



## Review on Collection Assessment and Record ADR – Luliconazole And Antifungal Drug

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### ABSTRACT :

Pharmacovigilance was officially introduced in December 1961. Pharmacovigilance is defined as the pharmacological science relating to the detection assessment, understanding and prevention of adverse effects, particularly long-term and short term adverse effects of medicines".Luliconazole is in a class of antifungal medications called azoles.Luliconazole, trade names Luzu among others, is an imidazole antifungal medication. As a 1% topical cream, It is indicated for the treatment of athlete's foot, jock itch, and ringworm caused by dermatophytes such as Trichophyton rubrum, Microsporum gypseum and Epidermophyton floccosum. Luliconazole is available in market in 1% Cream form, under the doctor prescription depends upon patient condition. After visiting ample amount of medical stores, precisely 5, they inform me about the availability of Lulimac 1% Cream at their stores which often shows adverse effect such as rashes, skin irritation, and itching. I also had an interaction with 5 patients across various hospital who had mild/moderate problems regarding infection. They explained how the said drug had an adverse effect on their fungal infection. Just like the treatment being varied from patient to patient, the effects too were observed to differ from patient to patient primarily depending upon an individual's infection and condition. The total score of Naranjo Alogrithm of Luliconazole drug on Naranjo Scale is **4** which indicates that the Luliconazole drug has **Possible** ADR.

### OBJECTIVE:

To detect, access, understand and prevent adverse effect and any other possible drug related problems

The aims of pharmacovigilance are to:

1. Improve patient care and safety in relation to the use of medicines and all medical andparamedical interventions;
2. Improve public health and safety in relation to the use of medicines;
3. Detect problems related to the use of medicines and communicate the findings in a timelymanner;
4. Contribute to the assessment of benefit, harm, effectiveness and risk of medicines,leading tothe prevention of harm and maximization of benefit;
5. Encourage the safe, rational and more effective (including cost-effective) use of medicines;
6. Promote understanding, education and clinical training in pharmacovigilance and itseffectivecommunication to the public.

### PHARMACOVIGILANCE

#### *Introduction:-*

Pharmacovigilance was officially introduced in December 1961 with publication of a later (case reports) in the lancet by w.mc bride, the Australian doctor who first suspected a casual link between serious fatal deformities and thalidomide a drug used during the pregnancy. Thalidomide used as anti-emetics and sedative agent in pregnant women.

In 1968, the world health organization (WHO) promised the programme for International drug monitoring a pilot project to centralized world data on nerverse drug reaction, the main aim of the WHO programs" was identify the earliest possible PV signal pharmacovigilance is the science and activities related to the detection, ment understanding and prevention of adverse effect or any other possible dnig problems.

Pharmacovigilance is defined as the pharmacological science relating to the detect assessment, understanding and prevention of adverse effects, particularly long-term and short term adverse effects of medicines".

Pharmacovigilance also known as drug safety and abbreviated PV or Phy. The word "Pharmacovigilance are: Pharmacon (Greek word for "Drug") and vigilance (Latin word for "to keep watch"). The aims to improve patients care and safety with respect to the use of medicines and other medicines interventions and also contributes to the risk benefit analysis of the medicines.

PV greatly focuses On ADR's which are defined as any reaction to a drug which is harmful and unintended including lack of efficacy used for the prophylaxis, analysis and therapy of illness or for the modification of physiological function. Hospital based ADR monitoring and reporting programmes aims to identify and quantify the risks associated with use of drugs. This information useful in identifying and minimizing preventable ADR's.

**Terminology:-**Adverse

**Drug reaction:-**An adverse drug reaction (ADR) is any noxious, unintended and undesired effect of a drug which occurs at a dose used in human for prophylaxis, diagnosis,therapy or modification of physiological function.

**Marketing surveillance:-** Post-marketing surveillance (PMS) is the practice monitoring the safety of a pharmaceutical drug or device after it has been released in the market.

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#### OBJECTIVES :-

1. To create a nation – wide system designed for patient safety reporting.
2. To identify and analyse latest signal ( ADR) in the Reported cases
3. To research the benefit risk ratio of marketed Medicaments.
4. To generate evidence based information on safety of Medicines
5. To support the regulatory agencies in the decision Making process on use of medicines.
6. To communicate the safety information on use of Medicines to various stakeholders to minimize the Risk.
7. To emerge as a national centre of excellence for Pharmacovigilance activities
8. To collaborate with other national centres for the Exchange of information & data management.
9. To provide training & consultancy support to other national Pharmacovigilance centres located across Globe.
10. To create awareness amongst healthcare Professionals about the importance of ADR reporting in India.
11. Support the CDSCO for formulating safety related regulatory decisions for medicines.
12. To promote rational use of medicine.

