasone-17-Valerate) New
Dipivefrine Hydrochloride	Dipivefrine Impurity B New
Fusidic Acid	3-Ketofusidic Acid New
Homatropine Hydrobromide	Homatropin Hydrobromide Impurity C New
Homatropine Hydrobromide	Homatropin Impurity B New
Leflunomide	Leflunomide Impurity C New
Levodropropizine	Levodropropizine Impurity B New
Meloxicam	Meloxicam Impurity A New
Methotrexate	Methotrexate Impurity C New
Paroxetine	Paroxetine Impurity A New
Procaine Penicillin	Benzyl Penicillin Potassium New
Repaglinide	Repaglinide Impurity A New
Rivastigmine	Rivastigmine related compound A New
Simvastatin	Simvastatin Impurity B New
Thiamine Hydrochloride	Thiamine Impurity C New
Tolbutamide	Tolbutamide Impurity A New