



Review on: Market Survey on Nimesulide

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ABSTRACT

Background: Although nimesulide has been shown in numerous clinical studies to have anti-inflammatory and antipyretic characteristics in a controlled environment, fever management in actual clinical situations is very different.

Objective: To evaluate Nimesulide's performance in managing acute fever in actual clinical settings.

Methods: A retrospective, multicenter study using electronic medical records (EMR) of 302 patients who visited three centres' outpatient clinics between January 2016 and January 2020 and were given the medication nimesulide for an acute fever was carried out. The change in fever from the baseline to the follow-up visit within 14 days was used to determine the effectiveness of Nimesulide, and the number of side effects reported after taking Nimesulide was used to determine its tolerability.

Keywords: non-steroidal anti-inflammatory drug, NSAID, appropriateness of use, European Medicine Agency, computer-aided telephone interviews

Introduction

As a branch of marketing, pharmaceutical marketing may be described as a procedure that actualizes the market for the pharmaceutical core. It includes all of the actions taken by various people or organizations to really advertise items. The American Association defines marketing as "the context in which buyers or sellers make decisions, or the setting in which buyers and sellers perform functions or conduct business operations that guide the flow of products and services from manufacturer/producer to customers." Pharmaceutical marketers are aggressively pursuing a strategy of optimising the market mix (product, price, place, and promotion) for certain marketing segments; nevertheless, one should keep in mind that many of the elements that drive marketing strategies are beyond of the marketers' control. Relieving pain is one of the fundamental responsibilities of medical practitioners and is frequently a primary goal of patients seeking care. The biopsychological impact of pain is difficult to underestimate, and its incidence is substantially. When stimuli threaten the homeostatic integrity of tissue, either directly or indirectly by disrupting the vasculature. Typically autonomic (ie, changes in blood pressure and heart rate) or hormonal (Adrenal and pituitary secretion) responses and the subjective sensation of pain are generated".

Post Marketing Surveillance Studies:

Post Marketing Surveillance (PMS) is a general term used to describe the research studies associated with product safety evaluation after a drug has been approved for marketing. The main objective of PMS is to provide signals about potentially serious safety problems with marketed drugs". These studies essentially contribute a major proportion of the safety information after a drug enters the market and is prescribed in various ways to a much more diverse population who, in turn take the drug for varied durations and /or schedule Adverse drug reactions (ADRs) are still considered one of the main problems of drug therapy. ADRs are associated with considerable morbidity, decreased compliance and therapeutic success as well as high direct and indirect medical costs. Several considerations have to come into play when managing a potential ADR. It is critical to establish an accurate clinical diagnosis of the adverse event. Combining information about drug exposure together with considering other possible causes of the reaction is crucial.

Special Need for PMS in India:

Population Variation

It is known that there is variation in adverse drug reaction between different countries on account of variation in genetic, environmental, dietary factors, disease patterns and drugs used. In India, we find great difference in the population, their food habits and culture from region to region.

Paucity of Data

There are very few functioning centers in India and adequate information is not available even on adverse drug reactions of old drugs. Thus there is special need of PMS in the country. Several epidemiological studies have shown that soft-tissue injuries comprise the largest part of all musculo-skeletal injuries. Injuries to the soft tissues like ligaments, tendons and muscles are classified as either acute or chronic injuries. Pain associated with the acute injuries like ligament sprains and muscle strains is called acute pain. Such pain and also pain associated with tooth extraction requires immediate medical attention.

Materials and methods

The objective of this study was to verify the appropriateness of use of nimesulide among GPs who gave their consent to be interviewed and use of the related information. The analysis was based on a survey of anonymized data and did not involve any new studies of human or animal subjects performed by any of the authors. The survey was conducted in October 2012 (about 6 months after the distribution of the DHPC) in Bulgaria, Czech Republic, Greece, Hungary, Italy, Poland, Portugal, Slovakia, and Romania. Computer-aided telephone interviews (CATI) methodology was used. This method is suitable for the scope of the survey as it allows surveyors to reach a large number of doctors across a wide range of sampling points, thus guaranteeing thorough representation. Previously this method has been successfully applied to medical research involving cardiovascular disease and asthma.^{4,5} CATI is based on telephone interviews read by the interviewer and selecting responses from multiple-choice options on a computerized questionnaire with built-in branch logic, hence skipping inapplicable questions and probing for more detail when required. The CATI approach enhances data accuracy and intercountry standardization.^{6,7} GP statistics and lists were obtained from official data derived from the Ministry of Health of the countries in scope along with the "One Key database", the world reference for information on health care professionals.⁸ Only prescribers of Nimesulide were recruited for the interview. The prescription screening question: "On average, in a month, how many

The interview questionnaire included the following items: Daily dose, patient characteristics, treatment duration, reason for use, and an estimate of the average number of patients prescribed nimesulide per month. Representativeness of the GP sample is supported by random selection of contacts and the distribution of samples by geographic area.

