ejpmr, 2019,6(12), 234-236

SJIF Impact Factor 6.222

EUROPEAN JOURNAL OF PHARMACEUTICAL AND MEDICAL RESEARCH

www.ejpmr.com

Review Article

ISSN 2394-3211

EJPMR

REVIEW ON WHY RANITIDINE WAS BANNED IN INDIA

G.V.K.S. Abhinav[1]*, Sushma Sandaka[1], Lokesh Dara[1], Dr. Naga Subrahmanyam S.[2], Shaik Irshad[3], Lokesh Masagiri[3]

*[1]II/VI Doctor of Pharmacy, Koringa College of Pharmacy, Korangi, Kakinada, Andhra Pradesh, India.
[1]II/VI Doctor of Pharmacy, Koringa College of Pharmacy, Korangi, Kakinada, Andhra Pradesh, India.
[2]Assistant Professor, Department of Pharmacy Practise, Koringa College of Pharmacy, Korangi, Kakinada, Andhra Pradesh, India.
[3]IV/IV B.Pharmacy, Koringa College of Pharmacy, Korangi, Kakinada, Andhra Pradesh, India.

***Corresponding Author: G.V.K.S. Abhinav**

II/VI Doctor of Pharmacy, Koringa College of Pharmacy, Korangi, Kakinada, Andhra Pradesh, India.

Article Received on 02/10/2019 **Article Revised on 22/10/2019** **Article Accepted on 12/11/2019**

ABSTRACT

Indian doctors have advised patients to avoid over the counter(OTC) use of popular antacid ranitidine, following concerns over its contamination by cancer causing substances, with the central drug standard control organisation (CDSCO) now having started the process of checking for any adverse reactions of the drug. State bodies have asked to verify product, and take appropriate measures for patient safety. Ranitidine is a generic name and sold under the trade name Zantac among others, is medication which decreases stomach acid production, it's a drug which is used in treatment of peptic ulcer disease, gastroesophageal reflux disease, and zollinger ellison syndrome. Indian pharma impacted by regulatory headwinds for ranitidine, ranitidine contributors 5% of solara's revenue; company has a presence in ratidine's alternative. Impact on pharma companies, global formulation market of ranitidine, and their details will be discussed in this article.

KEYWORDS: Ranitidine, gastroesophageal reflux disease, zantac, zollinger-ellison.

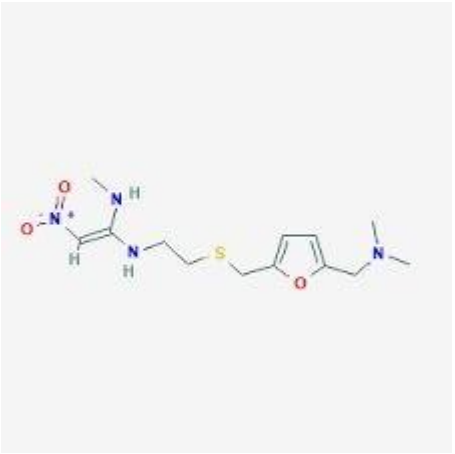
INTRODUCTION

Indian authorities are monitoring the sales of heartburn drug Ranitidine after US drug regulators said it had found a cancer causing impurities called N-nitrosodimethylamine (NDMA) in some product containing ranitidine.[1] In india it is commonly prescribed drug for countering acidity and it is on world health organisation model list of essential medicines. In india, over 180 products based on ranitidine are sold by various leading drug makers with market size of about Rs 750 crores. Ranitidine, an old molecule is prescribed for intestinal and stomach ulcers, gastroesophageal reflux disease, esophagitis, zollinger-ellison syndrome. Global sales of this drug are over $412 million.[2]

Indian pharma impacted by regulatory headwinds for ranitidine, ranitidine contributors 5% of solara's revenue; company has a presence in ratidine's alternative, minor impact on amine manufactures - ranitidine intermediate DMA HCL has multipurpose usage. Impact on pharma companies, global formulation market of ranitidine is estimated to be about 20,000 crores. The impact of development on indian drug formulators varies, but at an aggregate level, the overall market, which is at stake is about rs750 crores.[6]

Basic information about the drug

Ranitidine is a generic name and sold under the trade name Zantac among others, is medication which decreases stomach acid production, it's a drug which is used in treatment of peptic ulcer disease, gastroesophageal reflux disease, and zollinger ellison syndrome. Its proper name was ranitidine hydrochloride, chemical name was N-2-5-dimethyl-2-furanyl methyl thio ethy - N- methyl-2-nitro-1, 1-ethylenediamine, hydrochloride, and its molecular formula is $C_{13}H_{22}N_4O_3S{\cdot}HCl$ and its molecular weight was 350.87 as hydrochloride salt.[3] common side effects are headache and pain or burning if it was given by injection and serious side effects may include liver problems, slow heart rate, pneumonia, and the potential of masking stomach cancer. Its route of administration by mouth and IV.[3,4]



Ranitidine hydrochloride is a white to pale yellow granular substances. At room temperature, ranitidine hydrochloride is soluble in water, methanol, ethanol, and chloroform. Caution for ranitidine hydrochloride was as a contraindications, don't use for self medication if swallowing is difficult, don't use for self medication with other drugs that decrease gastric acid secretion, front use for self medication if expressing vomiting with blood, or if passing bloody or blackened stools. Instead, consult a clinician since such manifestation may indicate presence of a condition requirement alternative treatment. It's common adverse effects were oral or parenteral - headache, sometimes severe, IM therapy - transient pain at the injection site, IV therapy - transient local burning or itching.[5]

DISCUSSION AND CONCLUSION

Ranitidine, a histamine H2 receptor antagonist, is established as a potent inhibitor of gastric acid secretion effective in the treatment and prophylaxis of gastrointestinal lesions aggravated by gastric acid secretion. Similar doses of ranitidine have been shown to relieve the symptoms of reflux oesophagitis and heal or prevent gastrointestinal damage caused by ulcerogenic drugs. Ranitidine 150mg orally at night maintains ulcer healing in the long term. Ranitidine has also demonstrated good results in the treatment of Zollinger-Ellison syndrome and in the prevention of aspiration pneumonitis when given prior to surgery and to pregnant women at full term. The FDA announced that preliminary tests found low level of *N*-nitrosodimethylamine (NDMA) in ranitidine, it is used by millions of Indians, and this week the drug companies novartis and apotex announced that they were recalling all of their generic ranitidine products sold in the US also. The announcement came that online pharmacy informed the FDA that is had detected NDMA in multiple ranitidine product under certain test conditions. Doctors however maintained that NDMA causes harm in large amount. While there is no panic, indiscriminate use of drugs without proper assessment and prescription should be avoided.

REFERENCES

1. Ranitidine under lens after carcinogen alert https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/ranitidine-under-lens
2. -after-carcinogen-alert/articleshow/71286722.cms
3. Ranitidine ban: Indian drug regulator 'alerts' state authorities to ensure patient safety https://www.businesstoday.in/sectors/pharma/ranitidine-ban-indian-drug-regulator-alerts-state-authorities-to-ensure-patient-safety-dcgi/story/382345.html
4. Monograph of zantac (product monograph) january 15, 2015: 17-41.
5. Ranitidine wikipedia https://en.wikipedia.org/wiki/Ranitidine
6. Ranitidine monograph https://www.drugs.com/monograph/ranitidine-hydrochloride.html

7. Ranitidine controversy: Which Indian pharma companies stand to lose? https://www.moneycontrol.com/news/business/moneycontrol-research/ranitidine-controversy-nitrosamine-carcinogen-manufacturer-impact-4488351.html