ANNUAL REPORT 2000-2001

facilitating healing.

SUN
PHARMACEUTICAL
INDUSTRIES LTD.

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reconstitute
rectify
restore
rehabilitate
remake
reintegrate
reorganize
revive
recuperate
reprogram
renew
reprocess
revitalize
recondition
replenish
restore

Facilitating healing.

Simply stated, helping put the pieces back together.

So that the body's zillion synchronized cycles with its plethora of cross-links, some known and some yet only assumed-and its vast array of hypertexts and regeneration-friendly systems can work. An estimated 6 trillion reactions take place in every cell every single second, and this stream of transformation continues every single moment of our lives.

Maintaining a functional system of balance and equipoise, more or less. Much more than a simple biochemistry of cells, an outpouring of energy and several terrabytes of information.

Only one of a trillion enzymes may function less than perfectly, and only the rarest neuron may misfire, and of an endless chain of DNA, only one may fail to autocorrect when damage occurs. When things fall out of sync, blood pressure can rise or fall or fluctuate whimsically, biochemicals can vary from their required levels, and cellular mutations can multiply out of control. Or much more can happen.

It is only one in a million times that things don't work quite the way that they are supposed to, and nature's correction sytems are stretched past their tolerances.

The professional first spots and then quickly integrates a torrent of these trace and obvious signs across numerous organs and systems to first diagnose and then rectify. The process is pure alchemy-part science, part perception.

And the most precise equipment designed by astute minds, or the best drug discovered or developed to remedy is merely a tool - at best a secondary partner in this process of returning to the whole.

Measure your health by your sympathy with morning and spring.

Thoreau (1817-1862)

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Speciality area emphasis remains the single factor driving growth at the company and is central to all that we do. Replicating the strategy that has worked for us in the domestic market across the high growth international markets of our interest remains an area of the highest priority, as markets the worldover converge on quality and regulatory requirements.

As new entrants try to make a mark in speciality segments in the domestic formulations arena attracted by the sustainable nature of margins, price led competition seems to be the entry strategy of the day. However, increasing competitive interest in these therapy areas that are largely undertreated also increases the noise factor for a product in the long term and shifts existing prescriptions from older molecules to actively promoted therapies. There is, as such, no sure fire formula to building or protecting market shares in speciality therapy areas, and there is no short cut to building stable, carefully nurtured customer relationships.

This year too, growth is the sum total of 2 sectors: the domestic formulation market with leadership in key therapy areas and our continued efforts in the international market for bulk actives. Our well proven skills in research- both in dosage form development and process chemistry help support our growth plans in these sectors. With this rich speciality product basket the international market for dosage forms is virtually an untapped opportunity, and in context of structural changes we had put in place a year ago, the turnaround has begun and we expect this change to happen over the next 2 years.

We closed the year ended March 2001 with a domestic market ranking of 5th (note: and continue to hold this rank despite industry wide consolidation well into 2002). As we continue to build strong relationships with customers we recognize a fact: even as a well run , efficient pharma company, our role at best can be that of a facilitator or partner in the entire healthcare equation. As the doctor repairs, heals, corrects or reshapes, all that we do is to offer him a palette of treatment options that he can deploy as he thinks most appropriate.

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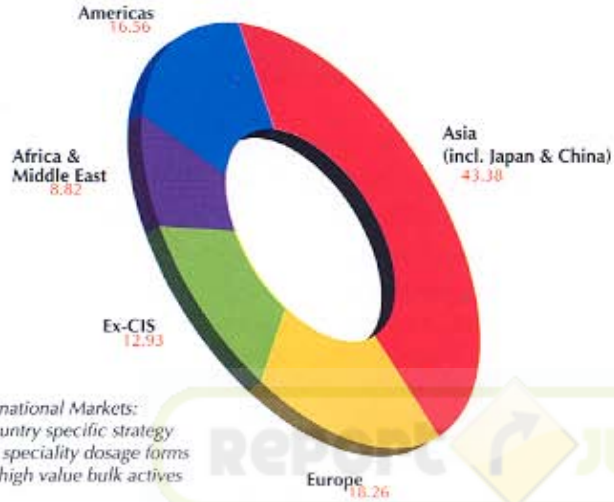
Summary



International Markets: A country specific strategy with speciality dosage forms and high value bulk actives

Sales Breakup by type	2000-01	1999-00*
		(Rs. cr)
Domestic Formulation	372.01	304.55
Domestic Bulk	121.35	74.63
Exports Formulation	33.75	23.54
Exports Bulk	84.16	90.03
Exports others	0.17	0.12

* Sun Pharma Export sales have been consolidated for the previous year on a notional basis for comparison.