The caseload of patients was collected by means of the last patient technique (each physician is asked to provide information on the last patient to whom nimesulide is prescribed); this indicates that one patient case per physician is collected for each response and carried forward to the base of physicians selected from each country. Owing to its random selection process, the last patient technique can be considered truly representative of prescribing behavior. Descriptive statistics are used to report data

SCOPE OF PRESENT WORK

Scope of marketing survey refers to the areas covered or the aspects studied under marketing survey. In other words, it implies where or on which areas marketing survey can be applied. In fact, marketing survey concerns with almost each and every activity of marketing management. It has a wide and comprehensive scope.

The scope of marketing survey covers following areas:

1) Survey on Products:

Products involve goods and services. This branch of marketing research covers all the issues related to firm's products.

2) Survey on Market:

This area of marketing research deals with market/consumers. It studies characteristics and compositions of the target markets. It covers both current as well as potential markets.

3) Survey on Sales Methods and Policies:

This area of marketing research, particularly, concerns with study and analysis of the sales-related activities.

4) Survey on Advertising:

Advertising is one of the powerful methods of market promotion. Major part of promotional budget is devoted to advertising activities. Therefore, it is imperative to conduct research on various aspects related to advertising

5) Survey on Pricing:

Price is an important element of marketing mix. In developing and underdeveloped countries, price plays a vital role. Suitable pricing policies and methods can contribute positively in attainment of marketing goals. It is clear that price has remained a major determinant of buying decision.

6) Survey on Distribution:

In today's marketing, distribution has unique role to determine success of product. A marketer can contribute to total consumer satisfaction by designing appropriate distribution network. Physical distribution and distribution channel are two important components of such research.

7. Survey on Business Environment and Corporate Responsibility:

This area is not concerned with solving any marketing problem directly. In order to collect and analyze data related to broad business environment, such research is conducted. The study on the area helps manager formulate strategies for the current and the future market as well. It also helps assess strengths and weaknesses of marketing department in relation to business environment

EXPERIMENTAL OR METHODOLOGY:

Irrational drugs :

According to the WHO, using medications in an illogical or non-rational manner involves. It does not adhere to the definition of sensible usage given above. According to statistics, 50% of patients fail to properly take their medications, and more than 50% of medications are given, administered, or sold inadvertently globally. Patient polypharmacy; excessive injectable usage when oral formulations would be more suitable; improper, frequently insufficient antibiotic dose for nonbacterial illnesses. Antibiotic usage that is irrational includes self-medication, giving inappropriate dosages, and treating conditions that are not bacterial. Antibiotic resistance has increased directly as a result of irrational antibiotic usage. There are many different types of irrational medication use. Drug usage can be assessed both generally.

1) Patients :

Drug misinformation Misleading beliefs • patient demands/expectations

2) Prescribers :

Lack of education and training Inappropriate role models

Lack of objective drug information • generalization of limited experience

3) Workplace :

Heavy patient load Pressure to prescribe

Lack of adequate lab capacity Insufficient staffing

4) Supply System :

Unreliable suppliers Drug shortages • expired drugs supplied

5) Drug Regulation :

Nonessential drugs available

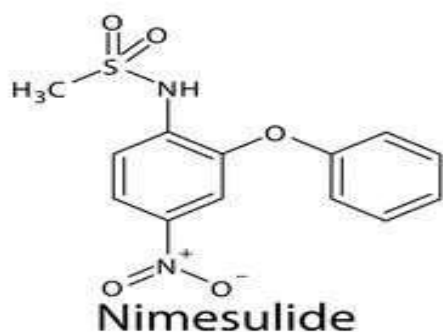
Informal prescribers

Lack of regulation enforcement

NIMESULIDE DRUG PROFILE:

i) Drug Profile:

