Internship
At

Submitted By
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STUDENT DECLARATION

I hereby declare that this report submitted in partial fulfilment of the requirement the award for Post Graduate Diploma in Pharmaceutical Management to IHMR Institute of Health Management Research, Jaipur is my original work and not submitted for award of any degree or diploma fellowship or for similar or for similar titles or prizes.

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Place: Mumbai

Date: 15th june 2013

Name: Tanvi Gupta

Class: PGDPM (IHMR)

Roll No.: 04-192

CERTIFICATE

This is to certify that the dissertation submitted in partial fulfilment for the award of IHMR College is a result of the bonafide research work carried out by Ms. Tanvi Gupta under my supervision and guidance, no part of this report has been submitted for award of any degree, diploma, fellowship or other similar titles or prizes. The work has also not been published in any journals/Magazines.

Industry Guide: Prasad Zore

Designation: Sr. Marketing Manager

Company: Sun Pharmaceuticals

Date: 15th june 2013

Place: Mumbai

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INTRODUCTION TO THE COMPANY

Sun Pharma started business in 1983 with just 5 products. Now it is leading Pharmaceutical company in India, ranked 3th largest in prescription by sales. It is the second largest and most profitable company with annual turnover of $ 13 billion. It is an international pharma company, with large presence in US and India and footprints across 41 countries, with total income of 59913 million Rs. By 2010-2011.

It is largest chronic prescription based company and market leader in psychiatry, neurology, cardiology, orthopaedics, ophthalmology, gastroenterology, nephrology. It has 23 manufacturing plants in 3 continents and 4 world class research centers over 1200 employee. 60% of the sales from international market.

HISTORY OF SUN PHARMA

- 1983 – Established by Mr. Dilip Shanghvi in 1983 in Kolkata with five products to treat psychiatry. Sales were only limited to two eastern states.
- 1987 – Products for cardiology were introduced, Monotrate, one of the first product launched, continues to be sold even today.
- 1993 – First research centre, SPARC, created the base for strong product and process development.
- 1994- Sun pharma was listed on the main stock exchange in India.
- 1995- First API Plant was built in Panoli for access to high quality activities.
- 1996-Ahmednagar API plant was acquired from the multinational Knoll Pharmaceuticals
- 1997 – Headquaters shifted to Mumbai. First international acquisitions with an initial of $7.5 million investment in Caraco, Detroit.

- 2000- Completed 8 acquisitions. A new research center was set up in Mumbai for generic product development for US market. Rank shifted from 38th to 5th with a leadership in 8 of 11 therapeutic areas. This year was a year of turnaround at US subsidiary, Caraco, as it began to receive approvals after successful inspection by the USFDA.
- 2004- A research center spread over 18 acres was inaugurated by the president of India
- 2005 – Witnessed important acquisition to strengthen US business, purchase of manufacturing asset for in Cranbury, NJ.
- 2010- Acquisition of Taro Pharmaceutical doubled the size of US business brought a range of generics including a strong line of dermatology.
- 2011 – 23 manufacturing plants in three continents, and 4 world class research centres. Now, 60% of the sales is from international business.
- 2013-Sun Pharma is now 2nd largest company in India with a MAT value of Rs. 350 crores.

Top ten brands in India

Brand	Therapy
Pantocid	Proton pump inhibitor/ antiulcerant
Glucored Group	Oral antidiabetic
Susten	Women's healthcare
Aztor	CVS, cholesterol reducing agent
Pantocid-D	Proton pump inhibitor/ antiulcerant
Gemer	Oral antidiabetic
Repace Group	CVS, Hypertension
Strocit	CNS, stroke
Clopilet	CVS, anticlotting agent
Encorate chrono	CNS, epilepsy

INTRODUCTION TO THE PROJECT

Osteoporosis

A systemic skeletal disease characterized by low bone mass & microarchitectural deterioration of bone tissue leading to enhanced bone fragility and a consequent increase in fracture risk."

Bone is made up of Living, growing tissue which Provides framework to the body. It is made up of 65 % minerals (Calcium, Magnesium , Phosphates etc) 35% matrix : collagen .

Bone Remodelling

Bone is living, growing tissue that constantly forms new bone while replacing older bone. Bone continuously renews and changes through a process called remodeling. The bone remodeling cycle consists of two distinct stages: (1) bone resorption (breakdown or removal) and (2) bone formation. During resorption, special cells (osteoclasts) on the bone's surface dissolve bone tissue and create small cavities. During formation, other cells (osteoblasts) fill the cavities with new bone tissue.

Anti-resorptive activity

Bisphosphonates, Calcitonin, Denosumab, Estrogen and Estrogen agonists/antagonists are anti-resorptive medicines. They slow the bone loss that occurs in the breakdown part of the remodeling cycle. When people first start taking these medicines, they stop losing bone as quickly as before, but still make new bone at the same pace. Therefore, bone density may increase. The goal of treatment with anti-resorptive medicines is to prevent bone loss and lower the risk of breaking bones.

Anabolic drugs

Teriparatide, a form of parathyroid hormone, increases the rate of bone formation and is in a distinct category of osteoporosis medicines called anabolic drugs. This is currently the only osteoporosis medicine approved by the FDA that rebuilds bone. The goal of treatment with Teriparatide is to build bone and lower the risk of breaking bones.

TREATMENT TO MANAGE OSTEOPOROSIS

Therapy	Efficacy	Safety	Convenience
Bisphosphonates (1^{st} line drug therapy)	Reduces vertebral , non vertebral & hip fractures	Short term GI tract tolerability and renal toxicity	PO daily , weekly , or monthly or IV every three months or once a year
SERMs (Raloxifene) 2^{nd} line therapy for women	Reduces vertebral risk factors	Risk of coronary heart disease , thromboembolic events	PO administration once daily
Calcitonin (elderly people)	Reduces vertebral risk factors	Minor adverse effects	Itranasal or IV
Teriparatide	Reduces vertebral & non vertebral fractures	Osteosarcoma observed in rats	Daily subcutaneous injection
Strontium Ranelate	Reduces vertebral & non vertebral	Higher incidence of eczema , dermatitis	PO administration daily(granules dissolve in the water)

Bisphosphonates

1. Ibandonate
2. Alendronate
3. Residronate
4. Zolidronate

Ibandronate Sodium

Ibandronate is approved for the prevention and treatment of osteoporosis in postmenopausal women. It is also approved for the treatment of glucocorticoid-induced osteoporosis in men and women as a result of long-term use of steroid medicines (examples are Prednisone and Cortisone).

