

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use IMUNSTEM® safely and effectively. See full prescribing information for IMUNSTEM.

IMUNSTEM® for oral use, liquid, initial U.S. Approval: 2018

IMUNSTEM (olive leaf, yarrow flowers, rosemary leaf, yucca plant and cassia oil) liquid for oral solution use.

-----INDICATION AND USAGE-----

IMUNSTEM stimulates the immune system throughout the body. (1.0)

-----DOSAGE AND ADMINISTRATION-----

The recommended dosage is in liquid form orally taken ½ to ¾ quarter of a dropper, 1 to 4 times daily. (2.0)

-----DOSAGE FORMS AND STRENGTHS-----

Liquid form – use dropper: ½ to ¾ quarter of a dropper. (3.0)

-----CONTRAINDICATIONS-----

There are no contraindications for IMUNSTEM. (4.0)

-----WARNINGS AND PRECAUTIONS-----

IMUNSTEM should be taken only as prescribed and monitored by Qualified medical personnel. IMUNSTEM has been observed to increase the pulse rate and induce vomiting for individuals on rare occasion taking higher dosages of IMUNSTEM. (5.0)

-----ADVERSE REACTIONS-----

- In rare circumstances an adverse reaction in the mouth such as “mild blisters”.
- A burning sensation in the throat in the beginning of oral treatment may occur but subsides. If the burning sensation persists, capsules may be substituted for an improved toleration of administration. (6.0)

To report SUSPECTED ADVERSE REACTIONS, CONTACT Golden Sunrise Pharmaceutical Incorporation at 1-559-781-0658 or FDA at 1-800-463-6332 or www.fda.gov/medwatch

-----DRUG INTERACTIONS-----

IMUNSTEM has been combined with other drugs, but has not been thoroughly tested with significant combinations yet to show interactions with multiple combinations. You should always read product labels. (7.0)

-----USE IN SPECIFIC POPULATIONS-----

- Pregnancy: IMUNSTEM has not been tested on pregnant women. (8.0)

See 17 for PATIENT COUNSELING INFORMATION
01/2018

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FULL PRESCRIBING INFORMATION

1.0 INDICATIONS AND USAGE

ImunStem stimulates the immune system throughout the body. *ImunStem* aids in the cellular regeneration of damaged areas of the body through diseases and injuries. *ImunStem* also helps blood flow through the system especially in difficult regions such as body capillaries.

ImunStem is a highly mobile compound that has been shown as a central nervous system and immune system stimulant.

ImunStem can act alone safely or with other medical therapies to maximize efficacy and produce faster and lasting benefits to treat *Serious or Life-threatening* diseases or conditions by supporting immune system function. Physicians have observed that using *ImunStem* provokes a significant response, i.e., a reduction in symptoms in patients with these diseases: autism, alzheimer's, neuropathy, chronic lymphocytic leukemia, multiple sclerosis, parkinson's, schizoaffective disorder, fragile-X syndrome, and a significant decrease of side-effects to chemotherapy for cancer. *ImunStem* has been shown to help reduced loss of blood from surgical wound and menstrual periods (shorter and lighter periods).

2.0 DOSAGE AND ADMINISTRATION

Take $\frac{1}{2}$ to $\frac{3}{4}$ of a dropper of *ImunStem* under tongue one to four times daily. Leave under the tongue for approximately forty (40) seconds and then drink water.

If the patient has a sensitivity of the mouth and/or throat then an administration orally mixed with one (1) teaspoonful of yogurt or capsules can be administered.

The recommended dosage interval for *ImunStem* is between two (2) and three (3) hours when used in *Serious or Life-threatening* diseases or conditions and emergency situations, and it is strongly advised that four (4) doses of *ImunStem* be taken per day until a medical professional that is monitoring the illness finds it warranted to reduce the dosage interval.

ImunStem is effective at $\frac{1}{2}$ to $\frac{3}{4}$ of a dropper 1 – 4 per day:

Product	Dosage per day	Per Dose Size of a Dropper
<i>ImunStem</i>	1 – 4	$\frac{1}{2}$ to $\frac{3}{4}$

3.0 DOSAGE FORMS AND STRENGTHS

ImunStem is liquid form:

Product	Per Dose Size
<i>ImunStem</i>	1.0 ml

Active Ingredients (mg) per Dose of *ImunStem*:

Active Ingredients	mg
Olive leaf extract	260
Yarrow flowers extract	52
Rosemary leaf extract	63
Yucca plant extract	50
Cassia oil	2.6
Total:	<u>427.6</u>

4.0 CONTRAINDICATIONS

There are no contraindications for *ImunStem*.

