

# A Research Article on Determination of Safety and Efficacy of Antiviral Drug in Subject with Covid-19

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**Abstract:** Studied a male covid patient, during treatment maximum amount of drugs were given like Pirfenex tablet, Omnacortil tablet, Multitone tablet, Macdor ASP tablet, Budetrol 200 Tablet and Xplode protein powder for about 15 days . When checked after 10 days the patient was notcured successfully . And some of tablets were still in process like frestina tablet, Pirfenex tablet, etc. While treatment patient was injected Remdisivir and some high power drugs due to that side effects and interactions were noticed and treatment was started immediately with atorea ASP tablet, Budetrol tablet, Toyo 60 k orange tablet. For about 55 days drugs like Auxipam DSR, it's camp + 10 tablet, CZ daily tablet, and KT oral DT tablet were given and the patient was back to normal condition and cured successfully and is healthy.

**Keywords:** Pirfenex, omnacortil Tablet, Frestina Tablet, Remdesivir injection

## I. INTRODUCTION

### 1.1 What is Pharmacovigilance?

WHO defines Pharmacovigilance as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems. The scope of Pharmacovigilance had grown remarkably and is now considered to include the following domains:

- Medication errors
- Counterfeit or substandard medicines
- Lack of efficacy of medicines
- Misuse and/or abuse of medicines
- Interaction between medicines

### 1.2 Objectives

1. To monitor Adverse Drug Reactions (ADRs) in Indian population
2. To create awareness amongst health care professionals about the importance of ADR reporting in India
3. To monitor benefit-risk profile of medicines
4. Generate independent, evidence-based recommendations on the safety of medicines
5. Support the CDSCO for formulating safety related regulatory decisions for medicines
6. Communicate findings with all key stakeholders
7. Create a national center of excellence at par with global drug safety monitoring standards

### 1.3 Components of Pharmacovigilance

Core Capabilities: Pharmacovigilance delivers four primary capabilities to pharmaceutical companies

#### A. Types of Pharmacovigilance

They may vary in presentation and occurrence and are commonly divided into type A (augmented pharmaceutical response) and type B (bizarre or hypersensitivity) adverse drug reactions throughout a drug's market life. Pre-marketing safety assessment is generally limited for children.

**Pharmacovigilance Programme of India (PvPI)**

1. Launched by the MoHFW, Govt. of India in the year 2010 at AIIMS New Delhi as National Coordinating Centre (NCC).
2. The Programme transferred to IPC as NCC in April, 2011 by a Notification issued by the MoHFW, Govt. of India.
3. IPC-PvPI became the NCC for Materiovigilance Programme of India (MvPI) from July, 2015
4. IPC, NCC-PvPI became a WHO Collaborating Centre for Pharmacovigilance in Public Health Programmes & Regulatory services from July, 2017

In India, PvPI is closely working with CDSCO, drug regulatory authority of India. CDSCO understands that Pharmacovigilance plays a specialized and pivotal role in ensuring ongoing safety of medicinal products in India and it seeks inputs from NCC before taking any kind of regulatory decisions. NCC-PvPI is working in close coordination with CDSCO zonal offices also for technical, administrative, and logistics matters related to PvPI. The role of NCC in collaboration with other national and international organizations to promote patients safety is illustrated

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| Functions of the Stakeholders |  |                     |   |