For both prevention and treatment, Ibandronate is taken once monthly as a 150 mg tablet. For treatment, it is also available as an intravenous (IV) injection of 3 mg given every three months. Ibandronate increases the bone density and reduces the incidence of spine fractures by about 50 percent over three years. Meta analysis study says that Ibandronate lead to 30% reduction in non vertebral fractures. It has also launched in India in kit form with calcium and vitaminD3.

Alendronate Sodium

Alendronate is approved for the prevention and treatment of osteoporosis in postmenopausal women and for the treatment of osteoporosis in men. Alendronate reduces bone loss, increases bone density and reduces the risk of spine, hip and other fractures by about 50 percent over two to four years.

For prevention, Alendronate is taken daily as a 5 mg tablet or weekly as a 35 mg tablet. For treatment, it is taken daily as a 10 mg tablet or weekly as a 70 mg tablet with or without vitamin D3.

Risedronate Sodium

Risedronate is approved for the prevention and treatment of osteoporosis in postmenopausal women and for the treatment of osteoporosis in men. Risedronate slows bone loss, increases bone density and reduces the risk of spine and non-spine fractures by 35 to 45 percent over three years.

For both prevention and treatment, Risedronate is taken daily as a 5 mg tablet, weekly as a 35 mg tablet that is available with or without separate calcium carbonate tablets, twice monthly as a 75 mg tablet.

Zoledronic Acid

Zoledronic acid is approved for the prevention and treatment of osteoporosis in postmenopausal women. It is also approved to increase bone mass in men with osteoporosis and for the prevention of new clinical fractures in patients who have recently had a low-trauma hip fracture. In 2009, it was approved for the prevention and treatment of glucocorticoid-induced osteoporosis in men and women as a result of long-term use of steroid medicines (examples are prednisone and cortisone).

Zoledronic acid is given once a year as an intravenous (IV) infusion to treat osteoporosis. It is also given every two years as an IV infusion to prevent osteoporosis.

Zoledronic acid increases bone density and reduces fractures in the hip, spine and non-spine areas (such as the wrists and arms). In one major study, zoledronic acid reduced the risk of spine fractures by 70 percent and hip fractures by 41 percent. Zoledronic acid also reduces the risk of more broken bones in people who have recently broken a hip.

Side Effects of Bisphosphonates (Alendronate, Ibandronate, Risedronate and Zoledronic Acid)

Side effects for all the bisphosphonates (Alendronate, Ibandronate, Risedronate and Zoledronic acid) may include bone, joint or muscle pain. Side effects of the oral tablets may include nausea, difficulty swallowing, heartburn, irritation of the esophagus and gastric ulcer.

Side effects that can occur shortly after receiving an IV bisphosphonate include flu-like symptoms, fever, headache and pain in muscles or joints. These generally stop within two to three days and usually do not happen with future infusions.

There have been rare reports of osteonecrosis (death of bone cells or tissue) of the jaw (ONJ) with bisphosphonates. There have also been recent reports of unusual fractures of the upper femur (thigh bone) in people taking bisphosphonate medicines.

OTHER THERAPIES TO CURE OSTEOPOROSIS

Calcitonin-Salmon

Calcitonin is a synthetic hormone for the treatment of osteoporosis in postmenopausal women who are at least five years beyond menopause. The naturally occurring hormone is involved in calcium regulation and bone metabolism.
Calcitonin slows bone loss and increases bone density in the spine. It reduces the risk of spine fractures but has not been shown to decrease the risk of non-spine fractures.
Calcitonin is available as a nasal spray (200 IU daily) or an injection (dosage varies). An oral form of the drug is also being tested in clinical trials.

Denosumab

Denosumab is approved by the FDA for the treatment of osteoporosis in postmenopausal women at high risk of fracture and to increase bone mass in men with osteoporosis at high risk of fracture.
A healthcare professional gives Denosumab by injection every six months. Patients need to have a blood test before each dose to confirm that blood calcium level is normal.

Raloxifene (SERM)

Raloxifene is approved for the prevention and treatment of osteoporosis in postmenopausal women. It is in a class of drugs called estrogen agonists/antagonists that have been developed to provide the beneficial effects of estrogens without their potential disadvantages. It is neither an estrogen nor a hormone. Raloxifene used to be called a selective estrogen receptor modulator (SERM).
Raloxifene increases bone density and reduces the risk of spine fractures. There are no data showing that Raloxifene reduces the risk of hip and other non-spine fractures.
For both prevention and treatment, Raloxifene is taken daily as a 60 mg tablet with or without meals.

Teriparatide Parathyroid Hormone (PTH)

Teriparatide, a type of parathyroid hormone, is approved for the treatment of osteoporosis in postmenopausal women and in men who are at high risk of breaking a broken bone. This medicine rebuilds bone and significantly increases bone mineral density, especially in the spine.
In clinical studies of postmenopausal women using Teriparatide, fractures were reduced in the spine and throughout the skeleton.
Good candidates for Teriparatide include those who have had an osteoporosis related fracture and those with very low bone density (T-scores lower than -3.0). Teriparatide is also an option for patients who continue to lose bone density or break a bone during treatment with other osteoporosis medicines.
Teriparatide is self-administered as a daily injection from a pre-loaded pen containing a one month supply of medicine. It can be taken for a maximum of two years. At the end of two years, to retain the benefits of treatment with Teriparatide, most experts recommend that patients start an anti-resorptive medicine.

