

MARKET ASSESSMENT OF NUTRACEUTICAL BRANDS IN MALE INFERTILITY

Dissertation Submitted to



The IIHMR University, Jaipur

for the partial fulfilment for the award of the degree of

Master of Business Administration (MBA)

in

Pharmaceutical Management

by

Raj Singh Rajput

Under the Supervision and Guidance of

Dr. Prachi Ahire

Head Medical Affairs

Shield Healthcare Pvt Ltd

Dr. Ashok Peepliwal

Associate Professor

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DECLARATION BY STUDENT

I hereby declare that this dissertation titled '**Market assessment of nutraceutical products in male infertility**' is the bonafide record of my original research work. I declare that it has not been submitted to any other University or Institution for the award of any degree or diploma. Information derived from the published or unpublished work of others has been duly acknowledged in the text.

Signature: *Raj Singh*

RAJ SINGH RAJPUT:

Date: **June 25, 2021**

COMPLETION CERTIFICATION

CERTIFICATE

This is to certify that Mr. Raj Singh Rajput in partial fulfilment of the requirements for the award of the degree of MBA (Pharmaceutical Management) from the IIHMR University, Jaipur has successfully completed her internship at Shield Healthcare Pvt Ltd. during March 22, 2021 to June 19, 2021.

Place: Chennai

Date: June 30, 2021



A handwritten signature in blue ink, appearing to read "S. V. Kumar".

Sr. Manager HR & Systems

CERTIFICATE

This is to certify that dissertation titled '**Market assessment of nutraceutical products in male infertility**' is a record of the research work undertaken by **Raj Singh Rajput** in partial fulfilment of the requirements for the award of the degree of MBA (Pharmaceutical Management) from the IIHMR University, Jaipur under my guidance and supervision and her approach to the research study has been sincere, scientific, and analytical.

Faculty Guide

IIHMR University, Jaipur

Date:

School Dean

IIHMR University, Jaipur

Date:

ABSTRACT

Nutraceuticals are food products that can provide medical or health benefits by preventing or treating disease processes. The high costs associated with assisted reproductive techniques for male infertility have led consumers to find less expensive alternatives for potential treatment. Nutraceuticals are widely available and have many antioxidant properties. Throughout the survey it was noticed that there were various nutraceutical brands available in the pharmacy stores out of which most prescribed nutraceutical brands by the doctors were Fertisure-M, Mac-q10 and Spercus followed by some other brands like Coq forte, Oligocare, Zoamates. Moreover, on the basis of data analysis and interpretation the sales of Fertisure-M seem to be greater followed by Mac-q10 and Spercus. it was observed that mostly Gynaecologist are prescribing Nutraceutical Products in the treatment of Male infertility. Through this study it was found that maximum numbers of doctors prefer Zinc, followed by Coenzyme q-10, L-carnitine, lycopene as specific molecules in nutraceutical combinations, most of them consider effectiveness followed by, composition, availability and cost as the important attributes while prescribing any brand of nutraceutical. many of the them have suggested that the pricing of the nutraceutical should consider as an important issue in the developing country as India and it should be economic. This research focuses on regarding readily available nutraceuticals and their potential effects on male infertility.

Key Words: - infertility, antioxidants, combinations, effectiveness, Coenzyme q-10, L-carnitine

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“No one who achieves success does so without acknowledging the help of others. The wise and confident acknowledge this help with gratitude.”

It would be almost impossible to achieve excellence without all the luminaries who helped me throughout the completion of this Dissertation.

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Raj Singh Rajput

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INTRODUCTION

Infertility is a disease of the male or female reproductive system that is determined by the inability to conceive after 12 months or more of normal unprotected sex; sexually active couples do not take contraceptive measures and cannot become pregnant within a year. It can be caused by many factors, whether it is the male or female reproductive system. However, sometimes the reasons behind infertility cannot be explained.

Infertility affects millions of people of childbearing age around the world, and affects their families and communities. Of the 186 million people in the world, an estimated 48 million couples suffer from infertility. In the male reproductive system, the main reason of infertility are sperm flow problems, insufficient or low sperm count, or abnormal sperm shape and movement. In the female reproductive system, various irregularities of the ovaries, uterus, fallopian tubes, and endocrine system can cause infertility;

There are two types of infertility that is primary or secondary; primary infertility means that a person has never been pregnant, Secondary infertility refers to pregnancy at least once before.

In the US, approximately 6% of married women between the ages of 15 and 44 still cannot get pregnant (infertility) after a year of trying. In addition, approximately 12% of women aged 16 to 44 in the US have difficulty in getting pregnancy. Or impaired fertility.

The World Health Organization estimates that the prevalence rate of primary infertility in India is within 3.9% and 16.8%., Andhra Pradesh 5%, Kashmir 15%.

