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REVIEW: PHARMCOVIGILANCE CLINICAL AND NON-CLINICAL TRIALS OF RIFAMPICIN

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ABSTRACT

The WHO has initiated the program of reporting all adverse drug reactions co-ordinated by the Monitoring Centre in Uppsala Sweden with oversight by an international board. This presents in the relevance functioning importance pathway and the procedure of reporting adverse drug reactions. Dermatologists the greatest opportunity in reporting various reactions the happen as they come across majority of these drug reactions prescribed by all sectors of the health system.

In clustering analysis the peroxisome proliferator activated receptor-γ (PPARγ) signalling pathway cytochrome P450 glutathione metabolism chemical carcinogenesis and related proteins increased dose-dependently in rifampicin-treated livers. this study showed molecular mechanism of rifampicin-induced liver injury by comparative toxic proteomics approach

Keywords: ICH Guideline, Drug Reaction, Consumption Report, ADR Monitoring Form.

I. INTRODUCTION

Concept of pharmacoviglince.

Pharmacoviglicance - It is Science & activates relating to the detection, assement understanding prevention of adverse effect of any other possible drug related Problems.

The ultimate of this activity is to improve the safe & rational use of medicines thereby improving patient Care & public health.

Pharmacovigilance in to take In Order to market of test pharmaceutical product most counteris adverse event data received by license holders. Ultimately pharmacovigilance is conceded with identifying the hazards associated with pharmaceutical product minimizing any harm that may come to patients.

Objective

- Improve Public health & safety in relation to use of medicines:
- Contribute to the assement of benefit harm.
- effectiveness & risk of medicines encouraging this safe, rational & more effective.
- Mission is to achieve greater harmonisation worldwide to ensure that safe effective & high quality medicines developed & registered maintained in the most resource efficient manner whilst meeting high standards.

Components of pharmacivigilane

The major Components pharmacovigilance system are data collection which passive, active or mandatory data analysis & reporting

- Adverse event Case management
- Aggregate report management
- Safety Signal Risk management
- Risk of management
- Individual Case reporting.

Adverse event case management.

when a Safety registry is created Condition of regulatory, approval a data safety monitoring Bored data monitoring Committee (DMC) Adjudication. Committee established with primary may be role of reviewing.

The management of AE reporting of should clearly specified in registry protocol including explanation of roles rsponsibities Process & method for handling AE report by various registry.

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- **Aggregate repot of management**

The Safety evaluation of medicinal product can be achievement of by aggregate product report & submitting it to various regulatory agency Primary goal of overall report is periodically to measure the medicinal product safety experience workwise .

Aggregate report is the process that review cumulative safety information from a wide range of sources on periodic basis &submits the finding to regulator world wide

Types of Aggregating report

- Pre marketing repost.
- NDA annual report
- Clinical study report (CSR)
- IND annual report
- **Post marketing management**

Periodic Benefit Risk Evaluation report management.(PSUR)

➢ **Safety Signal Management:**

signal detection.

Signal validation

Signal prioritization

Signal assement

The EU signal management process include single detection single validation single confirmation signal analysis & prioritisation signal assessment & recommendation for action

➢ **Risk management:**

The management of signal risk management

1) disk communication

2) Risk assessments.

3) safety signal management

4) risk of minimisation

Therefore the assement of benefit versum risk must begin during preclinical evaluation of a medical product &must extend for life cycle As a result there is now added focus on a product Safety & risk assessment after product has received regulatory approval.

Type of pharmacovigilance

- Targete clinical Investigation
- Active Surveillance
- Passive surveillance
- Cohot even monitoring
- Targeted clinical investigation
- **Passive Surveillance.**

The identity of reporter anonymous but patient-related Country age recovered remains gender & pre existing pre co-morbidities. Can adverse events patients marketing authorisation holder regularly authority be Exporting from Passive Surveillance ispontaneous Reports voluntarily sent by professionals of

- **Active Surveillance:**

This method aims monitor certain specific day related advise event & no. of ADR Entirely through... a pre-planned process.

- **Cohort event monitoring – HSN code 30049057** this method the Surveillance study is planned perior to beginning the treatment with the medications Adverse drug of the event of target drug associated with One of more medicines taken with that may monitored.