How Long to Treat on Bisphosphonate

When a patient has a good response to treatment with an osteoporosis medicine, some healthcare providers will consider a drug holiday. This means stopping the medicine for a period of time and continuing to monitor bone mineral density. Some healthcare providers consider a drug holiday after five years when there has been a good response to treatment. Others view it as an option when bone mineral density tests are performed two years apart, and the test results are similar and show a good response to treatment

MARKET FORMULATIONS

Name	Composition	Company name	Pack size	MRP
Idrofos 150mg	Ibandronic acid 150 mg	Sun Pharmaceutical	One tablet /Once a month	198
Fosavance 70mg/5600IU	Alendronate sodium(70mg) /cholecalciferol 5600IU	MSD –Merck Sharp & Dohme	4 tablets/One tablet every week	390
Osteofos 35mg	Alendronic acid 35mg	Cipla	4 tablets/One tablet every week	74
Osteofos 70 mg	Alendronic acid 70mg	Cipla	4 tablets/One tablet every week	127
Risofos 35 mg	Risedronate sodium 35mg	Cipla	4 tablets/One tablet every week	133

MARKET KITS

name	composition	company	Pack size	MRP
Idrofos Kit (monthly kit)	Ibandronic acid 150mg + coral calcium 225mg & vitamin D3 800IU	Sun Pharmaceutical	1 tablet Ibandronic acid & 30 tablets calcium + vitamin D3	299
Calinta kit (monthly kit)	Ibandronic acid + calcium carbornate 500mg +calcitriol .25 mcg +zinc 20 mg	Intas Pharmaceutical	1 tablet Ibandronic acid & 30 tablets calcium + vitamin D3	295
Risofos kit (weekly kit)	Residronate +calcium 250 mg + vitamin D3 400 IU	Cipla	1 tablet Residonate + 14 tablets calcium and vitamin	79

MARKET ANALYSIS JAN-2013

IBANDRNATE Total value -22 crores	**MV (market value)**	**MS% (market share)**	**Growth%**
Ibandronate +kit	22 crores	100%	7%
Idrofos group	8.16 crores	17%	26%
Bandrone (Natco)	2crores	5%	-32
Vebalone(Ranbaxy)	1.5crores	3%	-10

ALENDRONATE Total value -13 crores	**MV (market value)**	**MS% (market share)**	**Growth%**
Alendronate	13 crore	100%	-7
Osteofos (Cipla)	6 crore	12%	-8
Fosavance(MSD)	5.13 crore	11%	17

RESIDRONATE Total value -8 crores	**MV (market value)**	**MS% (market share)**	**Growth%**
Residronate+kits	8crores	100%	-13
Risofos(Cipla)	3 crore	6%	-9
Gemfos(Alkem)	3 crore	6%	-3

ZOLIDRONATE Total value - 7.5crores	**MV (market value)**	**MS% (market share)**	**Growth%**
Zolidronate	7.5crores	100%	-2
Zobone (Sun Pharma)	50lakh	9%	26%
Zyrona(Ranbaxy)	50 lakh	9%	26%

RESEARCH METHODOLOGY

This part of the report includes market research, research methodology, and interpretation of collected data following the major findings in the end.

Research Objectives: To understand the perception of doctors towards bisphosphonates in the management of osteoporosis.

- To find the perception towards management of osteoporosis amongst the orthopaedic in Mumbai.
- To find the perception of treatment modalities of osteoporosis amongst the orthopaedics.
- To find the prevalence and market potential of oral and injectable bisphosphonates.

Methodology:

Research Method: One to one interaction with the doctors.

Research Instrument: Questionnaire

Types of Questions: Structured , open and closed ended

Sampling Techniques:

Random sampling

Sample size: Quantitative data was collected from 75 doctors.

Respondents: Target respondents comprises of orthopaedics, Rheumatologists.

Research Area : Andheri, Vile Parle, Santacruz, Khar Rd, Bandra, Mahim, Matunga, Borivali, Kandivali, Malad, Goregaon, Dadar, Elphinston, Lower Parel, Mahalaxmi, Mumbai Central, Grant Road, Charni Road

DATA COLLECTION METHOD:

Primary Data:

Questionnaire Method – Verbal

Interview type –In depth personal interview

Secondary Data:

Thorough understanding of the subject was achieved in terms of medical aspects and market of Osteoporosis. Various sources like books, training manuals, journals, internet and Org IMS data and SMSRC data.

Information was collected regarding the following:

- Details about the disease and its pathophysiology.
- Various molecules used in the treatment of osteoporosis.
- Its mode of action, side effects, pharmacokinetics and its contraindications.
- Clinical trials of various molecules.
- Market share of various molecules from ORG IMS.

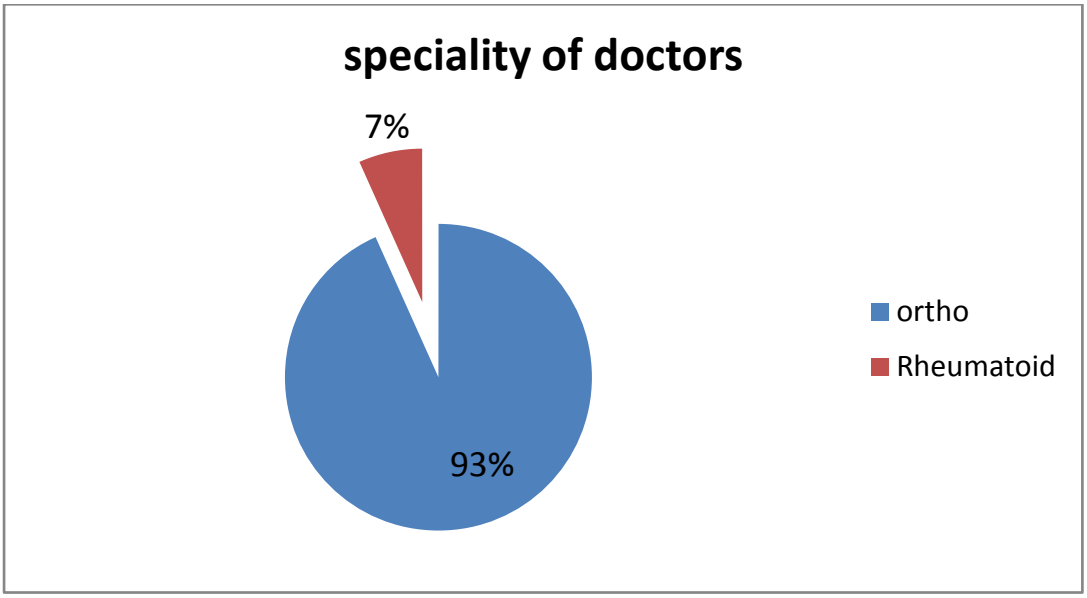
Data analysis:

The survey findings were compiled into MS- office and then graphical interpretations were made from the research findings.