5.0 WARNING AND PRECAUTIONS

ImunStem should be taken only as prescribed and monitored by qualified medical personnel. *ImunStem* has been observed to increase the pulse rate and vomiting in individuals on rare occasions if taking excessive/higher dosages of *ImunStem*. Physicians should advise their patients administered *ImunStem* that a mild fever may occur, typically this condition can last for one (1) to two (2) days then subsides.

ImunStem should only be taken under a doctor's supervision. The formulation creates high energy levels in patients with *Serious or Life-threatening* diseases or conditions and low immune system levels. Patients should not engage in any activity greater than they can tolerate after taking *ImunStem*. Also, *ImunStem* should not replace any existing medication that is prescribed by the primary physician. Only the prescribing physician should alter, modify or update any medications taken by the patient.

Patients interested in changing their medication regimen should consult their physician before modifying any prescribed medication program.

6.0 ADVERSE REACTIONS

- In rare circumstances an adverse reaction in the mouth such as mild blisters have occurred.
- A burning sensation in the throat in the beginning of oral treatment may then usually occur but subsides. If the burning sensation persists, capsules may be substituted for a beneficial response.
- Vomiting.
- Yarrow flowers can cause severe allergic skin rashes.

7.0 DRUG INTERACTIONS

ImunStem has been combined with other drugs, but has not been thoroughly tested with significant combinations yet to show interactions with multiple combinations. You should always read product labels. If you have a medical condition, or are taking other drugs, herbs, or dietary supplements, you should speak with a qualified healthcare provider before starting a new therapy.

8.0 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

ImunStem has not been tested on pregnant women. It is recommended that consultation with a health professional be sought before use of *ImunStem*.

8.2 Nursing Mothers

ImunStem is not recommended for nursing mothers.

8.3 Pediatric Use

ImunStem is not recommended for pediatric patients.

10.0 OVERDOSAGE

Excessive doses of *ImunStem* may cause reactions with a cause a variety of symptoms from central nervous system stimulation to damage of the heart, liver and kidneys in extreme overdosing situations. Please refer **5.0 Warning and Precautions**.

Possible side effects may include vomiting, nausea, diarrhea, constipation, dry mouth, dilated pupils, gastrointestinal discomfort, irritations, flushing, and cold sores.

No cases of *ImunStem* overdose have been reported.

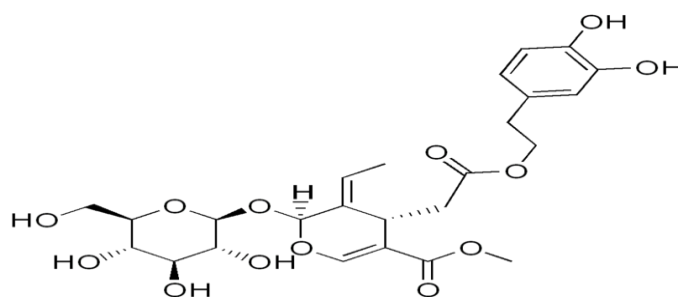
11.0 DESCRIPTION

Golden Sunrise Pharmaceutical Incorporation (Golden Sunrise) is currently marketing *ImunStem* dietary supplement product that is comprised of Olive leaf extract, Yarrow flowers extract, Rosemary leaf extract, Yucca plant extract and Cassia oil under the dietary supplement guidelines. *ImunStem* is developed as a drug product for treatment of *Serious or Life-threatening* diseases or conditions. Based upon the information provided, at least fifty (50) patients with *Serious or Life-threatening* diseases or conditions (Autism, Viral diseases, Cancer, Hypertension, Epilepsy/Seizure, Thalassemia Major B, Stroke, etc.) have received treatment with *ImunStem* dietary supplement.

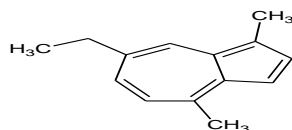
ImunStem is an herbal (botanical) drug substance that provides a stimulation effect of the immune system throughout the body to support human health and overall health. *ImunStem* aids in the cellular regeneration of damaged areas of the body from diseases and injuries, such as surgical mitigation and bleeding. *ImunStem* also helps blood flow through the system especially in difficult regions such as body capillaries. *ImunStem* is a highly mobile compound that has been shown as a central nervous system and immune system stimulant.