The crude birth rate in India is 2.2 As of 2017, due to the large population, poverty and scarcity of resources. the Indian government has introduced family planning measures to reduce the fertility rate to the current target of 2.1 children per woman. Globally, 15% of couples of childbearing ages suffer from infertility. Infertility rate In India, the infertility rate has dropped by 7.7%, NFHS2 is about 2%, and NFHS3 is about 1.85%. The infertility rate increases with increasing age at first marriage. However, in approximately 35% of infertile couples, male factors are determined together with female factors. In around 8% of infertile couples, the male factor is the lone identifiable cause. Nutritious foods are foods that provide health benefits or can improve health by preventing or treating disease processes. Consumers need to find cheaper alternative treatments to replace possible treatments. The drug is widely used and has many antioxidant properties.

Male infertility can be due to many various factors and is commonly recognized with the aid of using semen evaluation. Concentration), agility (movement), and form (form) are evaluated with the aid of using experts. A barely extraordinary sperm evaluation does now no longer suggest that a person ought to be infertile. Conversely, semen evaluation facilitates decide if and the way male elements make a contribution to infertility. Among the reasons of male infertility, many latest research has emphasised the position of infection of the reproductive tract and terrible way of life choices. Style and malnutrition. In this sense, weight problems and different diseases, along with metabolic syndrome, alcoholism, smoking, publicity to environmental pollutants, etc. They are intently associated with terrible sperm high-satisfactory and infertility. The most important speculation is that those situations can alternate the redox stability of the steroid-generating mobileular populace and the germ mobileular populace with the aid of using inducing the boom of ROS and RONS, main to deterioration of hypothalamus-pituitary gland-testicular axis and sperm high-satisfactory.

The state and parameters of sperm use diverse mechanisms. Nutraceuticals are used as additives of DS (BAA), which might be extensively used to save you or deal with diverse pathological situations. From a felony factor of view, the EFSA does now no longer outline this DS because the remedy or prevention of human diseases, however most effectively helps particular physiological fertility abnormalities.

There are many Dietary Supplements to be had available in the marketplace in diverse formulations, which include exceptional doses of vitamins and herbs. Although many authors have tested those sure elements have a wonderful impact on sperm parameters. And fertility results, many different human beings additionally display useless or even probably dangerous facet effects. the kingdom of the artwork for every component presently used on this work. The authors concluded that clinical know-how approximately the viable function of dietary tablets in andrology continues to be limited, and using antioxidants can simplest be furnished to sufferers with idiopathic infertility after a selected diagnosis. However, so far, there aren't any any regulations or tips for using those products, which has delivered confusion to medical doctors and sufferers. In addition, numerous elements make it hard or maybe hard to choose the proper elements for the proper patient. Especially hard. Determine the best DS due to the fact every product carries exceptional elements and exceptional dosagess. Due to public consciousness and developing hobby from the clinical network and consumers.

Therapeutic nutritious foods are becoming more and more popular. In addition, nutritional health products are becoming more and more popular. Part of dietary supplements. Deficiencies caused by eating over-processed junk food, which make up most of the Western diet.

Nutraceutical is a far-reaching term used to describe foods, ingredients and DS. Additionally, to the potential nutritional value of foods, these foods, food ingredients and DS also have special health benefits, because more and more Evidence suggests the use of nutritious foods to treat clinical manifestations of the reproductive system. service.

When traditional treatments for reproductive disorders are ineffective due to many fundamental diseases, nutritional deficiencies, and responses to traditional treatments, they become more and more popular. Basic foods are becoming more and more popular, including DS, antioxidants and vitamins.

It has been proven to improve reproductive function and effectively treat human fertility and infertility. Despite their success, most nutritious foods have not undergone any scientific research or proven effectiveness. Side effects and evidence vary by product and type. It is hard to discuss the scientific behaviour of all foods used to treat reproductive disorders.

This research focuses on the role of nutritional supplements in human infertility, endocrine disorders, puberty and success.

The purpose of this research is to identify use of nutraceuticals in the treatment of male infertility.

The general scenario of the research determines the market potential of nutraceutical for the treatment of infertility.

LITERATURE REVIEW

[Malik Adewoyin (2017)] The purpose of this research is to test the latest findings and the effects of many antioxidants on male fertility. Higher levels of polyunsaturated fatty acids are observed in the cell membranes of mammalian permanent animals, which makes them vulnerable to lipid peroxidation. ROS play a central role in reproduction. They are closely related to oxidative stress. Factors such as pollutants, smoking obesity, and inflammation, are negatively related to spermatogenesis. There is also an endogenous antioxidant system that mediates injury. Seminal plasma contains an antioxidant enzyme mechanism that can further inhibit ROS to protect competing sperm from possible damage. However, excessive ROS will be oxidized and precipitated by inflammatory cells and fatty acids. If you are overweight, the situation will get worse. In addition, it minimizes the antioxidant mechanisms that cause oxidative stress. Assessing this OS is the first and foremost footstep in the treatment of male infertility by controlling enough antioxidants. Interestingly, with weight loss programs E and C, carnitine and carotenoids, antioxidants have been shown to help restore the balance between the ROS era and excretion activity. More and more evidence show that plant foods can also improve male fertility. However, a good lifestyle, normal exercise, avoiding stress, and finding safety advice in art are all behaviors that can combat male infertility.