Numbers for 2001 do not mention Sun Pharma Exports seperately since these are already included postmerger with Sun Pharma

PSR Team size

by division

Symbiosis	64
Inca	152
Synergy	83
Spectra	248
Sun	231
Aztec	136
Solares	249
Milmet	93

(March 01)

Customer centred teams have earned Sun Pharma strong ranks with specialist consultants

Total income was up 29%, largely due to continued domestic market growth.

Domestic market formulation growth of 22% factors in a much larger base and increasing competitive interest in our key therapy areas. The correction plan for dosage form exports which was put in place in 2000, clearly requires more time to pan out- the direction is clear, and the correction process has begun: pruning product lists in some markets and a clear definition of the number of high growth therapy areas that we intend to be identified with.

The export of speciality bulk actives crossed Rs. 84cr. The approval by the USFDA of the Ahmednagar bulk active plant has helped in selling to large customers across the regulated markets of North America and Europe , and a number of bulk actives that have been filed for, await approval. (note: Panoli was submitted for USFDA approval in 2001-02).

As per data from the ORG Retail Chemist Audit for March 2001, across segments we registered a growth of over 24%, a rate that is clearly 3 times that for the industry (note: and in 2001 despite a slowdown in industry we maintained these numbers). Market share for March 2001 was 2.61%, up from 2.49% for March 2000 (and was 2.77% in Dec 2001). With newer treatment options and increased usage, our speciality therapy areas continue to grow faster than industry average.

29%

GROWTH

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The Heart, Brain and Lungs - high growth areas with unmet needs

CMARC RANKS	March-June	July-Oct	Nov 00-Feb 01
Cardiology	2	2	3
Psychiatry	1	1	1
Neurology	1	1	1
Diabetology	7	7	6
Gastroenterology	2	1	3
Orthopedics	3	3	3
Ophthalmology	5	3	3
Chest Physicians	5	5	4
Consultant physicians	3	4	6
Oncologists	15	17	10
Gynaecologists	27	27	19

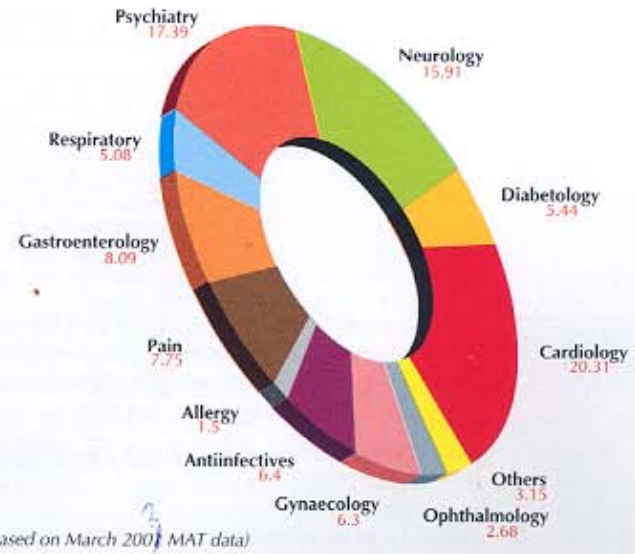
CMARC Audits for the periods mentioned, 2000-2001.

ReportJunction.com

Therapy review

Psychiatry and neurology accounted for over 33% of sales. Cardiology and diabetology accounted for 25.75%. 6 brands continued to feature among the top 300 pharma brands in the domestic market. Gynaec and orthopedics began to deliver on their high growth promise as new product successes were witnessed in these areas. Among recently launched brands, Oleanz and Celact were rated among the best launches in the pharma industry for 2000.

The CMARC audits continue to signal strong customer support in key therapy areas and highlighted action areas for correction well before prescription trends became evident. In 2000-01 a number of interesting bulk actives were scaled up, taking the total for active promotion to over 80.