ANALYSIS AND FINDINGS

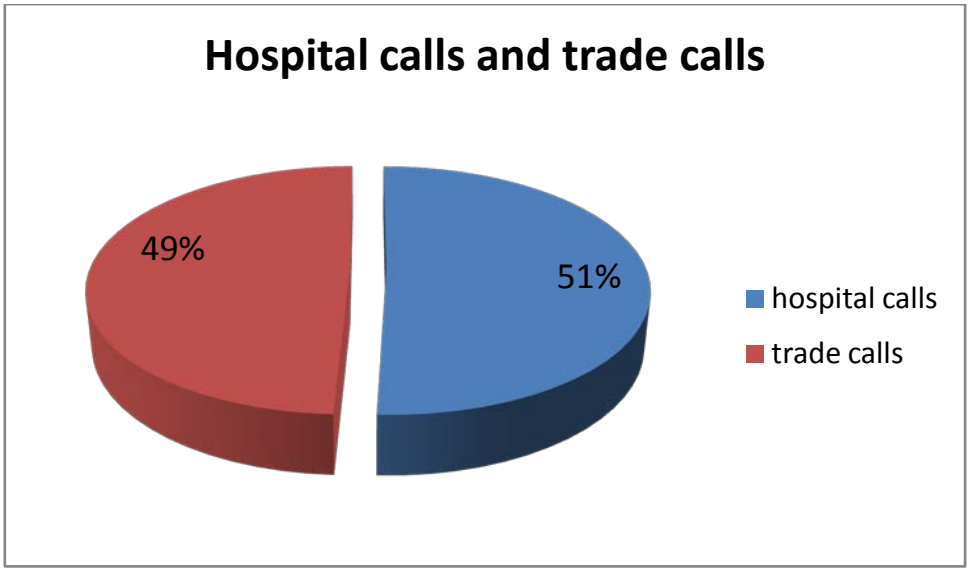
Speciality of doctors met

- 93% of doctors met were orthopaedic and 7% were Rheumatologist



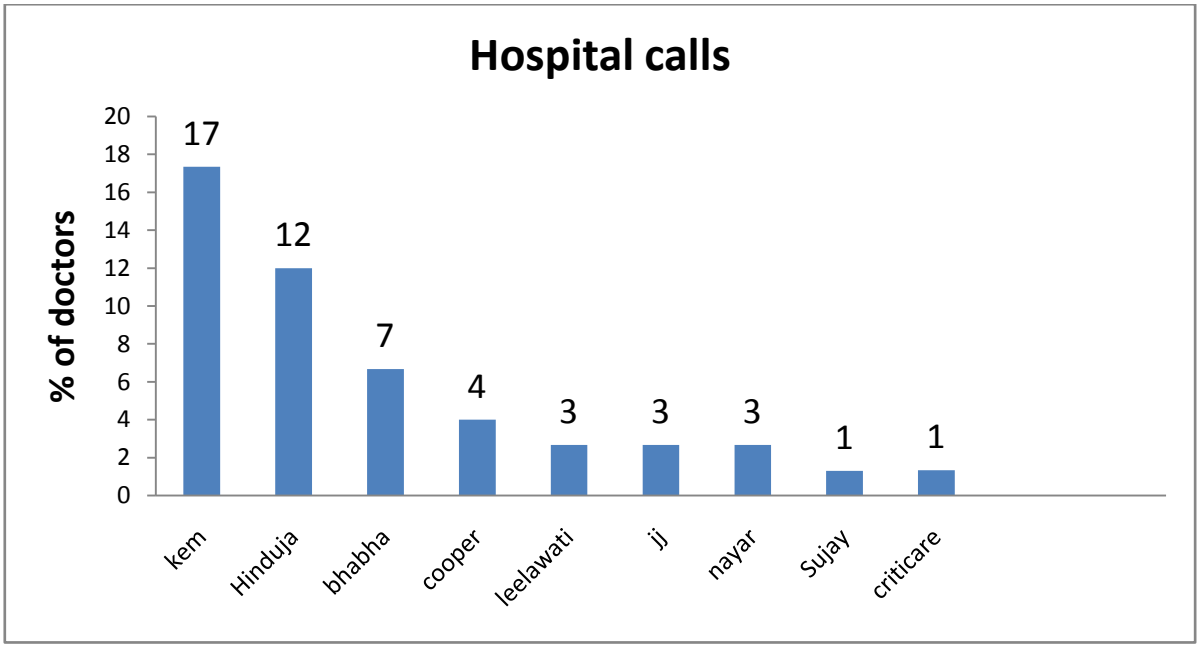
TRADE CALLS AND HOSPITAL CALLS

- 51% calls were made in the hospital and 49% calls were made as trade calls.



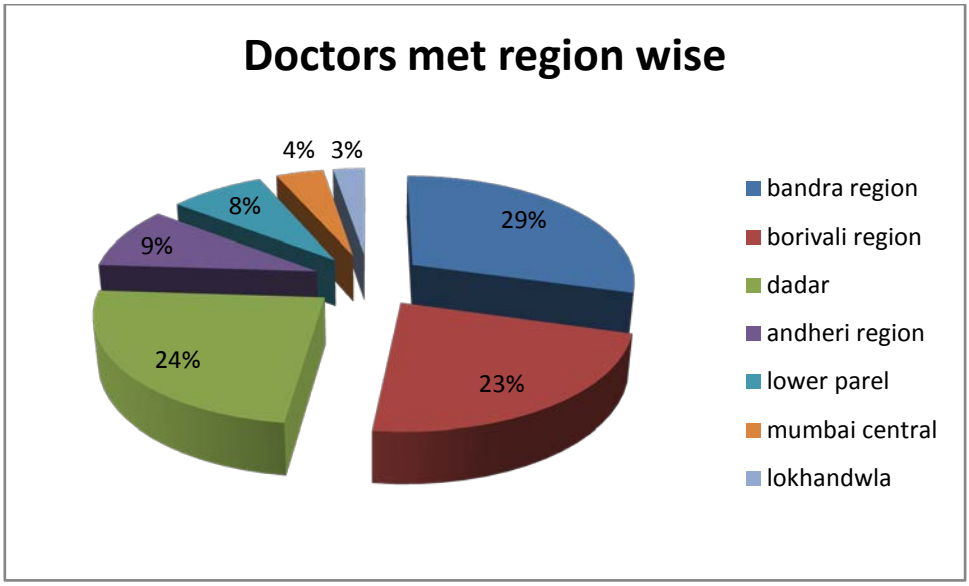
HOSPITAL CALLS

- Majority of covered were from KEM and Hinduja.