A drug called nimesulide is used to treat pain and prevent fever. Prescriptions are regularly written for acute pain, menstrual cramp discomfort, backache, postoperative pain, osteoarthritis, and fever. This medication is a kind of NSAID (Nonsteroidal anti-inflammatory drug). Nimesulide effectively reduces these symptoms because it inhibits cyclooxygenase. This medication tackles every factor that contributes to the formation of oedema, including free radicals, proteolytic enzymes, histamine, cyclooxygenases, and prostaglandin. The two aryl groups Nimesulide, an aromatic ether, are phenyl 2-methylsulfonamido-5-nitrophenyl. Both a cyclooxygenase 2 inhibitor and a non-steroidal anti-inflammatory medication, it serves these functions. It is a sulphonamide, an aromatic ether, and a C-nitro molecule. It is made of nitrobenzene.



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ii) IUPAC Name:

N-(4-Nitro-2-phenoxyphenyl) methanesulfonamide

Physical & Chemical Properties:

Formula C₁₃H₁₂N₂O₅S

Molar Mass: 308.31 g mol⁻¹

State: Solid (amorphous powder)

Solubility: Very sparingly in water (0.01 mg/ml)

Protein binding >97.5%

Pharmacology:

Pharmacokinetics:

Nimesulide is absorbed rapidly following oral administration. Nimesulide undergoes extensive biotransformation, mainly to 4-hydroxynimesulide (which also appears to be biologically active). Food, gender, and advanced age have negligible effects on nimesulide pharmacokinetics. Moderate chronic kidney disease does not necessitate dosage adjustment, while in patients with severe chronic kidney disease or liver disease, nimesulide is contraindicated. Nimesulide has a relatively rapid onset of action, with meaningful reductions in pain and inflammation observed within 15 minutes from drug intake. The therapeutic effects of Nimesulide are the result of its complex mode of action, which targets a number of key mediators of the inflammatory process such as: COX2 mediated prostaglandins, free radicals, proteolytic enzymes, and histamine. Clinical evidence is available to support a particularly good profile in terms of gastrointestinal tolerability.

Absorption:

Rapidly absorbed following oral administration. The drug nimesulide tablet granule and suspension to healthy volunteers, the drug was rapidly and extensively absorbed.

Mean peak plasma concentration of 2.86 to 4.58 mg/l Within 1.22 to 3.83 hours of administration.

Distribution:

Nimesulide is rapidly distributed and has an apparent volume of distribution ranging between 0.18 & 0.39 V/kg. It is extensively bound to albumin, the unbound fraction increased to 2-4% in patients with renal or hepatic insufficiency.

Metabolism:

Hepatic Extensive biotransformation, mainly to 4-hydroxynimesulide (which also appears to be biologically active). Route of Renal (50%), faecal (29%)

Excretion:

Excretion in the urine and faeces accounted for 50.5 to 62.5% and 17.9 to 36.2% of an orally administered dose, respectively. The total plasma clearance of Nimesulide, was 31.02 to 106.16 ml hkg, reflecting almost exclusive metabolic clearance. The drug has a low extraction ratio, close to 0.1.

Pharmacodynamics:

Nimesulide is a nonsteroidal anti-inflammatory drug (NSAID), acting specifically as a relatively selective cyclooxygenase-2 inhibitor. However, the pharmacological profile of nimesulide is peculiar, and additional, unknown yet-to-be-identified mechanisms appear to also be involved. One pathway that has been implicated in its actions is the ecto-adenosine diphosphate (ADP) receptor pathway.

Mechanism of action :

A non-steroidal anti-inflammatory medication (NSAID) of the class is nimesulide, a class of sulphonamide's. Its anti-inflammatory, analgesic, and antipyretic properties have been proven in several clinical studies as well as several common animal experimental models. Prostaglandin synthesis is only slightly inhibited by nimesulide, and it appears that other processes are involved in how it works. It exerts a scavenging action on hypochlorous acid without compromising neutrophil activity and prevents the production of oxidants from active neutrophils. Nimesulide also lessens the release of histamine from tissue mast cells and prevents human basophils from producing platelet-activating factor. Furthermore, nimesulide inhibits the release of thromboxane and prevents metalloproteinase activity when applied in vitro to cultures of human articular chondrocytes.