[Tammy J Lindsay (2015)] Infertility is described as the incapability to get pregnant after 12 months of normal unguarded sex. For patients with risk factors for infertility or those whose partners are over 35 years of age, the examination can begin sooner. Factors, ovulation disorders, fallopian tube obstruction, uterine abnormalities, peritoneal factors or cervical factors. Statistics and physical investigation can help with the assessment. Men want to be tested by semen analysis. Use useful tools to record ovulation based on the duration of serum progesterone levels on the 21st day of the cycle. The assessment of the uterus and fallopian tubes may be performed using useful resources using hysterosalpingography in women without the risk of obstruction. Hysteroscopy is recommended for patients who report endometriosis, pelvic infection, or ectopic pregnancy. Laparoscopy. Anovulatory women can receive clomiphene treatment in primary care clinics to induce ovulation. Treatment of blocked fallopian tubes usually requires referral to a professional nursing facility. Idiopathic infertility in men or women can be treated with 365 days of unprotected intercourse, or you can give up assisted reproductive technology and vitro fertilization.

[Audrey J Gaskins (2017)] The literature on the connection among diet and human fertility has substantially increased during the last decade, ensuing withinside the identity of some clean patterns. Intake of supplemental folic acid, in particular at doses better than the ones endorsed for the prevention of neural tube defects, has been continually associated with decrease frequency of infertility, decrease danger of being pregnant loss, and more achievement in infertility treatment. On the opposite hand, and no matter promising proof from animal models, nutrition D does now no longer seem to exert an essential function in human fertility withinside the absence of deficiency. Antioxidant supplementation does now no longer seem to provide any blessings to girls' present process infertility treatment; however, it seems to be useful whilst it's far from the male associate who's supplemented. However, the to be had proof does now no longer permit discerning which unique antioxidants, or at which doses, are liable for this benefit. Long-chain omega-three fatty acids seem to enhance woman fertility, even though it stays uncertain to what quantity infection of shared meals sources, which includes fish with excessive stages of environmental toxicants, can hose down this benefit. Lastly, adherence to healthful diets favoring seafood, poultry, complete grains, fruits, and greens is associated with higher fertility in girls and higher semen excellent in men. The cumulative proof has additionally piled towards famous hypotheses. Dairy and soy, as soon as proposed as reproductive toxicants, have now no longer been continually associated with negative fertility. In fact, soy and soy dietary supplements seem to exert a useful impact amongst girls present process infertility treatment. Similarly, due to the fact statistics from large, exquisite research hold to accumulate, the proof of a doubtlessly deleterious impact of mild alcohol and caffeine consumption at the cappotential to turn out to be pregnant appears much less strong than it as soon as did. While a whole photo of the function of vitamins on fertility is some distance from whole, a good deal of development has been made. The maximum salient gaps withinside the contemporary proof encompasses mutually thinking about the woman and male diets and trying out the maximum steady findings in randomized trials.

[Andrea Delbarba (2020)] This study was to evaluate, in decided on idiopathic infertile guys with excessive SDF, the impact on sperm DNA harm and on popular semen parameters of a nutraceutical formula containing myoinositol, alpha-lipoic acid, coenzyme Q10, selenium, zinc and B vitamins. They have a look at protected 60 idiopathic infertile guys with DNA fragmentation index (DFI) >20%. Semen evaluation and DFI willpower have been assessed at baseline and after 3 months of nutraceutical

remedy. Primary final results become extrude in DFI. The finding of this has a look at are Semen volume, sperm concentration, general sperm count, sperm movement and sperm Shape did now no longer extrude after remedy. Instead, sperm power appreciably elevated ($65.9 \pm 11.8\%$ pre-remedy vs. $69.4 \pm 9.4\%$ post-remedy, $P < 0.05$) and DFI appreciably reduced ($33.5 \pm 10.1\%$ pre-remedy vs. $26.8 \pm 8.7\%$ post-remedy, $P = 0.0001$) after remedy. The percent of fellows with everyday popular sperm parameters appreciably elevated (15% vs. 30%, $P < 0.05$). The imply lower in DFI become $-6.7 \pm 1.4\%$ and the share of fellows with $DFI \leq 30$ after remedy become 75.0% as compared to 48.3% pre-remedy ($P < 0.005$). Higher pre-remedy DFI (and no different parameters) correlated with more DFI discount after remedy.