ImunStem can act alone safely or with other medical therapies to maximize efficacy and produce faster and lasting benefits to treated subjects by supporting immune system function.

Oleuropein is component of *ImunStem* is chemically described as 4S,5E,6S)-4-[2-[2-(3,4-dihydroxyphenyl)ethoxy]-2-oxoethyl]-5-ethylidene-6-[(2S,3R,4S,5S,6R)-3,4,5-trihydroxy-6-(hydroxymethyl)-2-tetrahydropyranyl]oxy]-4H-pyran-3-carboxylic acid, methyl ester. Molecular formula $C_{25}H_{32}O_{13}$ and structure formula as following:

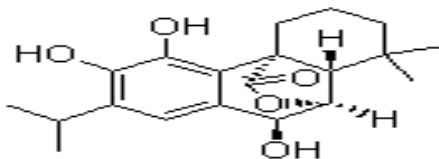


Achillea Millefolium is component of *ImunStem* is chemically described as 7-Ethyl-1,4-dimethylazulene. Molecular formula $C_{14}H_{16}$ and structure formula as following:



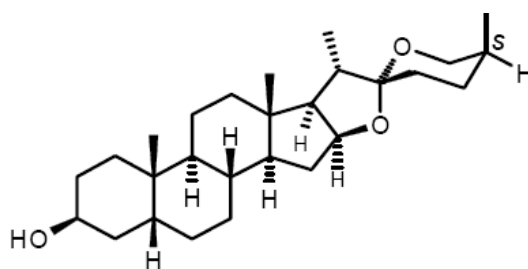
M.W. = 184.28

Rosmarinus Officinalis is component of *ImunStem* is chemically described as [4aR-(4aa,9b,10a,10ab)]-1,3,4,9,10,10a-Hexahydro-5,6,9-trihydroxy-1,1-dimethyl-7-(1-methylethyl)-2H-10,4a-(epoxymethano)phenanthren-12-one. Molecular formula $C_{20}H_{26}O_5$ and structure formula as following:



M.W. = 346.42

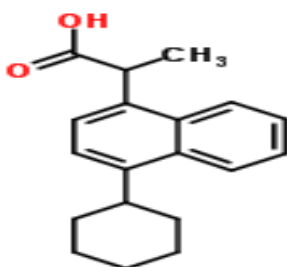
Sarsasapogenin Glycoside is component of *ImunStem* is chemically described as 3-O-[[O- α -D-galactopyranosyl(1 \rightarrow 2)]-[-O- β -D-galactopyranosyl(1 \rightarrow 6)]-O- β -D-glucopyranosyl-(1 \rightarrow 4)- β -D-glucopyranosyl)-(25S), 5 β -spirostan-3 β -ol. Molecular formula $C_{27}H_{44}O_3$ and structural formula as following:



Sarsasapogenin

M.W. = 416.64

Cassia Oil is component of *ImunStem* is chemically described as 2-methoxy-4-prop-2-enylphenol; [(E)-prop-1-enyl]benzene. Molecular formula $C_{19}H_{22}O_2$ and structural formula as following:



M.W. = 282.37678

Inactive ingredients: d-Limonene, 2-Butoxyethanol, Benzenesulfonic acid, C10-16-alkyl derivatives, compounds with 2-Propanamine, Hydrocarbon and water.

12.0 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

ImunStem is an herbal (botanical) product, which has pathogenesis and homeostatic properties. *ImunStem* is taken in liquid oral doses for internal use. The component of the drug substance that makes the compound of *ImunStem* comprises the extraction of ingredients from Olive leaf, Yarrow flowers, Rosemary leaf, Yucca plant, and Cassia oil. The variety of components encompassing these botanicals has a wide use which provides antioxidant activity and a powerful positive effect on the immune system. *ImunStem* allows the active ingredients to disperse throughout the body and blood stream; it also has a direct effect upon immune-cell and cellular functioning.

ImunStem has immunostimulating properties in-vivo studies testing patients treated, increasing phagocytic activity and synthesis of helper cell function. ***ImunStem*** has shown to enhance Deoxyribonucleic Acid (DNA) repair before, during, and after chemotherapy drugs, toxic exposure, and chemical-induced damage. ***ImunStem*** modulates anxiety, initially including and then reversing these effects after long-term administration.