(based on March 2001 MAT data)

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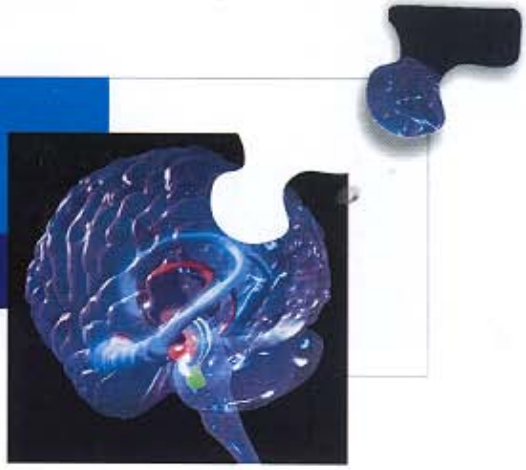
SYNERGY



TOP 5 PRODUCTS

(Rs. cr)

	val	gr%
Encorate	14.73	58
Zeptol	12.71	16.8
Syndopa	8.14	15.6
Lonazep	6.01	15
Oleanz	5.1	924

(ORG Retail Chemist Audit, March 2001)

NEW!

Veniz XR · Nodict

Two shades of brain healing :
In schizophrenia, therapy slowly helps to resculpt worldview.
In epilepsy, medication "resets" the firing of neurons restoring a state of synchronicity.

For the 5th year running, Synergy continued to reiterate its top standing with the key customer groups of psychiatrists and neurologists, backed by an increasing share of prescriptions. Several new entrants in these high growth therapy areas not only translated into aggressive new product introduction, but also helped grow the market in terms of faster pickup and acceptance of new products by doctors.

An interesting change in Synergy's top product roll call was the inching in of the antipsychotic Oleanz among its top 5 products-Oleanz , which was launched last year based on captive bulk active , seems to be displacing older antipsychotics on the strength of its side effect profile- a much lesser propensity for irreversible movement disorders, and a significant improvement on negative symptoms and cognitive impairment compared to older medication. The medication in Oleanz is also being tested in other indications where agitation is an accompanying symptom: agitation with bipolar mania, agitation with Alzeimer's (more than 75% of patients with Alzeimer's show agitation).

Antiepileptics continues to be mainstay of Synergy's business with Zeptol, Encorate, Lonazep, Gabantin firmly establishing Synergy as one of the top contenders in this area.

Encorate, the antiepileptic, seems well placed to cross milestones-the long acting form Encorate chrono offers compliance related advantages as also creates a technology related entry barrier for competitors. Gabantin's usage as the treatment of choice in diabetic neuropathy and post herpetic nerve pain has found increasing acceptance as reflected by a doubling of its sales.

"In Karnataka, about 3% of the population suffer from some kind of neurological disorder, of which approx. one third is epilepsy... In India there are an estimated 8 mill epileptics, and this is the most common neurological disorder after headaches, the incidences for epilepsy are 5.7/1000 in the urban, 11.9/1000 in the rural and an overall 9/1000 in the total population...other conditions like PD, stroke, mental retardation, tremors are much lower in the order of conditions...."

-Report on the Indian Pediatric Congress in Bangalore, Dec 12,2000, pharmabiz.com

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One of the most interesting facets of work reported last year seems to be the linkages that depression exhibits with other diseases, a fact that doctors were perhaps subconsciously aware of.

This year, Synergy topped up its depression product basket with the novel antidepressant Veniz XR, and introduced a product for alcohol de-addiction with Nodict.

Here comes the Sun! Putting together the pieces for a brighter, more complete day...

Veniz XR is a novel antidepressant with a dual mode of neurotransmitter action- blockade of the re-uptake of 2 important neurotransmitters, norepinephrine and serotonin. Veniz XR is positioned as the treatment of choice for major depression, targeted at the large subsegment of patients who do not respond adequately to antidepressant treatment, or patients in whom depression recurs after treatment. As an ailment, depression seems to be treated but not cured- about 30-50% of patients treated with existing antidepressants experience a relapse 6 months after treatment. The medication in Venix XR is being studied in the treatment of generalized anxiety disorder, mixed anxiety disorder and in non-psychiatric indications like diabetic nerve pain.

is depression the rogue factor?

Brain imaging studies at Yale indicate that in patients with depression, there is a decrease in the volume of the hippocampus(the part of the brain related to learning, moods, emotions) possibly because of neuronal atrophy and loss- antidepressants seem to promote nerve growth and protect cells in this part of the brain.