[Pietro Antonuccio (2020)] In this study, they examined the role of lycopene in an investigational model of varicocele. 14 Male rats underwent sham surgery and injected vehicle ($n = 7$) or lycopene ($n = 7$; 1 mg/kg intraperitoneally, daily. Surgery for varicocele; 28 days later, simulated animals and 7 Only the varicocele was sacrificed, all the operations and contralateral testes were weighed and processed; the last rat received lycopene (1 mg/kg ip, daily) for Thirties days, and the rats with varicocele displayed Testosterone levels, testicular quality, decreased Bcl2 mRNA expression, changes in testicular shape, augmented malondialdehyde status, and BAX gene expression. Experiments have shown that increasing cell counts and lycopene treatment significantly increase testosterone levels, testicular weight, and Bcl2 mRNA expression. Improve the tube shape, reduce the level of malondialdehyde BAX mRNA expression, d TUNELecesi you go. These results show that lycopene has a positive effect on the testis, indicating that adding carotenoids can continue to be made from tomatoes, which can be regarded as a treatment for spermatic cord New nutritional supplements for varicose veins and male infertility.

[Kelton Tremellen (2021)] This retrospective cohort examine changed into carried out analysing effects for couples' present process their first sparkling embryo transfer. Men had been categorised as controls in the event that they had been taking no dietary supplements, fitness-aware controls if taking "standard fitness" nutritional dietary supplements, or Menevit customers. Exclude men with abnormal karyotypes or cycles and donors, freezing and surgical removal of semen. In the final analysis of the 657 cohort, Menevit customers' initial cost of living was meaningly higher than the control group. but now it is not between the control group that does not take dietary supplements and the control group that uses general dietary supplements, which shows that health is

oriented the behavior applies to the behavior in the application. Customers may not be responsible for the great results achieved by Menevit customers. Interestingly, in the published sensitivity score, Menevit customers' initial cost of living was statistically higher than the thin male control group not their obese peers Human. Therefore, the influence of this large group helps the seemingly powerful male social group to use the antioxidant Menevit during IVF treatment and in the initial cost of living, especially among thin people.

[Sangmin Choe (2015)] A modified reason is discussed here to examine the results of KRG sperm in male infertile patients in placebo-controlled study. From April 2011 to February 2012, patients with infertility and varicocele were recruited, and then divided into the following four organizations: varicocele-free group (V) + placebo (P), V +P group, no V group+KRG (1.5 g Korean Red Ginseng per day) and V + KGR group (1.5 g KRG per day). After 12 weeks, the semen value of each treatment group changed to the realization value and the hormonal value respectively. The team showed substantial developments in motility, morphology, sperm concentration, and viability to prevent testing. The frequency of bad physical activity is reduced to a low level, and it is assumed that all sports are not related to prescribed treatment.

[Chiara Di Tucci (2020)] The literature shows that from egg maturation ($0.87 \pm 0.9\%$ vs $0.81 \pm 3.9\%$ of egg in MII; $P < 0.05$) to conception and embryonic progress (57.7% vs 75.7% of grade 1), ALA application has achieved multiple procedures. Excellent results.) Embryo. $P < .05$) and reproduction results. Its routine control of infertile men and women shows reduction of pelvic pain in endometriosis ($p < .05$), regulation of menstrual rhythm and metabolic disorders, and pleasant sperm decoration molecule in the fight against infertility in couples requires further medical research to improve its application in medical practice.

[Fateme Haidari (2015)] This observation became goal to analyze Spermogram results of alpha-lipoic acid (ALA) supplements and promising biomarkers of oxidative stress. In imaging studies, the total number, concentration and motility of sperm in the involvement tissue were meaningly high than those in the control group. ALA tissue, total sperm count, sperm concentration and motility are all meaningly higher than the initial value during gaze transmission. However, there were no unexpected fluctuations in exclaim volume, percentage of normal morphology. Related with placebo, the addition of ALA resulted in a surprising increase in the antioxidant capacity of semen (TAC) and malondialdehyde.

According to the results, scientific treatment of asthenospermia supplemented with ALA should meet satisfactory semen parameters. Related researches are also proposed.

Research Objectives

1. To determine what are the specific requirements of doctor in nutraceutical combinations in the treatment of Male infertility?
2. To understand how they make decisions, which brand they prescribes?

Research Methodology

Type of analysis: - Descriptive

Data collection: - Primary data was received by the respondents throughout questionnaire and secondary data was collected from the printed journals, literature, and reference books, besides this statistical data was even be accessed within the research study.

Duration: - three Months

Sample size: - 200 (100 Gynaecologist & 100 Retailers)

Data Analysis: - the data analysis in the present study was done by using easy statistical tools like frequencies, percentages, average, and so forth that was used as per the need of the data. during this study, the suitable statistical tool is EXCEL.

Inclusion and Exclusion criteria: - All respondents i.e., gynaecologist who understood English and Hindi were eligible to participate and were enclosed within the study. except gynaecologist each speciality of the doctors is excluded and those who are mentally incompetent, unable to pay attention or speak are excluded from the study.