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- **Targeted Clinical Investigation**

This Kinds to investigations perform identify & characterize to adverse reaction related to drug among special population like people with some Like genetic disorder pregnant women & older people

- **Constitution & objective of PVPI**

The CPSCO directorate general of health services Under the ages ministry of Health& family welfare of India in association with Indian pharmacopeial corrosion Goziabad is initiating a Nation wide pharmacoviglance program for protecting health of patient by promising drug Safety. The PVP1 started by government of India on 14 July 2010.

➢ **Objective**-

To Create nation wide system for Patient Safety reposting.

To system for identify & analyse the new signal (ADR) from reported cases.

To analyse the benefit-risk ratio of marketed medications.

To generate the evidence based information on safety of

To Support regulatory agencies. decision making process on use of Medication.

TO provide training to consultancy Support to other national centred located across globe

- **list of national adverse drug monitoring Centres & their function**

Department Pharmacology GIME R Chandigarh

2) department pharmacology pharmacology R.G kar medical college kolkata.3) department of pharmacology medical college Gaeahan Assam. 4) permit of pharmacology

Function-

Identification & analysis of new adverse reaction signal from case report

Provision of WHO database as refers for Source for signal strengthening.

Pharmacovigilance is post marketing tool that ensure the safety medical product.

Having a Pico vigilance system in Place requires harmonization different Criteria and well through plan perfect execution of corporeal advantages.

- **Aggregate Reporting**

periodic safety update reports (PSOR) objective of the PSUR is to present a comprehensive & Critical analysis of risk the benefit balance of Product taking into account new oe emerging Safety, information in the Context of cumulative information of on risks benefit of drug

Periodic Benefit risk evolution:-

A Periodic benefit risk evolution is format of safety report described by the ICH E2 guideline which is used basis for EV periodic safety update report. The report is produced by the marketing authorisation holds at defined time points after a medicine has been given marketing authorisation -

Integrated Analysis

Discovering rare unexpected in patient out groups

Improving the precision of result with larger the population sites by integrating.

1. Clinical research

- **Phase of clinical trials**

Clinical trial systematic investigation in human subject for evaluating the safety & efficacy drug Grades Of Strength of evidence.

Grade 1 - Systemic reviews | meta analysis. Most reliable may form the basis of clinical division

Grade 2 -well powdered randomised controlled trials Reliable but may be Supported

Grade 3 -open label trials less reliable Need more testing.

Grade 4 -case reports least reliable

a. Grading strength of evidance. The strength of conclusion of Various kinds of trials Studies & reports has been agraded from strong to weak as present.

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Preclinical studies- After Synthesing identifying a prospective Components it is tested animal. Experiments generally performed on animals.

- on rodent -

eg – mouse ,rata, Quoined ,Pig rabbit

- large animals-

Monkey animals , cat ,Dog , are test performed

- Screening test-

Clinical Trials The trials in identified by Studies are approaches by IND. The drug formulated of dosage from of clinical trials are conducted logical manner . These are decide into 4 phases.

Phase O- Micro dosing study. These have alarmed FDA & Cost cutting approches in drug development. Many drug fail in clinical trials due to sub- optimal. pharmacokinetics- on healthy volunteers.

Phase1-Human pharmacology & Safety

The first the drug human administered drug Carried of out by qualified pharmacolognist.

Mostly healthy volunteer. patients at used.

The emphasis on safety lerability & to detect dangerous effect to on the vital function.

Phase2- Therapeutic exploration of dose

In volve 100-500 patient Tolarity pharmacokinetic are studies

Phase 3 - Therapeutic conformation comparison

500-3000 patients Safety tolerability study. By FDA & NDA convined marketing Permission

Phase 4 - Post-marketing surveillance

further therapeutic trials the drug has been marketed for general Use some drug Continue their after marketing

pre-clinical studies

In India the pre clinical studies are act according to regulatory guidline Name schedule'Y" of drug.

- Introduction description of drug therapeutic class
- Chemical & Pharmaceutical information.
- Animal pharmacology Toxicology.
- clinical trials
- Determination of pharmacological action. The determination pharmacological action of Chemical substance potential drug These are screened on series of biological system
- eg- Isolated cegan

General pharmacological action :

Eseential safety Pharmacology study needs to conducted Investing which Understand pharmacodynamic. Which are Safe to human adverse codynamic. The aim essential is pharmacology study of effect of drug of vital function specific Pharmacology Demonstrate therapeutic potential for human. These design individual Uses of investigational drug

Pharmacokinetic studies Pharmacokinetic testing is done to provide data an haw is absorbed distributed and metabolic execrated by body

- **function of NDA**

The NDA application. is the vehicle through which drug Sponsors formally the purpose FDA approve new pharmaceutical for Sale & marketing The data animal studies & human clinical trials of an Instigations drug become function of IND Exploratory in IND - conducted early phase first Allow the experiment dells in emergency situation.