ImunStem can play an integral role in hypothalamic activity, easing both parasympathetic and sympathetic nervous systems towards a state of homeostasis. Since blood pressure level is directly linked to the sympathetic nervous system, the lower blood pressure levels exhibited following administration of ***ImunStem*** is compatible with the stabilization of sympathetic nervous system activity. The pulmonary benefits observed are likely due to the focus of deep breathing, this places less pressure on lungs and increases lung capacity, as well as overall improvement seen in breathing efficiency. ***ImunStem*** reduces inflammation by affecting immune responsiveness through neuroendocrine factors. Its positive effect on balance is attributed to the improved use of vestibular input and wider stances.

12.2 Pharmacokinetics

ImunStem is readily absorbed into soft tissue matter when taken as an oral dose. This is accomplished because ***ImunStem*** readily passes through membrane tissue by passive diffusion penetrating to the circulatory system.

ImunStem is a fast acting substance. Once the onset of action takes place patients can notice calmness, improved breathing, mental clarity, and alertness immediately.

It is postulated that in arresting abnormal cellular mutation, the precursors for normal and enhanced cellular regeneration and cellular division can be accelerated in relation to the selective existing disease pathology. Observations of in-vivo testing that display the ability for ***ImunStem*** components to dissolve in hydrophilic substances propose that in the finished chemical form of the product and with its unique makeup, ***ImunStem*** produces a bipolarity that facilitates molecular diffusion through various permeable and selective membranes. It is therefore theorized that the combination of the bodies' thermal energy particularly during variance mutation and inflammatory processes, potentiates the self-propelling of molecules by possible passive membrane transportation or passive diffusion of the ***ImunStem*** compound intact to cross the blood brain barrier also displaying lipophilicity (or lipophilic quality) to retain efficacy and activity for the central nervous system.

In-vivo studies involving treated test subjects have immune system activity in tests including blood tests and have provided the efficacious ability to improve immune system function while maintaining the cellular structure to tissue intact. These studies also reveal that ***ImunStem*** continues to provide improved immune system function with long term use.

13.0 NONCLINICAL TOXICOLOGY

13.1 Genotoxicity

PURPOSE: The purpose of this study is to evaluate ***ImunStem*** for its ability to induce reverse mutation at the histidine locus in *Salmonella Typhimurium* tester strains both in the presence and absence of an exogenous mammalian metabolic system (S9) containing microsomal enzyme.

CONCLUSION: Under the test conditions in this study, *ImunStem* was not mutagenic in the tested strains of the *Salmonella typhimurium*, histidine auxotrophs TA97, TA98, TA100, TA102 and TA1535 both in the presence and absence of metabolic activation system. The results indicated that, at the dose concentration of a 25-fold dilution to a 15,625-fold dilution of original liquid, 100µl/plate, *ImunStem* did not induce point mutations by base substitutions and/or frame shifts in the genome of these tested strains.

14.0 RESULTS OF PATIENTS AFTER TREATMENT

A small group of patients with *Serious or Life-threatening* diseases or conditions found that *ImunStem* dietary supplement improved the immune system and alertness immediately.

Physicians have observed that using *ImunStem* provokes a significant response, i.e., a reduction in symptoms in patients with these diseases: autism, alzheimer's, neuropathy, chronic lymphocytic leukemia, multiple sclerosis, parkinson's, schizo affective disorder, fragile-X syndrome, and a significant decrease of side-effects to chemotherapy for cancer. *ImunStem* has been shown to help reduced loss of blood from surgical wound and menstrual periods (shorter and lighter periods).

Fifty (50) patients test subjects administered *ImunStem* dietary supplement over the course of time from a few weeks up to three (3) years were made and included observations from attending physicians, nursing staff, care givers and Golden Sunrise medical personnel. Blood reports were also included and medications (if any) were documented. The observations compiled from family physicians and specialists were entered and compared with observations by Golden Sunrise medical staff.

Safety was monitored and throughout these studies no adverse side-effects were noticed. A representative number of test subjects were diagnosed with *Serious or Life-threatening* diseases or conditions that required close monitoring by both the attending physician, specialist of that field and by Golden Sunrise medical staff.