**List of ADR monitoring centers under pharmacovigilance programme of India**

|   |   |
|---|---|
| PvPI ADR Monitoring Centre in Medical College (PvPI AMCs)   | <ul style="list-style-type: none"> <li>• Collection of ADR reports</li> <li>• Perform follow up with the complainant to check completeness as per SOPs</li> <li>• Data entry into Vigiflow</li> <li>• Reporting to PvPI National Coordinating Centre (PvPI NCC) through Vigiflow</li> <li>• Training/ sensitization/ feedback to physicians through newsletters circulated by the PvPI NCC</li> </ul> |
| PvPI ADR Monitoring Centre other than medical colleges [Corporate hospitals, autonomous institutes, public health programmes] | <ul style="list-style-type: none"> <li>• Collection of ADR reports</li> <li>• Perform follow up with the complainant to check completeness as per SOPs</li> <li>• Report the data to CDSCO HQ</li> </ul>  |
| A   | <ul style="list-style-type: none"> <li>• Preparation of SOPs, guidance documents &amp; training manuals</li> <li>• Data collation, Cross-check completeness, Causality Assessment etc as per SOPs</li> <li>• Conduct Training workshops of all enrolled centers</li> <li>• Publication of Medicines Safety Newsletter</li> </ul>  |
| C   | <ul style="list-style-type: none"> <li>• Publication of Medicines Safety Newsletter</li> <li>• Reporting to CDSCO Headquarters</li> <li>• Analysis of the PMS, PSUR, AEFI data received from CDSCO HQ</li> </ul>  |

|                              |  |
|------------------------------|--|
| ZONAL/Subzonal CDSCO Offices | <ul style="list-style-type: none"> <li>• Provide procurement, financial and administrative support to ADR monitoring centers</li> <li>• Report to CDSCO HQ</li> </ul>  |
| CDSCO, HQ, New Delhi         | <ul style="list-style-type: none"> <li>• Take appropriate regulatory decision &amp; actions on the basis of recommendations of PvPI NCC – AIIMS.</li> <li>• Propagation of medicine safety related decisions to stakeholders</li> <li>• Collaboration with WHO-Uppsala Monitoring Center – Sweden</li> </ul> |

## II. SELECTION OF DRUG CLASS

### Antiviral

Antiviral drug are a class of medication used for treating viral infection Most antiviruses target specific viruses, while a broad spectrum antibiotic is effective against a wide range of viruses and like most antiviral drugs do not destroy their target pathogen, instead they inhibit its development.

### Mechanism of action

The virus settles in the nasal passage and starts replicating throughout the body.

↓  
They across the healthy cell

↓  
If the virus enters the lungs it can invade tiny,air sacs

↓  
And causes pneumonia

↓  
At this point the lungs will become inflamed and it's harder to breath.

↓  
CT scan test

↓  
COVID – 19 detected

### Selection of Drug

**Pirfenex 200 tablet**

Structure-

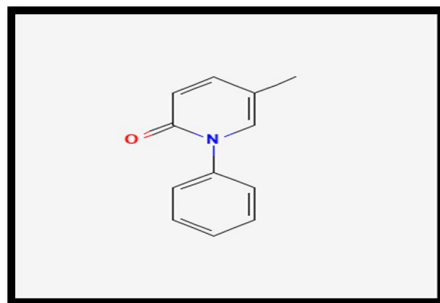


Fig No. 1

Chemical name- Pirfenidone

IUPAC name- 5-methyl-1- phenyl pyridin-2(1H)-one

Molecular weight- 185.22

Manufactured by- Cipla

Mechanism of action-

A number of said base studies have shown that pirfenidone reduces fibroblast proliferation, inhibits transformation growth factor beta stimulated collagen production and reduces the production.

Side effect.-Nausea, Vomiting, Headache, Stomach pain, Diarrhea.

**Omnacortil tablet**

**Structure-**

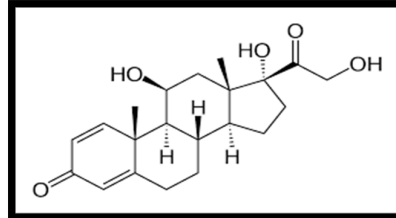


Fig No.2

Chemical name-Prednisolone

IUPAC name-Metacortadrolone hydroretrocortione.