RESULTS

FINDINGS AND INTEPRETATIONS:

1. Analysis of Nutraceutical brands (Fertility supplement) available in Pharmacy store



Chart 1: Nutraceutical brands available in retailer store

Interpretation:

The above column graph shows the number of Nutraceutical brands available in their retailer pharmacies. About 5-10 brands are available in 68% of retailer pharmacies whereas 11-20 brands are available in 32% of retailer pharmacies, 3% of retailer pharmacies has 21-50 brands available in their stores.

2. Analysis of nutraceutical brands prescribed by the Doctors for the treatment of male infertility.

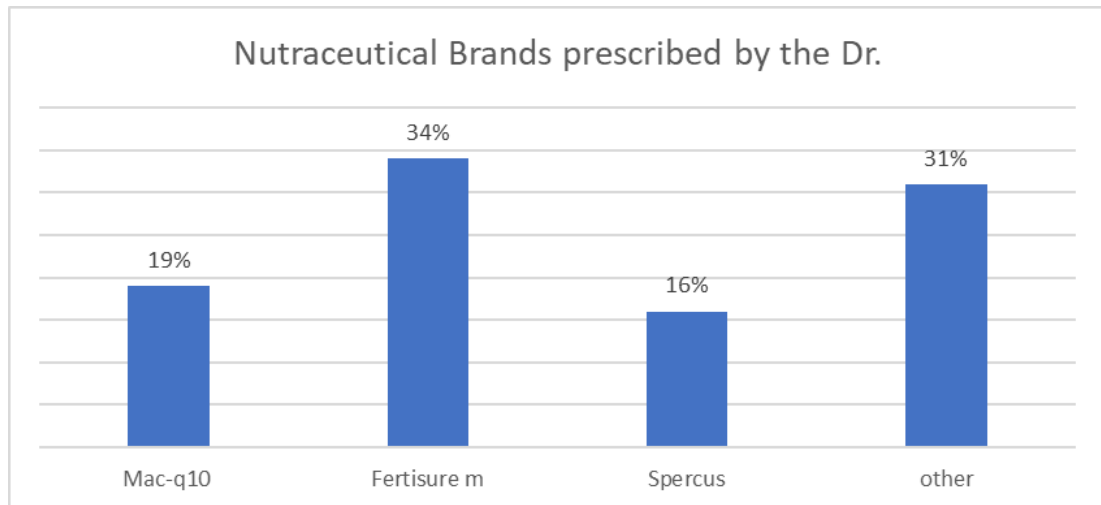


Chart 2: Nutraceutical brands prescribed by the Doctors.

Interpretation:

The above graph displays certain brands of Nutraceutical that are mostly prescribed by the doctors, according to the data collected from the retailers, 34% of retailers stated that doctors. Mostly prescribe Fertisure M, 19% of them said Mac-q10 is the most prescribed brand of nutraceutical whereas 16% of retailers showed Spercus as highly prescribed brand of multi vitamins and rest of the 31% of retailers stated other brands of nutraceuticals as mostly prescribed ones that comprises of Coq forte, Oligocare, Zoamates.

3. Analysis of monthly sales of Fertisure -M

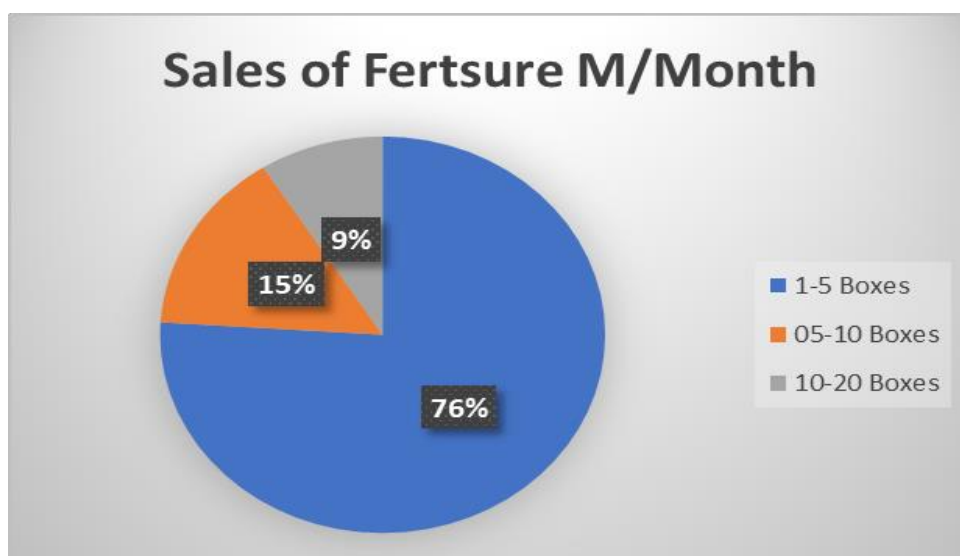


Chart 3: Monthly sales of Fertisure -M

Interpretation:

The monthly sales graph above represents the monthly sales of Fertisure-M brand in terms of number of boxes per month here, 76% of retailers stated the sales of 1-5 boxes of Fertisure-M/month, 15% of retailers showed sales of 5-10 boxes while 9% of them said 10-20 boxes monthly.