- **Technical requirement for medical product containing new.**
- **Scope of GCP-**

In New rule 2019 such reserch has been defined to include studies Studies basic applied and operational research of clinical reserch disigned primary to inerse Scientific knowidge about disease & Condition

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behavioral and case evoving stratergies Beam promotion prevention amelloration disease rehabilitation. does not include

Academic Clinical Trials-

New Rule drug describe academic clinical trials of alredy approved for certain and clam initated by investory. Academic reserch institution. new indication of new of now route does a new route administrated new dose or new dosage form.

EthicsCommitice (ECS)

As delinated in mo and additional Resource india has decenteonized process for the ethical reviews of cinical trial application and required ethical comitee CEC) approval for each trial Use.

- One social scientist representation non- goverment Voluntary: agency .
- One phiolsopher. /emicist theologian.
- One lay person from community
- member secretory Altranative members sestery Optional
- one member independant. institution is non- Scientific.
- **Phase 4 and post marketing Studies (PMS)**
- previously there was ambigity defination requirement reducing phase and PMS.
- New rules 2019 was diffentiated Eequirement. Reducing phase-a post marketing Survetiane for new drug.
- New study Rules 2019 Phase stud
- Drug -Drug interaction nose-response or Safety studies.
- **Post-marketing survellionce studies**
- Such studies are conducted with approval condition of its use scientific objective of approval.

post-trial Acess

New rules 2019 define post trials essays as marketing new drug converting as marketing investigational new drug available to trial subject after complication of Clinical trial found beneficient to trials.

Now long post trial acess medicine should Provide to patient this is of special importance there is chronic disease with long treatment.

How is safety signal manifeted. for this period whould spasor investigators /ethics Committee.

• impost manufacture of Unapproved New drug.

under the rule 36 of Drug cosmetic rule 1945. Provision made for patient to apply for licence to import in unapproved new drug.

The applicant. is required toapply using from Registred

medical Practional (RMP) indicating

- **protcol & amendantes Components-**

-Policy Publication

safety Assement.

Assurance f quality.

mangement & hadling data

clinical trial Application process (CTA)

- Validation Submitted document
- No complete
- Requesting complete the submitted dose
- Defficiency requirement request on data missing on submitted file.
- No finding of missing data
- Evaluation Report Recommendation
- SFDA response (study food & drug authority)

The clinical trial application of approval Recommendation

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➢ **International conference on harmonization (ICH) E2e guidelines.**

- The main focus of guideline is on a safety specification and pharmacovigilance plant that might be submitted at the time of license application the guidelines are for sponsors.
- **Scope** -:
- The guidelines important for development for development of new drug.
- safety specifications
- Pharmacovigilance plan
- Annex pv method

The following principle under this guideline

1) planning of PV activities through the product Life cycle.

2) Science based approach to risk documentation.

3) Effective calibration between regulatory and IND.

The purpose of this guideline is to purpose a structure for a plan and safety specification that summarize the identified and potential risk of the product to be addressed in the plan it derived into the

A) Safety specification

B) Pharmacovigilance plan

C) Annex pharmacovigilance method.

For product with important identified risk important potential risk or important missing information the PV plant should include additional action design to address this concern.

Objective -:

This guideline are intended to aid planning pharmacovigilance activity specially in the preparation for the earlier post marketing period of a new drug.

- The main focus of this guideline is on the safety specification at pharmacovigilance plan that mightof be submitted at the time of licence application .
- This guidelines does not cover the entire scope of PharmacoVigilance is used that WHO definition of the term PV as the science and activities.
- Relating to the detection assessment understanding and prevention of effect or any other drug related problem.
- **Non-clinical** -:
- within the specification the section present non clinical safety.
- Inding that have not be adequate adressed by clinical data.
- **Toxicity** :
- including repeat dose toxicity reproductice development toxicity nephron toxicity hepatotoxicity genotoxcity curvonogencity.
- General Pharmacognosy cardiovascular including or interval prolongation nervous system

Drug interaction.

Other ttoxici related information or data.

If the product is intended for use in specific population consideration give to specific data needs exist.