Molecular weight-360.4

Manufactured by- Macleods

Mechanism of action-

After administration Prednisone is converted to prednisolone. Anti-inflammatory effects are complex but involve binding to cellular glucocorticoid receptors, prednisolone acts to inhibit inflammatory cells & suppresses the expression of an inflammatory mediator.

Side effects--Upset stomach, Weight gain, Mood change, Reduction in bone density

**CASE REPORT:**

**Patient personal information**

Gender -male

Age -45

Habit-no

Blood group-o+

Weight-80kg

**Diagnosis**

Swab nasal test -positive

Aspirate -positive

Blood test -positive

| Test Name        | Test Value | Normal Range                   |
|------------------|------------|--------------------------------|
| Hemoglobin       | 12.7       | 13-18                          |
| RBC              | 4.51       | 4-5.4 10 <sup>6</sup> /ul unit |
| blood sugar      | 164.4      | 70-160 unit mg/dl              |
| Serum creatinine | 1.2        | 0.6-1.4 unit mgs%              |

C.R.P (C reactive protein)  
Method - Turbidimetry  
Observation - 10.9  
Result - Positive  
C T Scan  
Level of suspicion covid-19

**C T SCAN**

Level of suspicion covid-19

**Table CT scan report**

|            |              |  |
|------------|--------------|--|
| CO-RADS 1  | NO           | Normal   |
| CO-RADS 2  | Low          | Abnormalities Consistent with infections other than covid-19 |
| CO-RADS 3  | Intermediate | Unclear whether covid-19 is present                          |
| CO-RADS 4  | High         | Abnormalities suspicious for covid-19                        |
| CO-RADS 5  | very high    | typical covid-19   |
| CO- RADS 6 | PCR plus     | Normal   |
| CT-Score   | 9/25         | Moderate severity  |

**Treatment:**

**1) Pirfenex tablet-**

Uses- It is used in the treatment of idiopathic pulmonary fibrosis  
Dose- 200 MG tablet used twice in two times at morning and night.  
Daily Dose- 400 mg 10 days.  
Dose frequency- 400mg or 4 gm.

**2) Omnicortil tablet-**

Uses- It is used in the medical condition search as severe allergic reaction,an allergic condition, asthma, skin, eye disorder and rheumatic disorderProvides relief from implementation.  
Dose- 10mg tablet use in the one time at morning Daily dose10 mg 5 days  
Dose frequency- 50 mg or 0.05 g m  
Dose route- Oral

**3) Multitone tablet-**

Uses- is used in the treatment of mineral deficiency heart attack chest pain,leg pain, due to blocked arteries,high blood pressure, pregnancy-relateddigestive disorder, infection of the intestine and other condition  
Dose - It is used in the 1 time at morning  
Daily Dose- 10days

**4) Maodor ASP tablet:-**

Uses- It is used in combination with a drug of blood thinning agent and cholesterol lowering agent. Primary taken for the prevention of heart attack and stroke.  
Dose- 75 mg tablet use at one time at night.  
Daly dose - 75 mg 10 days  
Dose frequency- 750 MG or 0.75 gram

**5) Budetrol 200 Tablet:-**

Uses- It is used to treat chronic obstructive disease and asthma, The symptoms may include wheezing, shortness of breath and 200 mg tablet.

Dose- use in two time at morning and night.

Daly dose- 200 mg one day.

**6) Xplode protein powder:-**

Uses - It is used for aphrodisiacs, stimulant folic acid deficiency, vitamin b12 deficiency Addisonian anemia small bowel bacterial overgrowth.

Dose- At 2 time morning and night. Trestina Tablet Uses It is used in the treatment of depression

At one time night 10 days

**After 10 days**

**Pirfenis tablet:-**

Uses- It is used in the treatment of idiopathic pulmonary fibrosis It reduced scaming and swelling in the lungs and help to breathe better.

Dose- 200mg tablet use in a two time at morning and night

Daily dose- 400mg 15 days.