- Journal of Neuroscience, Dec 15,2000

Diabetes and depression:

Diabetics seems to be twice as likely to suffer from depression as those without the disease, say doctors at the University of Washington after analysis of 25 years of data, and this may be a typical chicken and egg situation.

Diabetes Care, June 2001

Diabetes gets worse with depression:

Findings presented at the American Diabetes association indicates that depression impairs glycemic control in diabetics over time- selfcare does not affect this link- depression linked physiological changes could be to blame.

Hypertension and depression:

People who experience depression/anxiety are at increased risk of developing hypertension, says the result of a 2-decade study with the CDC. The increase in risk is comparable to a 10 point change in baseline diastolic pressure or a 10 point change in body mass index. How depression and anxiety lead to the development of hypertension is not entirely known, but may be linked to the nervous system response to stress.

The national nutrition examination follow up study, Psychosomatic Medicine, March 2000

Heart disease and depression:

According to studies at the Duke University research center, which were presented at the annual meeting in March 2001 of the American College of Cardiology, the risk of death is twice as high in a group of congestive heart failure patients who were depressed, compared to patients who were not depressed- physicians had earlier assumed that heart patients were depressed because they were unhappy about being sick, but it now seems that depression in these heart patients independently predicts a poor outcome, and the occurrence of cardiovascular complications also increased in the depressed group. Apparently, heart rate variability in depressed patients is decreased and the depressed seem to have stickier platelets that are likely to clot together, setting up conditions for a heart attack...

... and the simply just depressed :

patients studied over a 4 yr period in Amsterdam showed that depression increases the risk of death in older patients whether or not they have cardiac disease.

- Archives of General Psychiatry, 2001, 58

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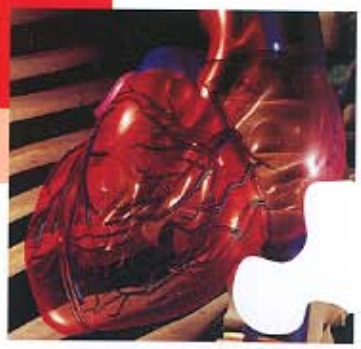
AZTEC



TOP 5 PRODUCTS

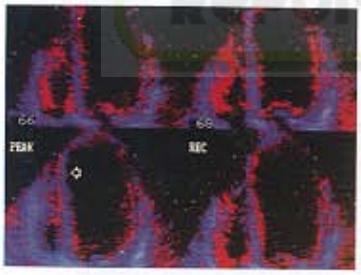
(Rs. cr)

	val	gr%
Monotrate	22.48	5.5
Glucored	15.71	33.1
Angizem	9.03	3.3
Cardivas	5.97	110.9
Repace	5.43	69.5

(ORG Retail Chemist Audit, March 2001)

NEW!

- **Glypride**
- **Rapilin**
- **Rezult**
- **Rezult A/AF**
- **Aquazide**
- **Sibutrex**
- **Monosprin**



An echocardiogram uses sound waves to take moving pictures of the heart. This test assesses the pumping function and will indicate if there is a problem with the heart valves.

Two primary factors that impacted Aztec's performance for the year increased competitive interest and a slew of new product launches. Aztec witnessed the largest number of new product launches concentrated in any single area, in the area of diabetology.

Internationally, the cardiovascular market is being driven by increasing candidate patient base for certain classes of drugs (particularly lipid lowering agents and antihypertensives) and expanding indications for existing drugs.

Monotrate, an antianginal and the largest selling product for the company was supplemented with the launch of Monosprin (a combination of the drug in Monotrate with the clot busting agent aspirin). The launch of Monosprin was based on actual co-prescription patterns seen with the single ingredient antianginal.

While there is no significant change in the list of leading products for the division, a number of studies were reported during the course of the year that point to increasing acceptance for Cardivas (carvedilol) and Repace (losartan).

Both Monotrate and Glucored were strongly promoted during the course of the year using an emotionally appealing campaign, the MG Golden Movement campaign.

Hypertension is associated with a continuum of renal damage, and patients with Type 2 diabetes are particularly vulnerable to renal disease. Results from a study called RENAAL* showed that the medication in Repace reduced the risk of end stage renal disease equal to an average delay of 2 years in the need for transplantation or dialysis. Doctors hypothesize that losartan not only controls blood pressure but also controls angiotensin 2 which adversely affects the kidney independent of the blood pressure.