Rifampicin

Discovery and development -Rifampicin we are first isolated 1957 from a fermentation culture of streptomyces mediterranei at the laboratory of gruppo lepetut SPA in Milan by a scientist named piero Sensi working with the Rifampicin also known as rifampicin is an asamycin antibiotic used to treat several type of bacterial infection including tuberculosis. Mycobacterium avium comple Monoisotopic: 822.40512334

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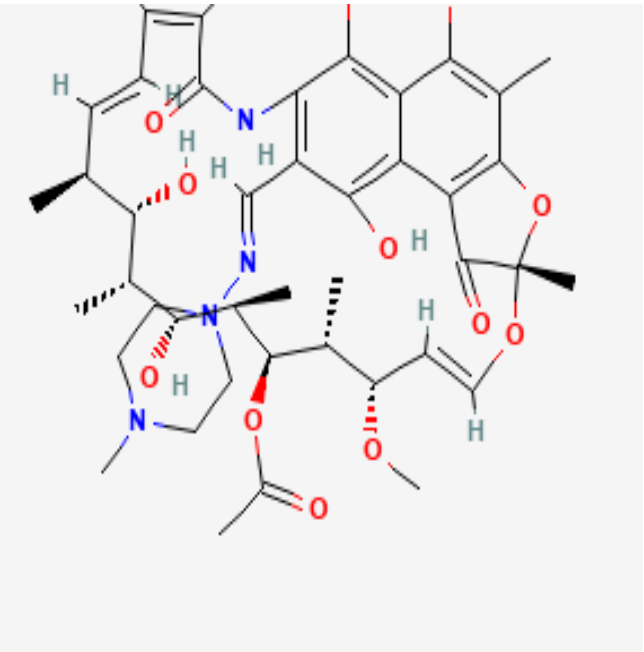
- **Structure**



- **Formula** –: C43H58N4O12
- **Brand name-:** Rifadin, Rimactane .
- **Generic name** -: rifampin
- **Bioavailability** -: 90% to 95%
- **Drug class** -: Antitubercular Agent
- **Absorption** –well absorbed from gastrointestinal tract.
- **volume of distribution**-NotAvailable-
- **Protein binding**-89%
- **Metabolism** : primarily hepatic, rapidly deacetylated.
- **Route Of elimination-** Less than 30% of the dose is excreted in the Usine as rifampin de metabolites.
- **Half-life-** 3-35 (+/- 0.66) hours.
- **clearance**-019+1-0.062 | hrling (300 mg IV]-0.14+/-0.031 |hr|kg [600mg lv
- **Toxicity**- LD so = 1570 mg/kg (rat), chronic exposure may cause nausea Vomiting inconsciousness.

- **Uses** -: rifampicin is used other medications to treat tuberculosis.
- **Rifampin is also used to treat the some people who have Neisseria meningitidis (a type of bacteria that can cause a serious infection called meningitis) infections in their noses or throats**.
- **Pre clinical research** -:

Tuberculosis remain the world dead infection disease.

In 2018 there were an estimated 10 million new tuberculosis patient or cases 1.5 million deaths Pulmonary delivery of anti tuberculosis drug is expected delivery high drug concentration of the desired site.

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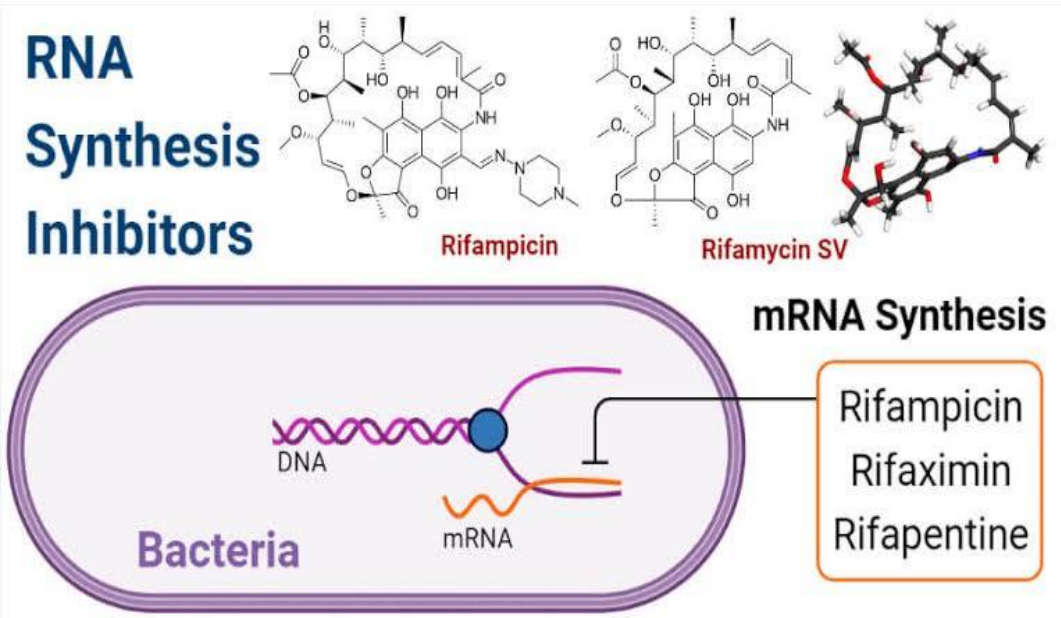
- It was by killing the bacteria that cause infection.
- Antibiotic such as rifampin will not work for cold flu or other viral .