DOCTORS COVERED REGION WISE

- Maximum doctors were covered in the Bandra region 29% and then Borivali 23% and Dadar region 24%.



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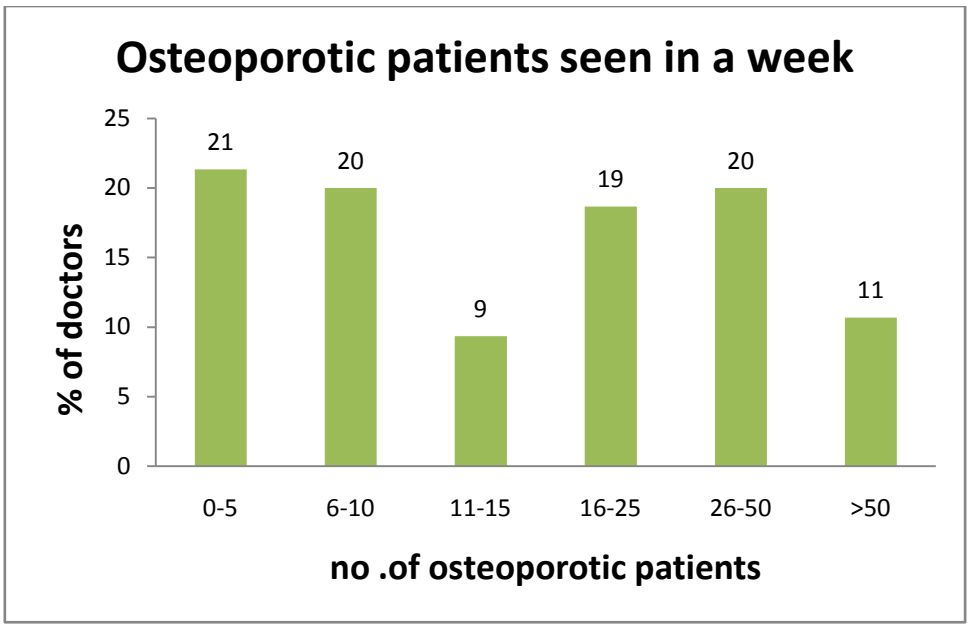
PATIENTS VISITING FOR OSTEOPOROSIS

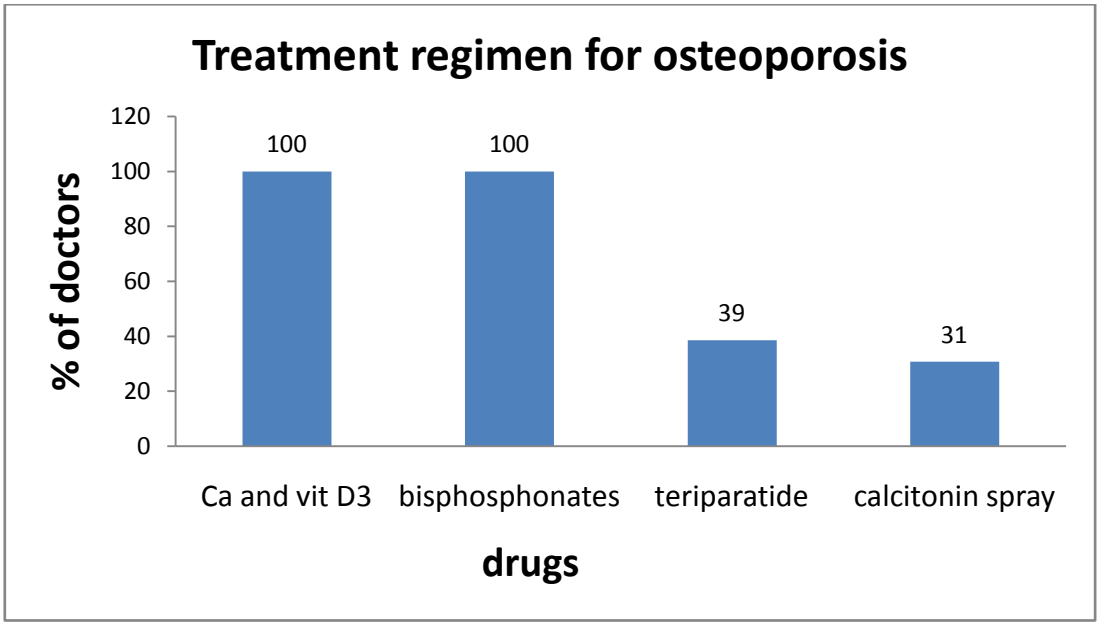
Q1. In your clinical practice, how many patients of osteoporosis do you observe in a week?

- 21% of doctors see 0-5 patients per week followed by 20% doctors who see 6-10 patients and 26-50 patients per week .So average number of patients seen by doctors varies from 5-25.



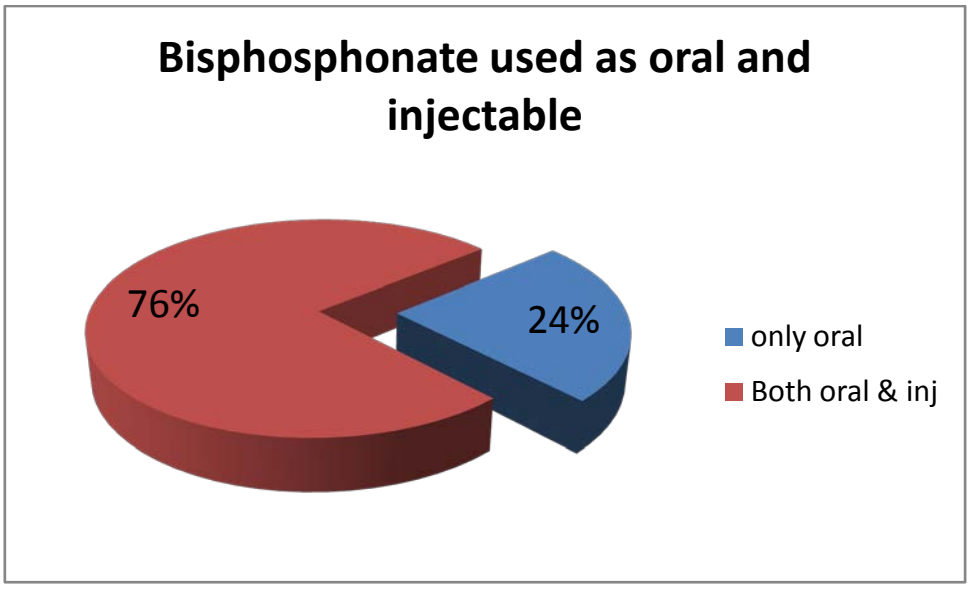
TREATMENT REGIMEN FOR OSTEOPOROSIS

- 100% doctors met are prescribing bisphosphonates along with vitamin D3 and calcium supplements as a first line treatment for osteoporosis, while 31% are prescribing Calcitonin nasal spray in both severe and moderate cases of osteoporosis.
- 39% doctors are prescribing Teriparatide in very severe cases of osteoporosis with fractures.