- a) J.W. is a 10-year-old white male who began treatment with physician psychiatrist in Visalia California when he 6-year-old. He has been diagnosed with fragile-X syndrome. He was diagnosed as Attention Deficit Hyperactivity Disorder (ADHD) (F90.1), and Intermittent Explosive Disorder (IED) (F63.81). He has been treated over the years with Tegretol, Vyvanse, Zoloft, Risperdal; he had a trial at another medical center of R Baclofen. Psychiatrist have also treated him with Gabitril, and Nudexta. He was taking Zoloft 150mg in the morning, Risperdal 1mg at bedtime, and Vyvanse 40mg in the morning.

In July 07, 2016 he was started *ImunStem* twenty (20) drops twice a day was started at that point in time. On July 25, 2016 his mother reports as of this date that he is more focused and calmer. His level of perseveration has decreased dramatically. His mother stated that the other day he was organizing the DVDs player in their home and "that's not like him."

- b) S.W. is a 64-year-old, white male, who began treatment with psychiatrist when he was 57-year-old. He was initially diagnosed as anxiety disorder Not Otherwise Specified (NOS) (F41.9) and ADHD without hyperactivity (F90.0). Stimulant medication was not effective in treating his focusing problems so Wellbutrin was used. Chlorazepate was used to help with his anxiety. He did well on this combination of medicines until November 2014. He was diagnosed at that point in time as having diabetic neuropathy and was treated with Lyrica. He complained at

that point in time that the medicine made him feel "fuzzy" and he was unable to be productive at work. In February 2015 he stopped the Chlorazepate because he was afraid of having Alzheimer's disease and decreased the Wellbutrin on his own to decrease the fuzziness. He did restart the Chlorazepate eventually. In April 2016 he was taking Cymbalta 60mg in the morning and Ambien 10mg at bedtime. His family doctor had stopped the Wellbutrin and Chlorazepate. He was being treated at that point in time with methadone and Lyrica. He complained again of feeling fuzzy, tired, and unable to do his work.

In July 2016 he was started with ***ImunStem*** twenty (20) drops twice a day. He reported two and half (2-1/2) weeks later that he had more energy and motivation. He was more productive and able to do his work and his pain had been reduced by thirty (30%) percent.

- c) S.R. is a 39-year-old white male, who was first seen when he was 28-year-old. He was transferred from another physician and was taking Wellbutrin-SR 100mg three (3) times a day, Clozaril 600mg at bedtime, Zoloft 200mg in the morning, Topamax 100mg at bedtime, and Aricept 20mg at bedtime. He had a significant history of substance abuse, including marijuana, crack cocaine, mushrooms, and acid between the ages of seventeen and 17 & 21-year-old. He was diagnosed as schizoaffective disorder (F25.9) and Polysubstance abuse. He was treated with multiple medications over the years to try to help reduce his psychotic symptoms and increased his sociability. In June 2016, he was taking Vraylar 6mg in the morning, Fanapt 6mg twice a day, Nudexta 20-10 twice a day, Chlorazepate 30mg at bedtime, Prozac 40mg in the morning, Clozaril 300mg at bedtime, Abilify 30mg in the morning, and Gabitril 4mg at bedtime.

In July 07, 2016 he was started with ***ImunStem*** twenty (20) drops twice a day were started at that point in time. He returned on July 21, 2016, reporting that he had decreased the Chlorazepate to 15mg at bedtime, his Prozac had been increased to 60mg in the morning and he had been on ***ImunStem*** for two (2) weeks as well as the other medications listed above. He reported "my brain can keep up with my mind". He stated "my brain is aware of my body". He reported increased energy, clearer thoughts, and non-racing thoughts. He also reported that he had a dry patch of skin on the back of his head that was now gone.

- d) L.H. is an 86-year-old, white female, who is diagnosed as having Alzheimer's disease and lives in a skilled nursing facility. She is on a liquid diet, sleeps most of the time, is confined to a wheelchair or a moving bed, and has intermittent episodes of agitation and flat facies. She was treated with ***ImunStem*** ten (10) drops twice a day for two and half (2-1/2) weeks. Both staff and family report that she is less agitated, more alert and is smiling.

After thirty (30) days on ***ImunStem*** the nurses' report there are no longer any agitated episodes. Skilled nursing report that she spends more time awake. On exam, the patient opened her eyes and focused on my face. There was no facial expression, but patient appeared to try and move her lips as if she wanted to talk. (This was a new behavior). When I asked her to move her finger if she could understand me, she did.

