

PACKAGE INSERT

1 SCHEDULING STATUS

Not Scheduled

2 PROPRIETARY NAME AND DOSAGE FORM

Product Name: Omnivir

Dosage Form: Gas

3 COMPOSITION

Oxygen: 95.5% (minimum).

Ozone : 0.06mg/ml of oxygen and ozone mixture (maximum).

4 PHARMACOLOGICAL CLASSIFICATION

Medical Device and Complementary Medicine

5 PHARMACOLOGICAL ACTION

Ozone, an allotropic form of oxygen molecule which contains large excess of energy and is very reactive and unstable. Ozone (O₃), has a molecular weight of 48, a density one and a half times that of oxygen, and contains a large excess of energy in its molecule (O₃ → 3/2 O₂ + 143KJ/mole). Although ozone is not a radical molecule, it is a very potent oxidant (E° = +2.076 V). Ozone is an unstable gas that cannot be stored and should be used at once because it has a half-life of 40 min at 20°C.

It has a bond angle of 127 ± 3, resonates among several forms, is distinctly blue as undiluted gas. and dark blue as a solid.

Medical ozone is produced by passing clinical oxygen through high voltage tubes and a cold spark method is used to generate uncontaminated pure medical ozone.

Ozone is unstable and cannot be stored and should be used at once or instantly because it has a very short half life especially in aqueous conditions.

The extra oxygen atom in ozone breaks away and leaves O₂, ozone has only a half life of about 10 minutes in water pH7, at body temperatures and 1 bar standard pressure.

Under standard conditions (21°C, 1 bar) the half-life of ozone gas is 20 minutes. Dissolved ozone half-life is 20 minutes at pH 6, 15 minutes at pH 7 and 5 minutes at pH 8.

Ozone dissolves physically in pure water according to Henry's law in relation to the temperature, pressure and ozone concentration, ozone reacts immediately as soon as it is dissolved in biological water (physiological saline, plasma, lymph, urine):



where atomic oxygen behaves as a very reactive atom.

Ozone's destructiveness nature on virus and bacteria is partly attributed to the oxidation of unsaturated bonds in the phospholipids and lipoprotein architecture of the bacteria, viruses. The oxidation generates hydro peroxides, which are transformed to peroxy and hydroxyl radicals and to other reactive species, including aldehydes. Peroxyl radicals attack proteins, and hydroxyl radicals induce disruptive structural changes in cell membranes. The reactive oxygen intermediates also contribute to the inactivation of viral reverse transcriptase.

In order of preference, ozone reacts with polyunsaturated fatty acids (PUFA), antioxidants such as ascorbic and uric acids, thiol compounds with -SH groups such as cysteine, reduced glutathione (GSH) and albumin

All of these compounds act as electron donor and undergo oxidation.

The main reaction:



shows the simultaneous formation of one mole of hydrogen peroxide (included among reactive oxygen species, ROS) and of two moles of lipid oxidation products (LOPs)

The fundamental ROS molecule is hydrogen peroxide, which is a non-radical oxidant able to act as an ozone messenger responsible for eliciting several biological and therapeutic effects.

Submicromolar LOPs levels can be stimulatory and beneficial, whereas high levels can be toxic, therefore ozone concentration used is very low, just above the threshold level to yield an acute, absolutely transitory oxidative stress capable of triggering biological effects without toxicity.

The ozone bio-oxidative process is therefore characterized by the formation of ROS and LOPs acting in two phases. ROS are acting immediately and disappear (early and short-acting messengers), LOPs, via the circulation, distribute throughout the tissues and eventually only a few molecules bind to cell receptors.

Formation of ROS in the plasma is extremely rapid and is accompanied by a transitory. In large quantities ROS and Ozone itself could very toxic, therefore controlled low level of therapeutic doses, 1 to 80 mg/L of oxygen mixture will be suitable.

The oxidative effect of ozone returns to normal within half an hour and the oxidized compounds such as dehydroascorbate are efficiently recycled back to ascorbic acid. H₂O₂ diffuses easily from the plasma into the cells and its sudden appearance in the cytoplasm represents the triggering stimulus: depending upon the cell type, different biochemical pathways can be concurrently activated in erythrocytes, leukocytes and platelets resulting in numerous biological effects.