USAGE OF ORAL AND INJECTABLE BISPHOSPHONATES BY DOCTORS

- 24% of doctors said that they only use oral bisphosphonates, while 76% of doctors said they are using both oral and injectable bisphosphonate.

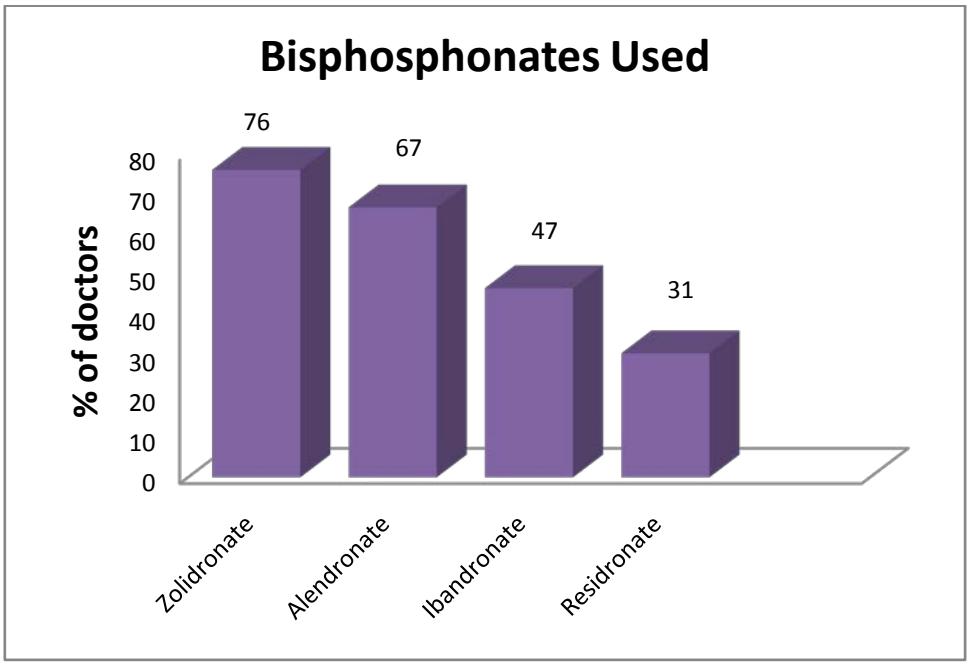


- Injectables are mainly used in the case of severe osteoporosis, patients who cannot tolerate oral Bisphosphonates due to GI tract intolerability or for the osteoporotic patient who are admitted in the hospitals.
- The doctors who are not using injectable bisphosphonate said that injectables are very expensive hence are not affordable by their patients, also patient needs to be admitted for the injectable treatment and sometimes injectables give serious side effects.

USAGE OF BISPHOSPHONATES

Q**.** Which Bisphosphonate do you use for the treatment of osteoporosis?

- 76% of doctors said they are using Zolidronate (injectable) whereas in oral bisphosphonates 67% doctors are using Alendronate and 47% doctors are using Ibandronate.

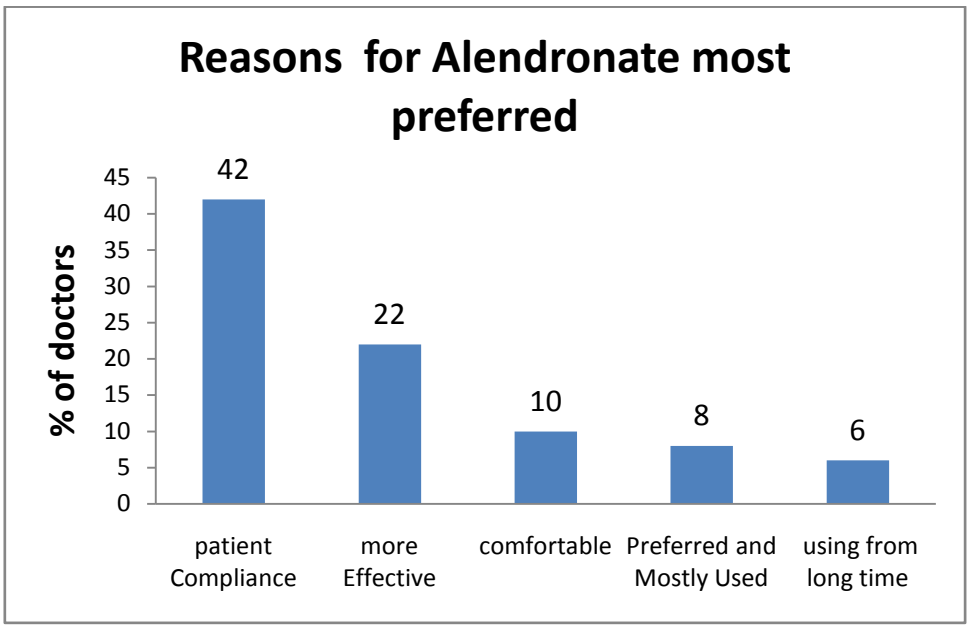


*multiple choice

- Bandra region – (Mahim, Matunga, khar, Santacruz) –(Hinduja, Leelawati)- majority of doctors (81%) use Alendronate.
- Borovali region- (Kandivali, ,Malad, Goregaon)- (maximum trade calls)- Majority of doctors (64%) use Ibandronate.
- Dadar region- (KEM, JJ, NAYAR hospitals)- mixed response – both towards Alendronate(60%) and Ibandronate(65%)
- Lower Parel, Mumbai central region- mixed response both towards Ibandronate(50%) and Alendronate(65%)

