

RE: ZOLEDRONIC ACID (Rokfos) ADVERSE DRUG REACTION

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D Drugsafety/CLINICAL/RPLAZA <drugsafety@Cipla.com>

 Reply |

Thu 7/7/2016, 7:31 AM

You: Product Queries/CQA/VKH R&D (productqueries)

Dear Umeshchandra,

Thank you information.

Warm Regards,
Drug Safety

From: Umeshchandra Barkur [mailto:umeshchandrabarkur@hotmail.com]

Sent: Thursday, July 07, 2016 12:20 PM

To: Drugsafety/CLINICAL/RPLAZA

Cc: Product Queries/CQA/VKH R&D

Subject: Re: ZOLEDRONIC ACID (Rokfos) ADVERSE DRUG REACTION

 Dear Sirs, This pertains to the death of my wife as is evident from your mail to me.

I think Dr.Akhtar had spokent to me and all the officials of your company had been kind and co-operated with me.

Attached herewith is a file giving the status of my enquiry regarding ADR in this case and i still have no answers from the treating doctor viz.Dr.Goswami of Maruti Nursing Horne.

I would like to meet CIPLA officials alongwith the Audio of the meeting at Maruti Nursing Home wherein 3 doctors have admitted categorically that ROKFOS caused the ADRs.

 Hoping for co-operation from your esteemed company as given to me earlier,

Yours Sincerely,

 Umeshchandra Barkur

From: drugsafety@Cipla.com <drugsafety@Cipla.com>**Sent:** Wednesday, August 27, 2014 7:47 AM**To:** umeshchandrabarkur@hotmail.com**Cc:** Product Queries**Subject:** ZOLEDRONIC ACID (Rokfos)

Dear Umeshchandra,

We have received your email dated 16th August 2014 and we are sorry to learn about the loss of your wife. Please accept our condolences.

A number of factors like historic information, accurate data, regular analysis, daily reports, physical examination, regular monitoring, blood report, other examination reports, condition of the patient etc., which are required to be considered to conclude whether a particular drug is required to be administered to a patient

at a specific time. Hence, a qualified medical professional, carrying out a treatment of a patient would be the right person to decide whether a particular drug can be administered to the patient. 121

The information of our product is available in the product information leaflet a copy of which is attached herewith for your ready reference. Apart from that we are also attaching herewith the frequently asked questions and the answers to the same, for your information.

The channel for sale of our product is Stockist - Wholesaler - Retailer - Consumer. Respective nursing home would be the right source to disclose where they purchased the medicine from.

We trust that the information attached herewith satisfies your requirement.

Yours faithfully,
Drug Safety,
Cipla Ltd.

ADVERSE DRUG REACTION

Product : IV ROKFOS (ingredients – Zoledronic Acid)

Patient : Smt.Kamini U.Barkur

Date of death : 24th June 2014 at Jupiter Hospital, Thane

ADR at : Maruti Nursing Home (Dr.Mihirgiri Goswami)

ADR reported to : National Pharmacovigilance Centre

under Central Drugs Standard Control Organisation (CDSCO), New Delhi

on 22/10/2014.

(Copy of ADR available)

Drugs Controller General of India – Letter sent alongwith ADR form enquiring

Indications for the use of Zoledronic Acid in India.

Director General of Health Services – Office of DCG : Reply received from Central

Public Information Officer giving indications for the use of Zoledronic Acid on

5th Aug.2015. Received reply from Mr.Sunil Kulshetra (Central Public

Information Officer, Dir.Gen of Health Services, FDA Bhawan, New Delhi).

2nd July 2014 : Patient's husband sends letter to Dr.Goswami seeking information on reasons for the sudden turn of events.

1st Aug.2014 : Dr.Goswami replies vide E-mail that patient died after diagnosis of Aplastic Anemia (Bone Marrow Failure) leading to complications.

20th Aug.2014 : Under pressure from patient's husband, Dr.Goswami arranges for meeting on 22nd Aug 2014 with patient's husband, brother and

daughter. Also says that he cannot assemble doctors from Platinum Hospitals and Jupiter Hospitals. Only Dr.Dolare, Dr.S.L.Korgaonkar and Dr.Satyen Mehta

will be at the meeting. Meeting was arranged after E-mails were exchanged between Dr.Goswami and the patient's husband Umeshchandra Barkur.

22nd Aug.2014 : Meeting was not attended by Dr.S.L.Korgaonkar and Dr.Satyen Mehta. Instead Dr.Dubey (TPA Health Services Officer)

attends the meeting and also argues on behalf of Dr.Goswami.

Dr.Dubey is the person procuring medicines for Maruti Nursing

Home as also for cash dealings with patients. Also Physician (Dr. Dolare) who certified the patient "fit for surgery" attended the meeting.

Meeting lasted for 2 hours and 43 minutes and was recorded on a mobile. A shortened edited version of 31 minutes is also available.