➢ **Mechanism of action -**:

- Rifampicin is throughout to inhibit bacterial DNA dependent RNA polymerase.
- Which appear to occur as a result of drug Binding in the polymerase sub unit Deep.
- Rifampicin at via the inhibition of DNA dependent RNA polymerase leading to a supression of RNA synthesis and cell death.
- Bacteria under DNA polymer is transcription in process are help in bacteria. RNA polymerase entered in action for unwined.. This and when polymerasfirst RNA polymerase are join for next polymerase are is separationRNA polymerase DNA tablet is open and m RNA create to this Templet

This mRNA is our unwind form in this DNA against the rifampicin a polymers **Adverse effects.**

1. Fever .
2. Chills .
3. Rash.
4. Difficult to swelling .
5. Swelling of eye.
6. Breathing shortnest of heart.



- **Pharmacokinetics:** approximately 80% of rifampicin of is transported in blood bound to plasma protein mainly albumin.
- **Absorption**
- After oral administration on a empty Stomach the absorption of rifampicin is rapid practically Complete with single 6oomg dose peak Serum concentration of the order of 10 microgram. 1ml generally occur 2 hours after administration.
- Rifmpin is well absorbed when taken including orally distributed widery in body tissue and fluids the CSF it is metabolized in the liver elimination. much lesser extent bile & to in Urine.. But dose adjustment are with renal insuffreiency.
- **Distribution-**

Approximately plasma 80% of rifampicin is in blood bound to proteins mainly albumin.

Rifampicin is well although to distributed different degree in the various tissue human body. rifampicin Hepatocyte undergoes process of desacetylation.

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Drug distribution of high dose of drug in rifampicin. Inhaled delivery the Potential of rifampain to achieve high "'concentration in lung blood efficient treatment of tuberculosis.

- **Metabolism & elimination.**

Rifampin is well absorbed when taken orally of is distributed in body including tissue .

It is metabolised in the liver and eliminated in bile to a much lesser extent urine. but dose adjustment are renal unecessary insufficency. rifmpicin is rapidly eliminated dsacetyl rifampicinthan the compound is more polar parent compound.

elimination –

rifampicin is rapidly in bile & undergoes. elimination/ progessive enterohepatia Circulation deacetylation to primary metabolite 25 de desacetyl rifampicin.

This metabolite 30% of the dose is excreted in the urine of metabolites. as rifmpicin.

- **Toxicology of Rifampicin:**

Rifampicin is associated coith transient asymptomatic in biliaubin aminotransferase. levels cause clinically elevation known apparent acute liver disease that can severe & even fatal

- **toxicity-**

In toxic dose rifampicin is to produce hepatic renal known hematological disorder & convulsions.

report case of fatal poisoning with isoniazid & Rifampicin.

- **Genotoxicity of Rifampicin** observed genotoxic effect of antituberculosis drug combinations On rats. rifampcin is an effective liver enzyme induces promoting the up-regulation of hepatic cytochrome enzymes.
- **Standard allium** (cepa linn)
- There was also absolute at the root growth of A . Cepa Compared to control group head intensity decreased tail intensity & decorare tail intensity increased group tail migration increase
- Causes to double stand break of DNA damage at different degree in bood Kidney & liver cell in rats
- Genotoxic Chemicals extent their adverse effect through interaction with genetic material of cells.
- Genotoxicity tests are designed to detected drug which induce genetic damage directly of Indirectly by various mechanism of action.
- **Contraindication**.
- Contract indicated after heat surgery.
- **Design & Conduct of observational:**

The purpose this study to evaluate the Potential high dose of rifampin of shorten treatment for tuberculosis. Causing more adverse events.