REASONS FOR ALENDRONATE MOST PREFERRED

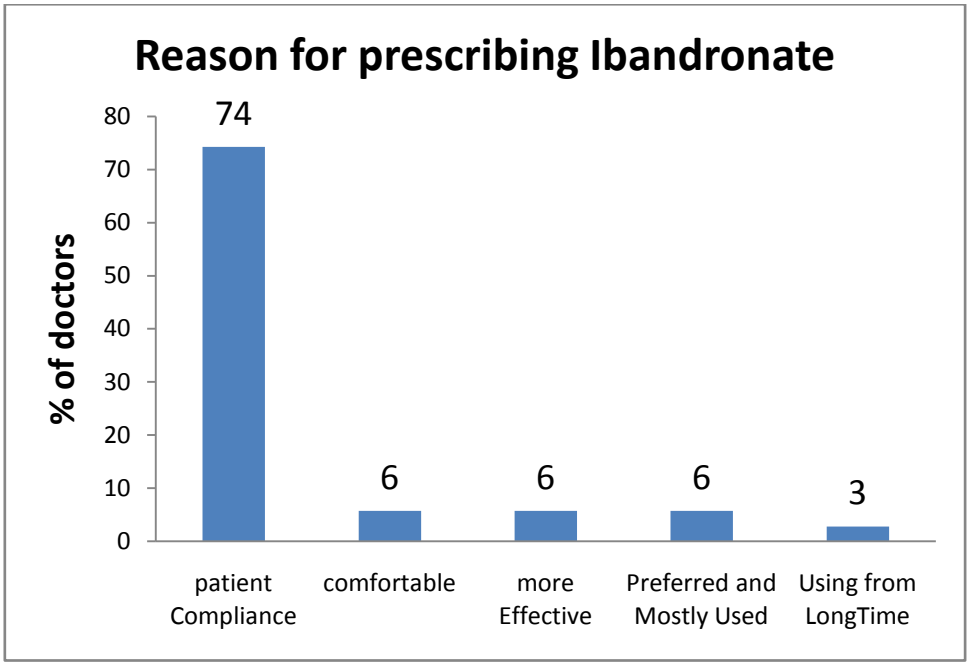
- 42% doctors said Alendronate is more patient compliance whereas 22% doctors said Alendonate is more effective than any other bisphosphonate.
- 10 % doctors say that they are very comfortable with Alendronate, it is mostly preferred, since all clinical studies are available on Alendronate, it is efficacious in both vertebral and non vertebral fractures.



- Doctors say that they are very comfortable and confident in using Alendronate since they are using it from very long, all the clinical trials are available on Alendronate.

REASONS FOR PRESCRIBING IBANDRONATE

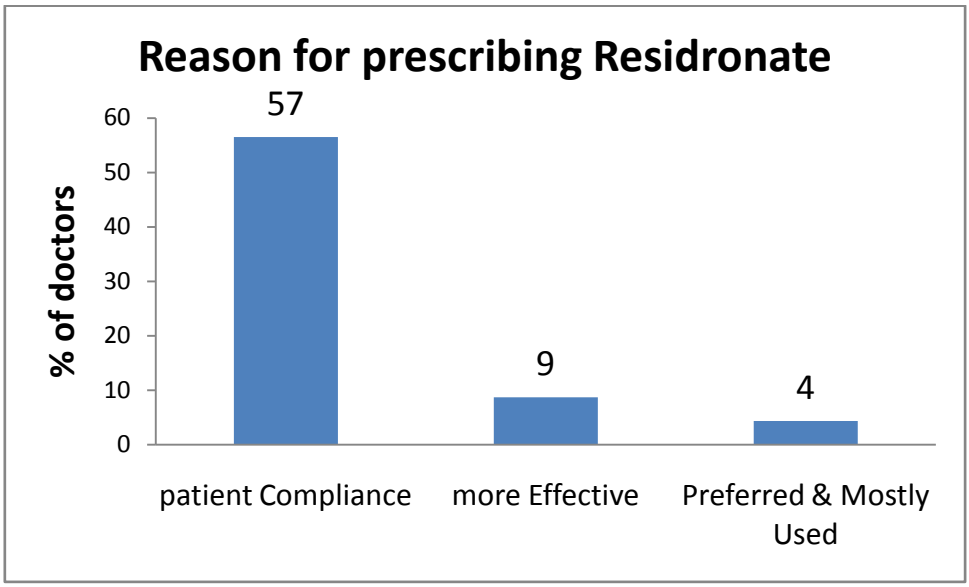
- 75% doctors said Ibandronate is more patient compliance(once a month tablet) and 6% doctors say they are comfortable using Ibandronate, 6% doctors feel it is more effective .
- The doctors who are not using Ibandronate says that clinical trials with Ibandroante are only available on vertebral fractures and it is not very effective in Non vertebral fractures.



- Ibandronate is mainly used by the doctors to cure spine fracture and it is more patient compliance for being once a month tablet.

REASONS FOR PRESCRIBING RESIDRONATE

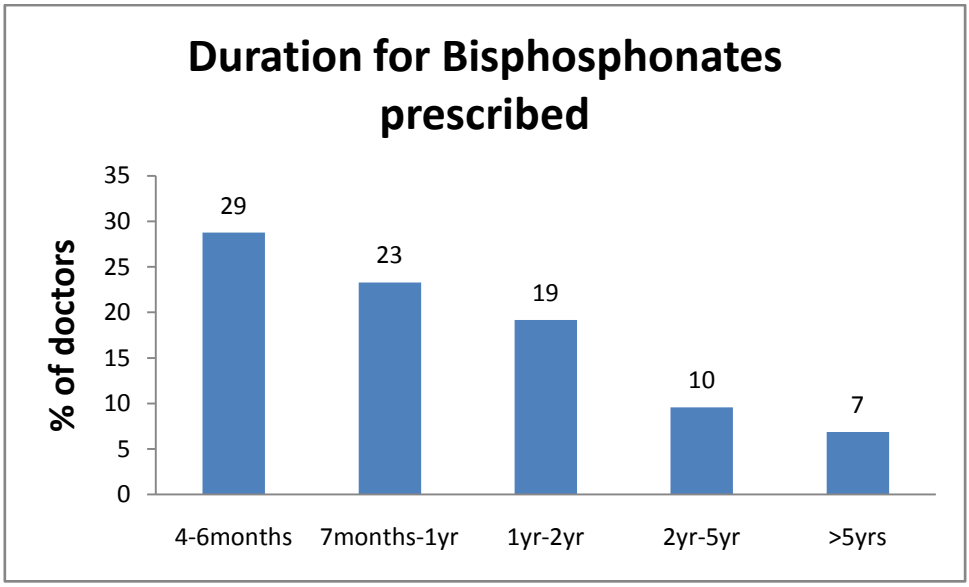
57% doctors said Residronate is more patient compliance, while 9% said it is more effective.