**2) Omnacortil tablet-**

Uses- It is used to treat a wide variety of medical conditions such as severe allergic reaction, allergic condition, asthma, skin and eye disorder, rheumatic disorder. nephrotic syndrome

Dose- 5 MG tablet use in one time at morning

Daily dose- 1 half MG 5 days

**3) Mactor ASP 75/10:**

Uses- It is to prevent heart attack and stroke. It lowers the bad cholesterol (LDL). triglycerides and raises the good cholesterol (HDL) level in the body.

Dose- One MG tablet use in one time at night

Daily dose- 1MG 15 days

**4) Budetrol:**

Uses- It is used to treat chronic obstructive pulmonary disease and asthma.

Dose- 200 mg tablet use twice in two mornings and at night

Daily dose -400 MG 15 days

**5) Frestina tablet**

Uses- It is used in the treatment of depression it is helped by increasing the level of chemical messengers in the brain that relax than brain and nerves

Dose-1 mg use in one time at night

Daily dose-1mg 15 days

**Remdesivir injection**

Uses- hospitalization is used to treat coronavirus disease 2019 covid-19 in a patient need Remdesivir is an antiviral medicine that works against severe acute respiratory syndrome coronavirus 2(SARS-cov-2).

Dose- 100 mg/20 ml our 5 mg per ml

For use only IV single dose viral. It is used for India only, not for export and for use in hospital set up.

**Side effects-**

- 1) Joint pain
- 2) Shortness of breath
- 3) Chest pain
- 4) Muscle pain
- 5) Sleeping problem
- 6) Dizziness when you stand
- 7) Fast or pounding heart beats
- 8) Loss of smell of test

**Treatment of side effects**

**1) Atoreo ASP 75/10:**

Uses- It is used to prevent heart attack and stroke. It's lower the bad cholesterol LDL, triglycerides and rises the good cholesterol HDL level in the body. Decreases the formation of blood clots.

Dose- Very MG use in time 1 at night

Daily dose- 1MG 30 days

**2) Budetrol 200:**

Uses- It is used to treat asthma symptoms and chronic obstructive pulmonadisease COPD.

Asthma is a chronic long-term respiratory condition in which Airways narrow, swell and produce extra mucus.

Dose- 200mg dose in one time at morning

Daily dose- 200 mg one day

**3) Tayo 60K orange Tablet-**

Uses- It is used to treat low blood calcium level eat effectively treat various condition in the body like v d deficiency. It contains cholecalciferol (vit D3).

Dose- 1 day

Dose frequency- 4 tablet

**After 55 days-**

**1) Auxipan DSR**

Uses- It is used to treat gastro-oesophageal reflux disease, acid reflux and ulcer disease by relieving the symptoms of acidity such as in digestic stomach pain, heartburn

Dose- 30 MG use in one time at morning. Daily dose 30 MG 10 days

**2) It camp +10-**

Uses- It is used to treat anxiety disorder. It is the combination medicine that the brain by decreasing the abnormal and excessive activity of the ncell.

Dose- 10 MG at one time at night.

Daily dose- 10 mg 15 days.

**3) CZ daily tablet-**

Uses- It is used to treat gynecological infections, teeth and urine infection, infection and abdominal infections such as acute diarrhea.

Dose- 600 MG use in one time at morning

Daily dose- 600 MG 7 days



**4) Kit oral DT tablet-**

Uses- It is short term relief of pain and inflammation and swelling in conditioaffects joint and muscles.

Dose- 10 MG used in to time at morning and night

Daily dose- 20 MG 7 days.

**III. CONCLUSION**

Studied a covid patient and their diagnosis test was done where the patient was covid positive and covid treatment was started immediately, where the patient was hospitalized and Pirfenex tablet, Omnacortil tablet, Multitone tablet were given. About 10 days later,Redmi Sivr was injected and drug interaction happened because of that side effects were noticed and further treatment was taken and the patient was cured successfully.

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