4. Analysis of monthly sales of Mac-q 10

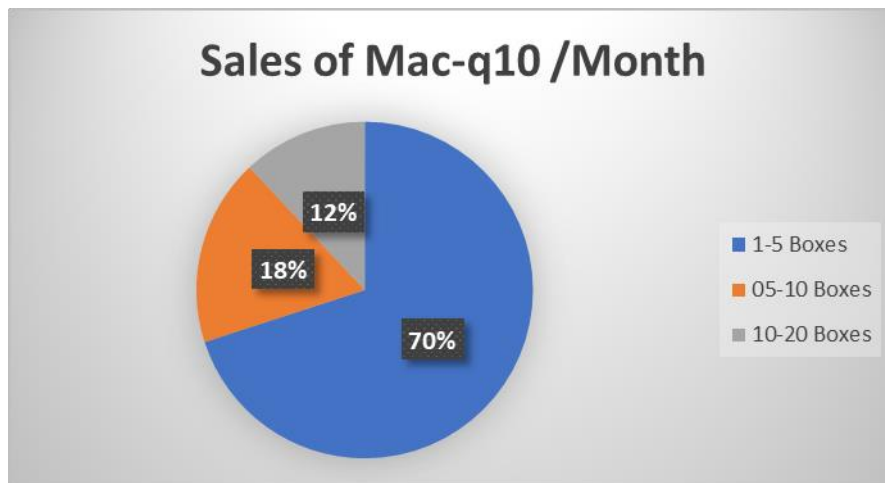


Chart 4: Monthly sales of Mac-q 10

Interpretation:

Above graphs state the monthly sales of Mac-q10 brand in context to the number of boxes usually sold per month ,70% of retailers responded the sales of 1-5 boxes of Mac-q10, 18% declared sales of 5-10 boxes monthly while only 12% of retailers showed sales of 10 -15 boxes in one month.

5. Analysis of monthly sales of Spercus.

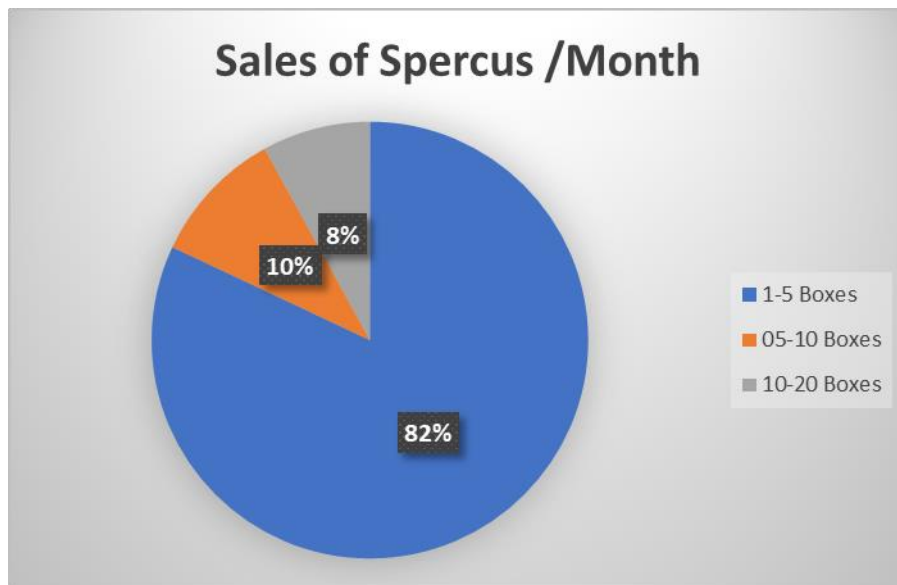


Chart 5: Monthly sales of Spercus.

Interpretation:

Above graph states the monthly sales of Spercus brand in with respect to the number of boxes per month here, 82% of retailers declared the sales of 1-5 boxes of Spercus per month, 10% of retailers told the sales of Spercus, 5-10 boxes per month and only 8% stated sales of more than 10 boxes monthly.