(=Reduction of end points in NIDDM with angiotensin 2 antagonist losartan study)*

diabetes the countdown

- Prevalence is up 32% in the US since the 90's, according to CDC surveys
- Diabetes is occurring at a younger age- this is serious since complications like retinopathy, renal damage, cardiovascular disease are dependent on the duration of the disease. Diabetics are 2- 4 times more likely to have heart disease than people without the disease.
- By 2025, over 300 million may suffer from diabetes- up from about 150 million people currently.
- Damage to the nervous system in Diabetics may affect the central as well as peripheral nervous system-so far only the peripheral nerve damage/pain have been studied, but the brain and spinal cord are affected as well.
- Women with type 2 diabetes have a dramatically raised risk of death from heart disease- this may be related to increased triglyceride levels and decreased levels of the 'good cholesterol' HDL.

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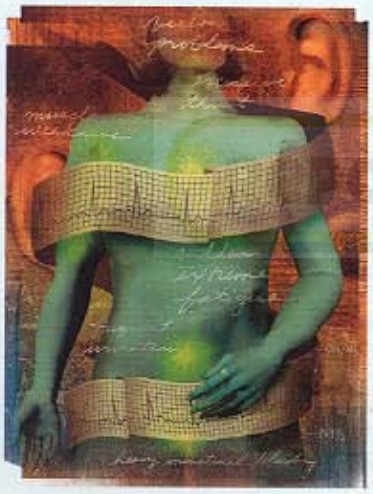
New cardiovascular guidelines:

Treat quicker.
The American Heart association and the American College of Cardiology recently updated guidelines on preventing heart attacks in people with existing cardiovascular disease (the earlier revision was in 1995) These new guidelines promote the use of betablockers and ACE inhibitors in heart attack survivors, more aggressive control of risk factors such as smoking and the benefits of lowering cholesterol. The guidelines are becoming more important because of the increasing incidence of heart disease and rapid increase in diabetes. It is estimated that 2/3rds of deaths in diabetes patients is from cardiovascular disease, and the growth of type 2 diabetes is staggering in proportion...

from the Journal of the American College of Cardiology, Nov 2001



Diabetes in India- on a silent rampage?

"By 2005, India will have the largest number of diabetics (30-35mill) and every 5th diabetic in the world will be an Indian. Incidences in South India have increased 40% over a 6 year span, from 8.2% in 1988-89 to 11.6% in 1994-95. The onset is at a much younger age and most cases come with complications at the time of diagnosis- Almost 50% have tissue damage- eye problems (23%), kidney problems (6%), nerve problems (28%), hypertension (38%), heart disease (12%).. the number of patients at the diabetes clinic a the Govt. Hospital in Chennai have increased from 6190 in 1993 to 19,991 in 1999..."

Reuters Health Report, Jan 31 '01.

An artist's representation of atherosclerotic deposits that gradually narrow and then block blood supply to the vital organs.

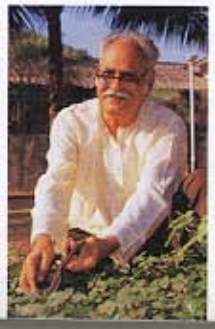
Cardivas, the medication for congestive heart failure and hypertension continued to race up the number charts with remarkable support from reported clinical trials. Betablockers are prescribed, at best, in 5-15% cases with heart failure. But the results of these trials were such that physicians would be compelled to use betablockers. One such trial was COPERNICUS, which studied what was probably the sickest collection of patients ever studied in heart disease- patients whose hearts were pumping less than 25%. Even in this statistically skewed patient group, there was a remarkable reduction in the risk of dying, regardless of the age, the etiology of the heart failure or the extent of impairment. This trial was stopped because the ethical committee monitoring the trial felt that it was unethical to continue the treatment of patients with a placebo, and all patients were then offered carvedilol. Another trial CAPRICORN reinforced these findings-people who have suffered a heart attack (even a class 4 heart failure) can prevent a second attack and reduce their risk of dying if they are taking the betablocker carvedilol.

Aztor, the cholesterol lowering medication launched last year witnessed substantial price related pressure as lower priced products were introduced by competitors prompted by a steady fall in bulk active prices. On the plus side, there is increasing evidence supporting quicker use of the medication in Aztor after angina. Currently this medication is prescribed for heart patients after they leave the hospital- but evidence is increasing for these to be prescribed much earlier, and the maximum benefit is when the drugs are prescribed within a 24-96 hour window after an angina attack.