Higher blood in concentration will result tuberculosis bugs being killing more both these are adverse events

The Study will the following among the 3 study arms. Oral dose of rifampicin10, 15 and 20 mg kg/day.

The amount after of rifampicin in the blood least 14 days treatments.

condition of disease Tuberculosis rifampicin. Intevention treatment- Drug higher Dose Rifampin .

Phase-2 Phase - multi-site dose-ranging phase trial Comparing rifampicin 3 doses of in a multidrug regime treatment smear positive Pulmonary TB.

The intervention phase Prospective randomized of the double-blinal trial will list 8 week the the duration. intensive Phase for for short course.

more than 85%was drug release over the period of 3 hr. Stability studies In stimulated Gastric fluid indicate that low realtive -decomposition of 18.5% was achieved with high drug.

- **Acute efficacy**

medinger A Death associated with rifampin & pyrazinamide 2- month treatment of Latent my cobacterium tuberculosis.

A 68 year old many history Positive tuberculin test requested antitubercuolsis therapy so as obulate the need for annual required employe.

He cas shorted on Rifampicin(600 mg dally) monitored monthly.

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Laboratory tests showed marked elevations in aminotransferase level of and bilirubin of 16.7 mg/dL.

He was given supporttive care but worsenin coma respiratory &renal failure & died 3 days after admission.

Froms &strength :

Rifadin (rifampin capsule usp) for orad adminstration contain 150 mg. 300 mg per capsule the also contains inactive ingredients corn as Starch D&C .

- **Selection of Drug:**

Identification of most drug Rifampin is a prescription medication Used for treatment. of tuberculosis

Bacteriologic cultures should be obtained before the start of threapy to confirm Susceptibility of organism of rifampicin be repeated to treament throughout therapy response to treatment

Dosage of consideration

Dosage Rifampin.

Adult & pediatric dosage capsules

- 150 mg
- 300 mg

➢ **Injectable powder**

- 600mg

➢ **side effect**

- heart burn
- abdominal pain
- Cibdominal pain
- loss of appetite.
- nausea
- Vomiting
- Yellowing Skin & eyes.
- destruction of red blood cells
- discoloration of the skin.

➢ **Conntraindications**: Hypersensitivity to receiving Contraindicated in patients receiving atazanavir, Saquinavir because rifampicin Substantial decreases in plasma conentration drugs which may result in loss of antiviral efficacy of development in viral **resistance**

➢ **Pediatric Dosage:** 10-20 mg / kg day intravenously of Orally.10-26 mg/kg orally twice weekly. not to exceed 600mg /day.

Storage- Rifadin IV rifampin for injection available in sterile. glass vials containing 600 mg rifampin .

➢ **Store :**

25°c prmitted to 15-30°c

Identification Adverse effect of selected drugs using different Search Lengines of adverse effects

➢ **ADR of Rifampicin :**

temporary discoloration

(yellow reddish-orange of brown colour of your skin, Saliva Urine stool Sweat & tears.

1) itching . flushing. headache & drowsiness . 4)Asthma.
2) **On lung**:swelling of eye. Shortness of breath

➢ **On skin** Rash blistering. Peeling of on loosing of the skin.
➢ **On CN** Headache.Drowsiness. AtaxiaDizziness.
➢ **On kidney-** Acute kidney from Injury is complication usually resulting interstitial nephritis . Hepatoxicity
➢ **On GIT:**Anorexia naused Gastrointestinal distribution
➢ **Heart Failute** Hpyertension Sodium retention.
➢ **Liver**: transient & asymptomatic 1 elevations in Serum aminotransfera & bilirubin levels. Cardiovasular problems.

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- **Selection of drug class:**
- selection of drug class for pharmacovigilance study using different criteria.
- **Commercial availability of Rifampicin:**

This **fact** are **the start** till 9 September 2022 based on volza's Goble supplier based in India product Rifampicin.