- e) M.B. is a 69-year-old white male who has been treated for chronic Lymphocytic Leukemia for the last five (5) years. He started taking *ImunStem* twenty (20) drops twice a day in October 2015. This was because of the concern of falling red blood cell counts and platelet counts. His white blood cell count, though elevated remained elevated and fluctuant. In October 2015, his red blood cell was four point zero five (4.05) and his platelet count was ninety (90). On April 2016 his red blood cell count was four point nineteen (4.19) and his platelet count was one hundred and five (105). It was felt that this was a significant increase in both his red blood cell count and platelet count. Please see table below as following:

Comparison RBC Count and Platelet Count from October, 2015 through April, 2016

DATE	RBC Count	Platelet Count	
October, 2015	4.05	90	Before <i>ImunStem</i>
April, 2016	4.19	105	After <i>ImunStem</i>

- f) R.B. is a 62-year-old white male who was first evaluated on August 19, 2016. He is taking Actos, Metformin, Lorstan, and Travastin for diabetes mellitus, high blood pressure, and glaucoma. There is no history of past substance abuse. He was interested in trying *ImunStem* to see if would make any difference with his medical problems. He also complains of mild symptoms of depression including anergia, lack of motivation and feeling depressed about his physical problems. He was diagnosed as depressive disorder NOS and started on *ImunStem* twenty (20) drops twice a day.

Patient reported after eight (8) weeks of *ImunStem* treatment that his energy and motivation have been increased. He also reported that he was feeling less depressed. He reported that he was able to tolerate higher loads of carbohydrates without changing his diabetes medications, which also affect directly his energy and motivation.

- g) J.O. is a 45-year-old white male diagnosed with advanced stage four (4) colon cancer. He was diagnosed in January 2016 and was not thought by the attending physician that he could have a positive outcome as the cancer was in mastitis and had spread throughout his body. His symptoms included a damaged liver, renal obstruction, lung polyps, anxiety, depression, and severe lack of energy. The patient received first cycle of chemotherapy on March 2016.

In April 2016 the patient received his first dose of *ImunStem* administered orally at forty (40) drops three times daily. At this time the patient showed noticeable improvement of overall health in minutes. The patient showed an improvement in energy levels as the next day he was playing basketball, mental focus, depression and anxiety improved noticeably and his outlook on life is a positive hope. His tumors have shrunk and since the treatments of *ImunStem* and chemotherapy he has had no major side-effects such as hair loss, debilitating constipation, depression, anxiety, weight loss, or nausea. He has not had to visit emergency for complications except for a staph infection at his injection port. Patient is doing well and can function without interference to his normal lifestyle. The patient has been motivated to tell others of the benefits of taking *ImunStem* that it can help others in *Serious or Life-threatening* conditions.

- h) J.A. is a 2½-year-old male that was diagnosed with Autism/Seizure. His symptoms included, seizure, drooling, hyperactivity, disorientation, lack of pain stimuli, poor communication skills and uncontrollable outbursts. He was diagnosed in October 2016 and was considered near the highest level of Autism that provided government programs to assist with his mental state. He has an unknown regimen of prescription medications and government assistance is provided for re-education of motor skills.

In December 2016 he began oral administration of *ImunStem* at two (2) drops per 12-fluid-ounces of milk. In about four (4) days was noticed by the parents that he was aware of his surroundings and responded to the parents' direction. He was also noticed to stop drooling and felt pain in normal situations (such as falling down while playing). He also began to have a reduction in seizures. He has improved where there are no known seizures being observed at this time and he is more responsive to direction, his drooling has not returned and he is beginning to act as a normal 2½-year-old.

- i) S.R. is a 62-year-old black male that was diagnosed with advanced stage Parkinson's disease. He was diagnosed 4-year-ago and has had a steady progression of the Parkinson's disease. The symptoms include, slurred speech, an unsteady (uneven) gait, memory loss, depression, tremors and occasional falling. He has taken the prescribed medication which had only intermittent results.

In April 2015 he began taking *ImunStem* oral administration at thirty (30) drops twice a day. He states that he feels more stable as he can walk on his own, has no more falling episodes, can focus better (clearer thought), has reduced tremors and has significantly reduced his depression. He has also returned to his previous employment.

- j) R.W. is a 16-year-old female that has excessive menstrual bleeding and long painful menstrual periods since 2013. She took Vicodin every month on the first day of her period. She had debilitating pain that interfered with her lifestyle and activities and kept her confined to her home.