CIPLA : Before the meeting Dr. Goswami gives the relatives copy of

"Indications for the use of ROKFOS" obtained by him from CIPLA

The drug manufacturer. CIPLA also sends the same to patient's

Husband vide E-mail. The entire meeting centred on ROKFOS and

ZOBONE (different brands for Generic drug name Zoledronic Acid).

ADMISSIONS BY DR. GOSWAMI, DR. DOLARE AND DR. DUBEY

* On being questioned by relatives regarding the death of the patient, Dr. Goswami says that it is an unfortunate thing and that he is also investigating. Hence he got the booklet from CIPLA regarding ROKFOS.

* Also says that ROKFOS is given by him frequently and on admission decided to give because of his experience of safety. Says given by him on daily basis (not given once in a blue moon). At times says that it is given once or twice in 12 months. Says adverse reaction is very rare.

* When asked that he thought he gave ZOBONE but actually gave ROKFOS he replies that both were at ICU places. These drugs were given at Maruti Nursing Home and not at Platinum Hospitals or Jupiter Hospitals.

* Says that he has given to his mother also. From a simple neck pain (given because of one day admission). Give today and discharge tomorrow. One very rare reaction – we are also shocked.

* Dr. Dubey says "Dramatic reaction never seen before"

* Dr. Goswami also says that he was following up at Platinum and Jupiter Hospital with the Haematologist. Also says that he will stop giving ROKFOS now.

* Dr. Dubey says that this is not so simple an injection and for this injection there is a procedure.

* When asked what is the procedure on adverse reaction Dr. Goswami says "We have

to report it and hence he got the indications for use of ROKFOS from CIPLA.

* Dr.Dubey says that he supplies drugs to 25 hospitals and 3 orthopedics with full responsibility but has not seen such a dramatic reaction before.

28th April 2015 : Patient's husband Umeshchandra Barkur wrote to FDA (Mumbai).

22nd July 2015 : FDA raids premises of Maruti Nursing Home and seizes drugs sold illegally i.e.without licence.

5th Aug.2015 : Received reply from Mr.Sunil Kulshetra (Central Public Information Officer,Dir.Gen of Health Services,FDA Bhawan, New Delhi) for Indications for the use of Zoledronic Acid.

ANSWERS REQUESTED BY PATIENT'S RELATIVES

* Since patient's relatives have not received any answer in writing regarding the Adverse Drug Reactions leading to the death of the patient from the doctors , I Umeshchandra Barkur am requesting CIPLA the following :

a) Whether Dr.Goswami has reported the ADR to CIPLA or to National Pharmacovigilance Centre or to the Drug Controllers.

b) I will be following up with National Pharmacovigilance Centre as well as Drug Controllers and as such would like to meet CIPLA officials to get full clarity about ROKFOS.

POINTS FOR CLARIFICATION

* From the meeting held on 22nd August 2014 the doctors at Maruti Nursing Home have admitted to Aplastic Anemia or Bone Marrow Failure due to drugs administered by them.

* Why does Dr.Goswami say "Both Zobone and Rokfos were given at ICU places i.e.Platinum Hospitals and Jupiter Hospital whereas they were given at Maruti Nursing Home.

* There is no record of these drugs at Platinum & Jupiter Hospitals In-Patient records whereas Dr.Goswami says that he was in touch with doctors at both the hospitals.

* Nursing records at Maruti Nursing Home says "IV Zolebon" and there is no mention of IV Rokfos.Only the outer box of the drug is attached to In-Patient records.

* There is no record of precautions and tests for Rokfos (contraindicated in patients with creatine clearance <35 ml/min).No Bone Density tests done.Administered on admission rightaway.

* CIPLA booklet Adverse reactions for Rokfos indications – All reactions have taken place in the case of Smt.Kamini Barkur (Blood disorders – Thrombocytopenia,Pancytopenia,Petechiae -- rashes,Nutritional disorders-unable to swallow,Arthralgia,bone pain,muscle pain,etc.Blood Calcium decrease and Blood Creatinine increase.

* What is the procedure for following up with ADR reported by patients?

* Whether Maruti Nursing Home have reported the ADR since it is their own admission that these reactions caused the death.

* Why no response from Dr.Goswami on ADR.

* What is the reason for misleading the relatives?

* Finger points to drugs given illegally – No licence for selling drugs at Maruti Nursing Home - (either expiry-dated or other drugs given which caused the ADRs).

* Since Dr.Goswami,Dr.Dolare and Dr.Dubey have admitted on record for ADRs that was responsible for the death,Why is there absolutely no mention of the same in the In-Patient records at Maruti Nursing Home or Platinum Hospitals or Jupiter Hospital?

* If prescription to treating Nurse was IV Zobone which is also Zoledronic Acid and Nurse also wrote IV Zolebon,why Rokfos box is attached to the In-Patient records.Was IV Zobone administered (could be expiry-dated) and Rokfos box attached to mis-guide relatives.