- **Seilling of drug :**

India export of Drug rifampicin sourced from 70 countries export import shipments with names of buyers suppliers top decision maker's information

Product category of Rifampicin 70 importsin world

- **Export data form /profile:**
  - **Date-** 20 Nov- 2016
  - **Indian port-** bombay air cargo
  - **CTH -** 30049057
  - **Item description-** Rifampicin tablet 24×28t
  - **Quantity –** 10
  - **UQC -** Box
  - **U. P. USD -** 19. 67
  - **Destination-** male
  - **Assess USD-** 196.70**Country -** malative
  - **Import of drug :** As per rifampicin import data of HS code Volza's India Rifampicin Exters & Suppliers directory, there are 15active Rifampicin exportinfg to 29 for maximum export market . These facts are starts till 21feb 2022 and are based Volza's of Rifampicin, sourced from 70 countries export import shipments with names of buyers, suppliers, top decision maker's contact information.
- **Adverse Drug reaction ADR Monitoring :**
  - prepration of ADR monitoring form as preguldlineAMCS.

e.g.- Indian pharmacopeial Commission.

  - process of induction AMC'S under PUPI
  - MCI approved medical college institution & Hospital.
  - furnishing letter of intent the sending.
  - Daily forward by head of the institution.
  - NCC -PVPI
  - Examining the stability by NCC

WHO - VMC

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Version-1.2

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For VOLUNTARY reporting of Adverse Drug Reactions by Healthcare Professionals

INDIAN PHARMACOPOEIA COMMISSION
(National Coordination Centre-Pharmacovigilance Programme of India)
Ministry of Health & Family Welfare, Government of India
Sector-23, Raj Nagar, Ghaziabad-201002

FOR AMC/NCC USE ONLY

AMC Report No. :

Report Type ☐ Initial ☐ Follow up

Worldwide Unique No. :

A. PATIENT INFORMATION

1. Patient Initials _____

2. Age at time of Event or Date of Birth _____

3. M ☐ F ☐ Other ☐

4. Weight_____Kgs

12. Relevant tests/ laboratory data with dates

B. SUSPECTED ADVERSE REACTION

5. Date of reaction started (dd/mm/yyyy)

6. Date of recovery (dd/mm/yyyy)

7. Describe reaction or problem

13. Relevant medical/ medication history (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/renal dysfunction etc.)

14. Seriousness of the reaction: No ☐ if Yes ☐ (please tick anyone)

☐ Death (dd/mm/yyyy) ☐ Congenital-anomaly
☐ Life threatening ☐ Required intervention to Prevent permanent
☐ Hospitalization/Prolonged impairment/damage
☐ Disability ☐ Other (specify)

15. Outcomes

☐ Recovered ☐ Recovering ☐ Not recovered
☐ Fatal ☐ Recovered with sequelae ☐ Unknown

C. SUSPECTED MEDICATION(S)

S.No	8. Name (Brand/Generic)	Manufacturer (if known)	Batch No. / Lot No.	Exp. Date (if known)	Dose used	Route used	Frequency (OD, BD etc.)	Therapy dates		Indication	Causality Assessment
								Date started	Date stopped		
i											
ii											
iii											
Iv											

S.No as per C	9. Action Taken (please tick)						10. Reaction reappeared after reintroduction (please tick)			
	Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown	Yes	No	Effect unknown	Dose (if reintroduced)
i										
ii										
iii										
iv										

11. Concomitant medical product including self-medication and herbal remedies with therapy dates (Exclude those used to treat reaction)

S.No	Name (Brand/Generic)	Dose used	Route used	Frequency (OD, BD, etc.)	Therapy dates		Indication
					Date started	Date stopped	
i							
ii							
iii							

Additional Information:

D. REPORTER DETAILS

16. Name and Professional Address:_____
_____
Pin:_____E-mail_____
Tel. No. (with STD code)_____
Occupation:_____ Signature:_____

17. Date of this report (dd/mm/yyyy):

Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. Programme staff is not expected to and will not disclose the reporter's identity in response to a request from the public. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction.

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II. CONCLUSION

The systematic review update provide evidence and utilize Rifampicin estimate the performance of rapid test for Rifampicin in resistance. they are significantly interfere to regiments that use the Rifampicin at least 6 mo this review limitation in test ppv for rifampicin.

In resistance MDR TB WHO high burdeTB countries for power clinical trial that dosing schedule management of Mono - resistance optimal duration of treatment to prevent relapse. as a predictors in resistance and MDR TB and Rapid trapy safety for rating drug resistance.

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