DURATION FOR BISPHOSPHONATE PRESCRIBED

Q. How long do you put the patients on bisphosphonate therapy?

71% doctors said they prescribe bisphosphonates for 4months - 2 years and then break for 2-3months, if required doctor can continue further bisphosphonate till 2-5 years with breaks for few months.

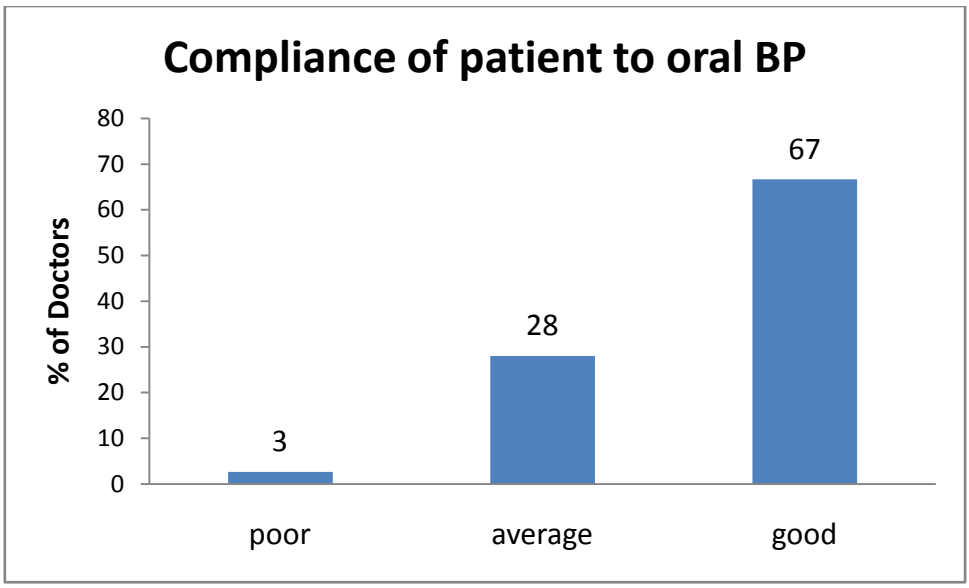


COMPLIANCE OF THE PATIENTS TOWARDS BISPHOSPHONATES

Q. How would you rate the compliance of your patients to oral bisphosphonates?

67% of doctors said compliance of the patients towards bisphosphonates is good, while 28% said it is average.

Doctors say, good response of the patients is because they do counselling of the patients before prescribing bisphosphonates.



KEY FINDINGS

- Number of patients visiting doctors for treatment of osteoporosis varies from 5-25 patients per week.
- 100% of doctors met are prescribing Bisphosphonates along with calcium and vitamin D3 tablets.
- Among bisphosphonates, 67% of doctors are prescribing Alendronate whereas 47% are prescribing Ibandronate.
- Reasons for Alendronate most preferred in Mumbai
  1. Doctors feel it is more efficacious than other bisphosphonates
  2. Patient compliance is good
- While Ibandronate is prescribed by the doctors because patient compliance is good being once a month and they feel it is only effective in vertebral fractures. Since no clinical studies are available in cure for non vertebral fractures.
- In case of oral and injectable bisphosphonates:
  1. 24% doctors use only oral,
  2. 76% doctors are using both oral and injectables.
- Injectables are only used in case of severe osteoporosis, patient who cannot tolerate oral bisphosphonates or patients who are admitted in the hospitals.
- Duration of bisphosphonates prescribed by the doctors is from 4months to 2 yrs as per the requirement with breaks.
- 67% of doctors said compliance of the patients towards bisphosphonates is good, while 28% said it is average. Doctors say, good response of the patients is because they do counselling of the patients before prescribing bisphosphonates

RECOMMENDATIONS

A. Suggestions for product promotion

- 76% doctors are using Zolidronic acid, so the injectables has huge potential in the market. Aggressive promotion of Zolidronic (Zobone) is recommended.
- Idrofos is not preferred by some of the doctors. These doctors not convinced that the drug is useful to cure non vertebral fractures. So, there is need to create awareness that Ibandronate is effective in both vertebral and non vertebral fractures by providing them more literatures and reference of clinical trials.

A. Suggestions for launch products

- Vitamin D3 and calcium tablets are used by 100% doctors, so vitamin D3 can be launched in the market. It can be launched in the form of flavoured vitamin D3 chewable tablet or in the granules form.
- Teriparatide could be launched, 38.6% doctors use Teriparatide in very severe cases of osteoporosis with fractures. Teriparatide total market is 11 crores, their are two major competitors, Bonista-(4.5 crores,GR-48%) ,Terifac-(3.3crores,160% GR)

APPENDICES:

Questionnaire

Topic: Perception of doctors on Bisphosphonates in the management of osteoporosis

Q1. In your clinical practice, how many patients of osteoporosis do you observe in a week?

_____

Q2. Do you grade the osteoporosis as mild, moderate, severe or in any other manner?

1. Yes
2. No
3. Any other manner_____

Q3. In the classification of osteoporosis, what would be your approach to treatment?

classification	Treatment
Mild	
Moderate	
Severe	
Any other	

Q4. Do you see the role of bisphosphonates in the management of osteoporosis?

1. Yes
2. No

Q5. If yes , would you prefer oral or injections ?

_____

Q6. If you use both oral and injection , in which patients you use oral and injections?

Patients	Reasons
Oral	
Injections	

Q7. Which bisphosphonate do you use for the treatment of osteoporosis?

_____

_____

Q8.Why?

_____

_____

Q9. How long do you put the patients on bisphosphonate therapy?

_____

Q10. How would you rate the compliance of your patients to oral bisphosphonates?

1. Poor
2. Average
3. Good

Q11. If the answer to Q4 is no , then why don't you see a role of bisphosphonate in the management of osteoporosis?

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Doctors name -_____ **Mobile No.**_____

Date and time of meeting;_____

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