Government expert committee bans fixed dose combination (FDC) drug having Etodolac + Paracetamol

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*The ban on Etodolac + Paracetamol FDCs was notified back in 2018 but challenged by drug makers in the Delhi high court.**(AFP)***

New Delhi: The Central government has banned the manufacture, sale and distribution of fixed dose combination (FDC) of Etodolac and Paracetamol immediate effect saying citing “there is no therapeutic justification for these drugs and may involve risk to human beings.”

The government's expert committee allowed restricted human usage of two FDC drugs comprising Naproxen IP and Antacid drugs under certain conditions. These drugs are pain killers.

Fixed-dose combination drugs or cocktail drugs are those contain a combination of two or more active pharmaceutical ingredients (APIs) in a fixed ratio.

The ban on Etodolac + Paracetamol FDCs was notified back in 2018 but challenged by drug makers in the Delhi High Court.

On the directions of Delhi High Court, the Central government’s Drugs Technical Advisory Board (DTAB) formed a sub-committee to examine the matter. It said the drug was “irrational” and recommended its prohibition in public interest.

On 25 January this year, the matter was further discussed in a DTAB meeting which recommended prohibiting its manufacture, sale and distribution for human use.

“Now, therefore, on the basis of the recommendations of the Drugs Technical Advisory Board, the Central Government hereby prohibits the manufacture for sale, sale and distribution for human use of drug fixed dose combination of Etodolac + Paracetamol with immediate effect as the said drug is found to have no therapeutic justification and may involve risk to the human beings,” the government notification said issued on 12 August seen by Mint.

“This Etodolac + Paracetamol composition has completely been banned. Both are painkiller and there does not seen to be any benefit of giving this compositing together,” said one of the state drug regulators.

Meanwhile, the Central Government has restricted the manufacture, sale or distribution of the drug FDC Naproxen IP 375mg + Esomeprazole Magnesium Trihydrate IP 20mg Capsule or Tablet and Naproxen IP 250/500mg + Pantoprazole IP 20mg hard gelatin Capsules or Tablets respectively subject to certain conditions.

These conditions include that Naproxen shall be in an enteric coated form that the FDC shall be indicated in adults for the symptomatic treatment of osteoarthritis rheumatoid arthritis, ankylosing spondylitis, or in patients who are at risk for developing non-steroidal anti-inflammatory drug (NSAID)- associated gastric or duodenal ulcers, or to reduce the risk of developing gastric and duodenal ulcers and as per treatment guidelines.

It said that the bioequivalence of the Naproxen IP 375mg + Esomeprazole Magnesium Trihydrate IP 20mg Capsule or Tablet shall be demonstrated with the internationally available innovator’s FDC within one year’s time.

It said that these drugs are likely to involve risk to human beings whereas safer alternatives to the said drug are available.

However, the bioequivalence of Naproxen IP 250/500mg + Pantoprazole IP 20mg hard gelatin Capsules or Tablets, shall be shown with Naproxen and Pantoprazole separately as per standard package insert within one year. The efficacy and safety equivalence shall be demonstrated with Naproxen Esomeprazole international innovator's FDC for the indication, within one year.

"Government committee review the usage of the drug from time to time. Naproxen is a high end drug and its anti-acidity compositions will be allowed for certain conditions only," the official mentioned above said.

The union health and family welfare ministry had last year banned human use of 14 fixed dose combination drugs.

In 2016, the central government had banned the manufacture, sale and distribution of 344 drug combinations after the government expert panel suggested that these drugs were being sold to patients without scientific data.

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