6. Analysis of Therapy duration infertility with nutraceutical brands prescribed by doctors.

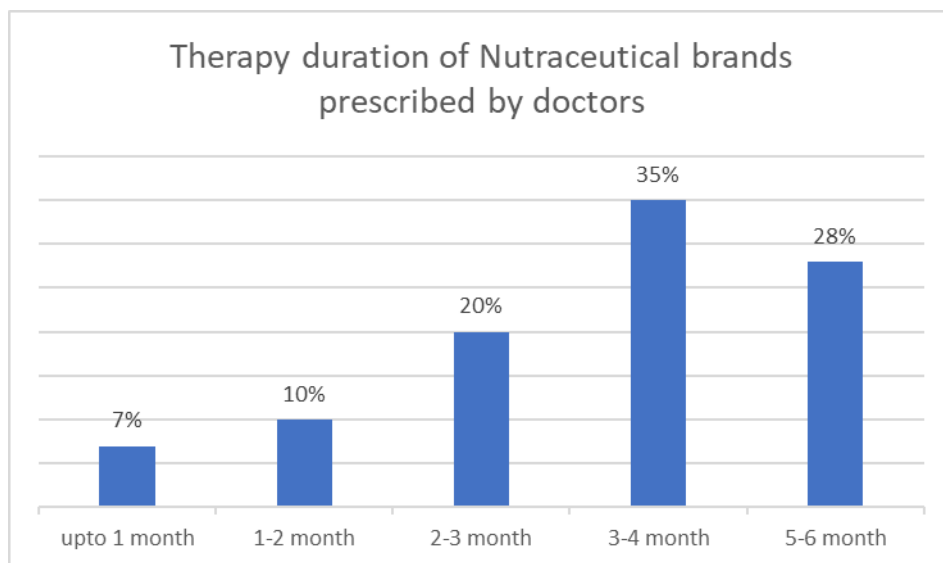


Chart 6: Therapy duration infertility with nutraceutical brands prescribed by doctors.

Interpretation:

Above graph explains the data of the therapy duration of nutraceuticals prescribed by the doctors. Here, the maximum 35% of doctors stated that they prescribe Nutraceutical products for 3-4 Months, 28% of them showed the therapy duration from 5-6 months while 20% of doctors said therapy duration from 1-2months days.

7. Analysis of element preferred by doctors in combinations

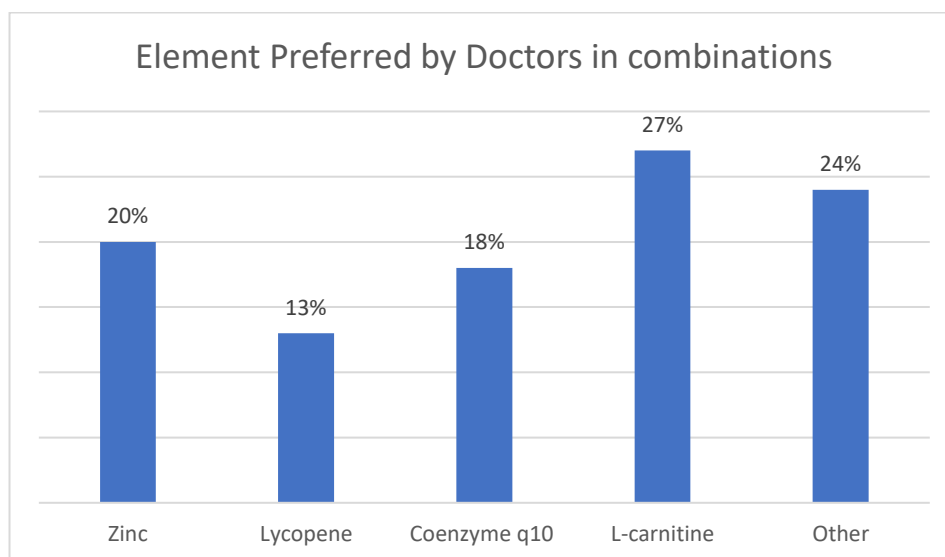


Chart 7: Element preferred by doctors in combinations.

Interpretation:

Above graph exhibits the data of what specific element doctors prefer most in nutraceutical combinations, graph shows, 27% of doctors prefer L-carnitine in nutraceuticals combinations, 20% of them prefer Zinc as a specific element in nutraceutical combinations, 18% of them stated Coenzyme-q10 as their specific requirement in the nutraceutical combinations followed by 13% of them Lycopene as their specific requirements in the nutraceutical combinations, while 24 % of doctors prefer other molecule like folic acid, selenium, vitamin E, vitamin A, myoinositol as their specific requirements in the same for the treatment of male infertility.