Usage:

Although nimesulide isn't sold in the United States, it is utilised in other medicine for extreme pain. Period aches are among the pains for which it may be used. In the case of long-term management of chronic illnesses like arthritis, nimesulide is not advised. This is because it has a higher risk of liver damage, which includes liver failure. A 2012 appraisal by the European Medicines Agency (EMA) found that nimesulide's overall benefit/risk profile is favourable and comparable to that of other NSAIDs like diclofenac, ibuprofen, and naproxen as long as the usage period is kept to no longer than 15 days and the dose doesn't exceed 200 mg/day.

Children

Less than 10 days of nimesulide does not appear to increase the risk of hypothermia, gastrointestinal bleeding, epigastric pain, vomiting, diarrhoea, or transient, asymptomatic elevation of liver enzymes compared to ketoprofen, paracetamol, mefenamic acid, aspirin, or ibuprofen in children. However, data does not speak to populations less than 6 months old.

Pregnancy and lactation :

Women should use the drug with caution during lactation and nimesulide is contraindicated during pregnancy, and research suggests that it is also contraindicated in lactating women.

Side Effects

Acid or sour stomach

Stomach discomfort and cramps

Dizziness

Skin rash

Nausea and Vomiting

Elevated Liver enzymes

Blood clotting disorders

Diarrhea

Precautions

Before taking Nimesulide talk with your doctor if you are allergic to it or any other medications. The product may contain some inactive ingredients which will cause some allergic reactions or some other serious problems. Before taking Nimesulide talk with your doctor if you are having any medical history such as:

Kidney disease Liver disease

Stomach problem

Heart disease



Storage

Direct contact with heat, air and light may damage your medicines. The exposure of medicine may cause some harmful effects. The medicine must be kept in a safe place and out of children's reach. Mainly the drug should be kept at room temperature between 68°F and 77°F (20°C and 25°C).

CONCLUSION

I have completed marketing survey on nimesulide tablet and in this survey.

Nimesulide (4-nitro-2-phenoxy methane-sulfonamide) is a nonsteroidal anti-inflammatory drug (NSAID) that has good anti-inflammatory, analgesic and antipyretic activity. And is well tolerated by patients as demonstrated in numerous clinical trials

.Nimesulide is a relatively weak inhibitor of prostaglandin synthesis in vitro and appears to exert its effects through a variety of mechanisms including free radical scavenging, effects on histamine release, the neutrophil myeloperoxidase pathway, bradykinin activity, tumour necrosis factor- α release, cartilage degradation, metalloprotease synthesis, phosphodiesterase type IV inhibition, platelet aggregation and synthesis of platelet activating factor.

Our study confirms and proves nimesulide to be a highly efficacious and very well tolerated drug in management of various acute painful states in Indian population. There were no changes in the liver function tests when studied at the time of commencement and end of study. The common side effects noted in both the groups were nausea (9%), vomiting (8.5%), heartburn (7.5%), gastritis (1.2%) and a few patients complained of giddiness (0.7%). None of the patients needed any hospitalization for the adverse events nor any of the patients withdrew from the study due to adverse events.

Thus nimesulide is an excellent and safe option in management of acute and chronic painful conditions in the Indian settings. I observe that many of physicians prescribe the nimesulide which is an irrational drug. I have done the survey on October month of 10 medical store and I have collected all the monthly sale of nimesulide & I was concluded that the weekly average sale of nimesulide is following:

Highlights of The Nimesulide Sales Market Report:

- 1)The market structure and projections for the coming years.
- 2)Drivers, restraints, opportunities, and current trends of Nimesulide Sales Market.
- 3)Historical data and forecast.
- 4)Estimations for the forecast period 2030.
- 5)Developments and trends in the market.

By Type:

Tablets

Capsule

Granules

Other

By Application:

Chronic Arthritis

Primary Dysmenorrhea

Traumatic Pain

Post-Operative Pain

Other

Market scenario by region, sub-region, and country. Market share of the market players, company profiles, product specifications, SWOT analysis, and competitive landscape. Analysis regarding upstream raw materials, downstream demand, and current market dynamics. Government Policies, Macro & Micro economic factors are also included in the report. We have studied the Nimesulide Sales Market in 360 degrees via both primary & secondary research methodologies. This helped us in building an understanding of the current market dynamics, supply-demand gap, pricing trends, product preferences, consumer patterns & so on. The findings were further validated through primary research with industry experts & opinion leaders across countries. The data is further compiled & validated through various market estimation & data validation methodologies. Further, we also have our in-house data forecasting model to predict market growth up to 2030.

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