The most aggressive addition to Aztec's product portfolio was in the surging area of diabetes. The Aztec team designed a special diabeto campaign to make their presence felt in this extremely competitive segment. Diabetes continues to be terribly undertreated, and drugs that try to treat diabetes complications like nerve damage, renal failure, retinopathy- continue to reach market.

Aztec's introductions spanned the oral antidiabetics Rezult (rosiglitazone), Rapilin (repaglinide), Glypride (glimiperide).

The most important amongst these perhaps is Rezult, an activator of PPAR gamma receptors (present in the liver, skeletal muscles, fat tissue) that decreases plasma levels of glucose with the amount of insulin that is available. Since it spares beta cells in the pancreas from exhaustion, it delays the need for external insulin. New data indicates that the medication in Rezult also decreases certain cardiovascular risk markers, suggesting that there could be a potential cardiovascular benefit in type 2 patients. These cardiovascular markers have a role in atherosclerosis.



Do Indians have a different sort of Diabetes?

"Diabetes in Indians has several distinctive features compared to diabetes in Europeans- the family history appears to be stronger, patients are less obese- this suggests that genetic factors may play a very important role.."

Dr Mohan, on setting up of a genetic lab at the Madras Diabetes research foundation, Chennai

Report in pharmabiz.com, Dec. 18, 2000.

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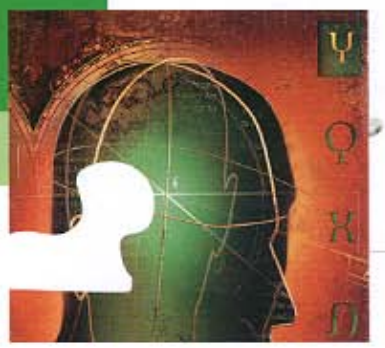
SUN



TOP 5 PRODUCTS

(Rs. cr)

	val	gr%
Alzolam	14.66	2.1
Pantocid	6.53	157.7
Celeact	5.95	999
Mesacol	4.12	3.8
Famocid	4.63	3.9

(ORG Retail Chemist Audit, March 2001)

NEW!

- **Pantocid IV**
- **Irovel ****
- **Mozex**
- **Edegra**
- **Prazopress XL****
- **Pioglit****

(Irovel, Pioglit and Prazopress XL were subsequently transferred to the new cardiac division, Arian as well as to Aztec, in 2001)

Alzolam and Pantocid remain as the star players for the Sun division. Alzolam witnessed inroads in its market from lower priced competitors. Pantocid, the proton pump inhibitor for the treatment of ulcers that was launched last year continued to notch success due to its efficacy and safety profile. The launch of Pantocid IV for the first time in India was another major landmark for the division.

With the introduction of Mozax, the latest treatment for gastroesophageal reflux, the division continued to make headway with Gastroenterologists and Physicians. Mozax offers a much better cardiac safety profile compared to its precursor molecules. The market for Mozax is promising as it is expected to replace the older molecule in this category, namely Cisapride.

Irovel (irbesartan), the follow on molecule to losartan (promoted as Repace by the Aztec division), and AT2 receptor blocker specifically indicated for hypertension with clear advantages for renal safety, was introduced in order to top up the line of commonly prescribed antihypertensives. The medication in Irovel appears to have advantages in patients with type 2 diabetes where it appears to delay the progression of renal disease, however the USFDA recently turned down approval for this use as a separate indication for the original research brand. Several earlier studies had indicated that kidney protection and the delay in dialysis were independent of irbesartan's blood pressure lowering effect.

In GERD, the acidic contents of the stomach can surge back into the oesophagus and cause cell damage.

In Anxiety disorders, Alzolam helps restore a sense of calm and order and all's right with the world...

Generalized anxiety disorder

Less than 50% of patients with generalized anxiety disorder (GAD) experience a partial or full remission over 5 years, according to a study reported in the British Journal of Psychiatry. A significant number of the world's population is affected by a chronic anxiety that is so severe that its disabling effects are more serious than lung disease, sleep disorders, drug addiction and major depression. GAD affects 5% of the population and is poorly recognized- less than 20% receive proper treatment. The key characteristic of GAD is loss of control over worrying. This worrying lasts for months and years, resulting in sleeplessness, irritability, poor concentration and muscle tension. The worry and anxiety can impair all social roles, and this can worsen coexisting health conditions and chronic depression.