8. Analysis of attributes consider by doctors while prescribing nutraceutical products.

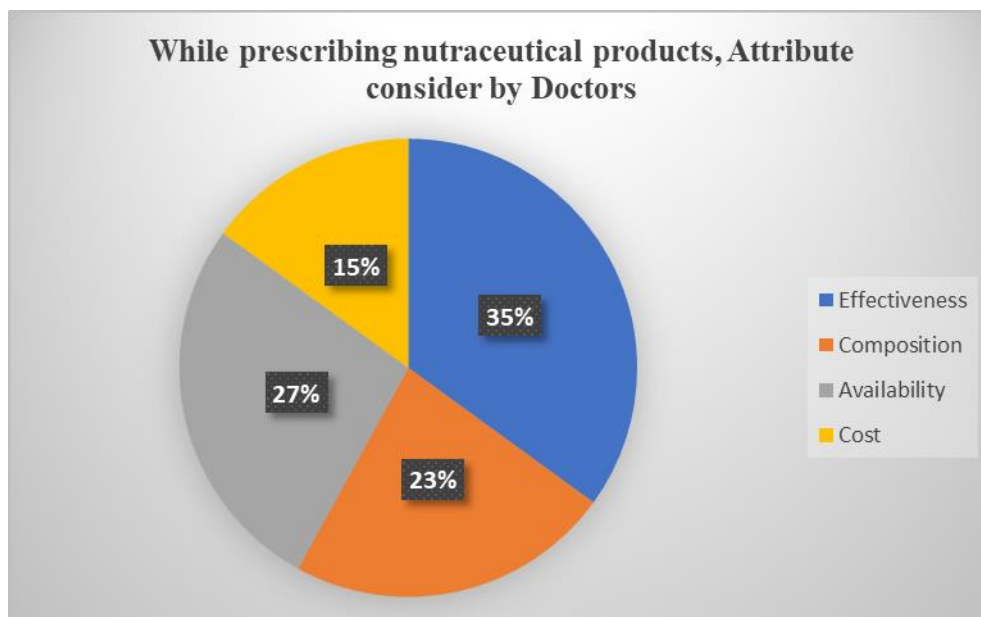


Chart 8: Attributes consider by doctors while prescribing nutraceutical products.

Interpretation:

Above bar graphs shows the data of the doctors considering certain attributes while prescribing nutraceutical combinations, graph states that maximum 35% of doctors consider effectiveness as attribute while prescribing any brand of nutraceutical whereas 27% of doctors consider its Availability as an important attribute during prescribing the same, 23% of doctors responded composition as an attribute moreover about 15% of doctors see cost as a main attribute need to be consider.

9. Analysis of things that help doctors to remember the brand name.

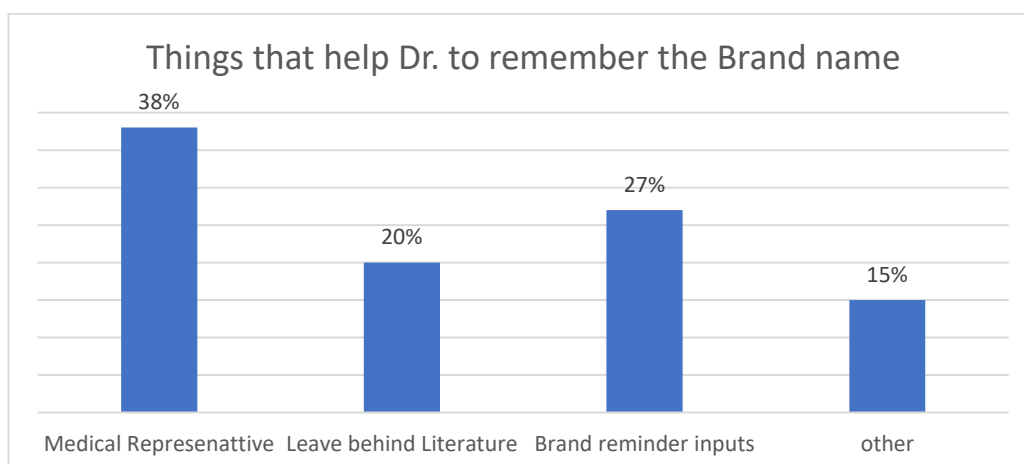


Chart 8: Things that help doctors to remember the brand name.

Interpretation:

Following Graph exhibit the data of the doctors responded, what helps them to remember the brand name, according to the data 38% of doctors remember the brand name through the medical representative further, 27% of them remember by brand reminder inputs while 20% of doctors recall brand name through Leave behind Literature, Some doctors about 15% recall brand name through other means like camps, patient feedback unique molecule content.

Conclusion:

Retailers:

Throughout the survey it was noticed that there were various nutraceutical brands available in the pharmacy stores out of which most prescribed nutraceutical brands by the doctors were Fertisure-M, Mac-q10 and Spercus followed by some other brands like Coq forte, Oligocare, Zoamates. Moreover, on the basis of data analysis and interpretation the sales of Fertisure-M seem to be greater followed by Mac-q10 and Spercus, further it is clear that the competitor brands of nutraceuticals are Fertisure-M, Mac-q10 and Spercus.

Doctors:

During the survey it was observed that mostly Gynaecologist are prescribing Nutraceutical Products for the treatment of Male infertility. Through this study it was found that maximum numbers of doctors prefer Antioxidants, followed by vitamin c, L-carnitine, lycopene as specific molecules in nutraceutical combinations, most of them consider effectiveness followed by, composition, availability and cost as the important attributes while prescribing any brand of nutraceutical. many of the them have suggested that the pricing of the nutraceutical should consider as an important issue in the developing country as India and it should be economic. Apart from that the composition of nutraceutical should meet RDA, recommended dietary allowances or adequate intakes so that its excessive use could be prevented.

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