In October 2016 she began taking *ImunStem* oral administration at thirty (30) drops per day. After three (3) weeks her menstrual bleeding reduced greatly and her pain had been alleviated. Her period duration had dropped by half and she is able to function in public as a normal.

- k) R.G. is a 60-year-old male diagnosed with an enlarged prostate. He had been to multiple medical professionals that have treated him for everything from bleeding eye to heart attack. Physicians have recommended various surgeries for his prostate but the patient did not want to have these surgeries because of the possible adverse outcomes.

In October 2017 he was administered *ImunStem* while in the hospital being treated, within three (3) minutes he felt an improved feeling to his prostate which felt like less pressure and less pain. He continued to improve over four (4) months and no longer requires invasive procedures to alleviate prostate swelling. Please see table below as following:

Comparison eGFR, WBC and Platelet Count from October, 2017 through December, 2017

DATE	eGFR	WBC Count	Platelet Count	
October, 2017	15	6.36	136	Before <i>ImunStem</i>
December, 2017	40	8.00	332	After <i>ImunStem</i>

- D) E.B. is a 46-year-old white male was diagnosed with Multiple Sclerosis (MS) in November 2016. He was first suspect as having lime disease but upon further testing it was found to be MS. He experienced a continual degradation of motor function until he was bedridden, he had almost total immobility of his legs and arms. The caregiver would assist the patient for all movement including bathroom activities.

Patient began taking *ImunStem* in October 2017 and showed positive response for the first dose. Over the course of treatments the patient has experienced improved motor function to where he can sit in a wheelchair and move himself and can sit on the toilet without the aid of the caregiver. The patient continues to show marked improvement as the treatment progresses. Please see table below as following:

Comparison WBC and Platelet Count from September, 2017 through December, 2017

DATE	WBC Count	Platelet Count	
September, 2017	6.04	206	Before <i>ImunStem</i>
December, 2017	9.60	254	After <i>ImunStem</i>

- m) R.H. is a 54-year-old white male was diagnosed in December 26, 2016 with esophageal cancer in stage two (2) after the patient collapsed for no apparent reason and began spewing blood. The patient was rushed to the local emergency room where testing immediately began and the diagnosis was made. The patient refused standard medical cancer treatment (chemotherapies).

The patient began taking *ImunStem* in February 20, 2017, and shown improvements in both reports the blood reports and medical scans. The physician at the hospital after reviewing the blood report and medical scans his recommendation “resume regular diet” and to receive another checkup in four (4) weeks. Please see table below as following:

Comparison WBC, Mean Platelet Volume and Platelet from January, 2017 through March, 2017

DATE	WBC	Mean Platelet Volume	Platelet	
January, 2017	6.40	6.90	375	Before <i>ImunStem</i>
March, 2017	9.40	8.40	332	After <i>ImunStem</i>

16.0 HOW SUPPLIED/STORAGE AND HANDLING

16.1 Storage and Stability

STORAGE: Store material at controlled room temperature 20°C (68°F).

STABILITY: *ImunStem* is chemically stable for one (1) year at room temperature. Do not freeze.

16.2 Medicine Classification

Prescription Medicine.

16.3 Packaging

SERVING PER CONTAINER: Boston round one (1fl.oz.) fluid ounce amber glass bottle 20mm-40 Neck Finish. Cap with cap band.

DROPPER ASSEMBLY: 20/400 black FRST PP closure; SR20 (1cc) black flourogazed monprene bulb; 7x76mm straight tip TYPE III (soda lime) glass pipette.

17.0 PATIENT COUNSELING INFORMATION

17.1 Administration

- Inform patients to shake bottle well before using and take $\frac{1}{2}$ to $\frac{3}{4}$ quarter of a dropper of ***ImunStem*** under tongue. Leave under tongue for approx forty (40) seconds and then drink water.
- Advise patients that ***ImunStem*** is present in liquid form consistency, and is administered orally. At present it is recommended in this form only.
- Instruct patients if an oral administration of ***ImunStem*** is necessary yet the patient has a sensitivity of the mouth and/or throat then an administration orally mixed between one (1) teaspoonful of yogurt can be administered.

ImunStem is an herbal (botanical) drug substance that is derived from Olive leaf, Yarrow flowers, Rosemary leaf, Yucca plant and Cassia oil.

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Part No.: GS-00001 / Revised: 01/2018

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U.S. Patent No.: 8,535,737