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#### OUTCOMES :-

After the completion of report on **lulicanazole**, it is understood

1. Basic understanding of clinical research.
2. Know the functions of DCGI and CDSCO.
3. Understand the objectives and scope of GCP and new drug and clinical trial rules.
4. Knows the concept of pharmacovigilance and ICH E2e guidelines.
5. Able to improve patient care and safety in relation to the use of medicines and all medical and paramedical innovation.

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#### CONCLUSION: -

Luliconazole is Antifungal class of drug used for treating fungal infection. The total score of Naranjo Algorithm of Luliconazole drug on Naranjo Scale is **4** which indicates that the Luliconazole drug has **Possible** ADR. So, this drug is suitable for use.

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**REFERENCE:-**

1. [https://www.google.com/search?q=clinical+trial+phases&client=ms-android-samsung-ga-rev1&prmd=invx&sxsrf=AOaemvI13SWPJeVsy72yq-KILdIAYHZSNA:1638523905420&source=lnms&tbm=isch&sa=X&sqi=2&ved=2ahUKEwjo\\_tmaqcf0AhVlq5UCHRraA5oQ\\_AUoAXoECAIQAQ&biw=412&bih=776&dpr=2.63#imgrc=POjdzKfLDWdKiM](https://www.google.com/search?q=clinical+trial+phases&client=ms-android-samsung-ga-rev1&prmd=invx&sxsrf=AOaemvI13SWPJeVsy72yq-KILdIAYHZSNA:1638523905420&source=lnms&tbm=isch&sa=X&sqi=2&ved=2ahUKEwjo_tmaqcf0AhVlq5UCHRraA5oQ_AUoAXoECAIQAQ&biw=412&bih=776&dpr=2.63#imgrc=POjdzKfLDWdKiM)
2. <https://www.google.com/search?q=function+of+CDSCO&oq=function+of+CDSCO&aqs=chrome..69i57j0i512j0i22i30j0i390.10871j0j9&client=ms-android-samsung-ga-rev1&sourceid=chrome-mobile&ie=UTF-8>
3. <https://www.fda.gov/drugs/how-drugs-are-developed-and-approved/types-applications>
4. Current Trends In Pharmacovigilance, Book By Pragi Arora, Varun Arora, Deepak Garg. Pee Vee Publication Page No. 152 and 153
5. Concise Course In PHarmacovigilance, Book By Pramod V. Burakale, Dr. Suresh G. Sudke, Manish R. Bhise, Vishal B. Patond. Pee Vee Publicaton Page No. 264 and 265
6. <http://www.pharmabiz.com/PrintArticle.aspx?aid=63422&sid=18>
7. [https://www.ema.europa.eu/en/documents/scientific-guideline/ich-guideline-m3r2-non-clinical-safety-studies-conduct-human-clinical-trials-marketing- authorisation\\_en.pdf](https://www.ema.europa.eu/en/documents/scientific-guideline/ich-guideline-m3r2-non-clinical-safety-studies-conduct-human-clinical-trials-marketing- authorisation_en.pdf)
8. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3191675>
9. <https://www.drugs.com/dosage/fluconazole.html>
10. <https://go.drugbank.com/drugs/DB08933>
11. <https://reference.medscape.com/drug/luzu-luliconazole-999891>
12. <https://www.webmd.com/drugs/2/drug-165453/luliconazole-topical/details>
13. <https://pubmed.ncbi.nlm.nih.gov/25285056/>
14. [https://www.google.com/url?sa=t&source=web&rct=j&url=https://cdsco.gov.in/openms/export/sites/CDSCO\\_WEB/Pdfdocuments/Consumer\\_Section\\_PDFs/ADRRF\\_2.pdf&ved=2ahUKEwjeysC3n870AhVLYDgGHe2qBFsQFnoECAUQAQ&usq=AOvVaw39IhYZeBBnKTInXFZAKsv](https://www.google.com/url?sa=t&source=web&rct=j&url=https://cdsco.gov.in/openms/export/sites/CDSCO_WEB/Pdfdocuments/Consumer_Section_PDFs/ADRRF_2.pdf&ved=2ahUKEwjeysC3n870AhVLYDgGHe2qBFsQFnoECAUQAQ&usq=AOvVaw39IhYZeBBnKTInXFZAKsv)
15. <https://www.evidencio.com/models/show/661>