Ozone also acts as a mild enhancer of the immune system by activating neutrophils and stimulating the synthesis of some cytokines. The by product of ozone, hydrogen peroxide, which after entering into the cytoplasm of blood mononuclear cells (BMC) by oxidizing selected cysteines, activates a tyrosine kinase, which then phosphorylates the transcription factor nuclear factor κB allowing the release of a heterodimer (p50+p65). This complex moves on to the nucleus and switches on some hundred genes eventually responsible for causing the synthesis of several proteins, among which are the acute-phase reactants and numerous interleukins. Once the ozonated leukocytes return to the circulation, they home in lymphoid microenvironments and successively release cytokines acting in a paracrine fashion on neighbouring cells with a possible reactivation of a depressed immune system.

According to the chemical equation 1 above, some of the ozone is converted into Oxygen which we already breathe and is available at 21% in the atmosphere. The basal oxygen consumption in man is about 250 ml/min for a body surface of 1.8 sq. metres, therefore the oxygen formed during the ozone

therapy is not huge enough to upset the body.

Below is the list of common pathogen susceptible to the antiviral and antibacterial power of ozone therapy.

Lipid-encapsulated viruses

Herpes viridae (simplex, varicella-zoster,
Cytomegalovirus, Epstein - Barr virus)
Paramyxoviridae (mumps, measles)
Orthomyxoviridae (influenza)
Rhabdoviridae (rabies)
Retroviridae (e.g., human immunodeficiency- virus,
simian immunodeficiency virus, equine infectious anemia virus)

Hepatitis viruses

Polioviridae

Echovirus

Coxsackievirus

Bacteria

Coliform bacteria
Staphylococcus aureus
Aeromonas hydrophila

Fungi

Candida utilis

6 INDICATIONS

OMNIVIR is used to : Help fighting HIV/AIDS.

Help Protecting the Immune System.

7 CONTRA-INDICATIONS

(i) The inspired dosage duration has to be shorter for young and elderly who have smaller bowels cavities .

(ii) Both oxygen and ozone supports combustion so smoking or naked flame should be prohibited near the OMNIVIR at all times.

(iii) Ozone react with ordinary plastic e.g. PVC or PET, therefore all tubes and humidifiers should be replaced with ones made from teflon or silicone.

(iv) Do no use if you have any of the following conditions.

- 1) After recent heart attack
- 2) Pregnancy or Lactating
- 3) Recent internal bleeding including menses
- 4) Hyperthyroidism
- 5) Cramping or spasms
- 6) Thrombocytopenia
- 7) Alcoholic intoxication
- 8) Allergy to ozone

(iv) Do not open the machine as this might result in harm from electrical shock.

(v) Avoid breathing oxygen/ozone mixture from the OMNIVIR machine as this might affect breathing system.

(vi) Always make sure there is distilled and sterilized water in the humidifier, un-humidified ozone can cause irritation in the dowel lining due.

(vii) Ensure only purified and sterilized water is used for humidification, to prevent cross contamination.

(viii) OMNIVIR uses electricity, so do not immerse or use in water as this may cause serious damage to both the user and machine.

8 WARNINGS

Always make sure the purity of the OMNIVIR gas is at least 95%, the purity level is shown on the LCD screen of the machine.

Do not administer the gas through any other orifice e.g. nose, ear or mouth. Administering through the nose may affect the respiratory/breathing system.

Always make sure there is pure and sterilized water in the humidifier, otherwise administering the gas directly may cause irritation and burning sensation in the rectum.

9 INTERACTIONS

Ozone is a powerful oxidant, exposing ozone to organic molecules containing double or triple bonds yields many complex and as yet incompletely configured transitional compounds (i.e. zwitterions, molozonides, cyclic ozonides), which may be hydrolysed, oxidized, reduced, or thermally decomposed to a variety of substances, chiefly aldehydes, ketones, acids or alcohols. Ozone also reacts with saturated hydrocarbons, amines, sulfhydryl groups, and aromatic compounds. Ozone interacts with tissue especially blood constituents, i.e. lipids carbohydrates, protein, glycoproteins and sphingolipids. Interaction with lipids results in lipid peroxidation and several agents derived from lipid peroxidation include free radical, singlet oxygen, hydrogen peroxide, hydroperoxide, ozonides, carbonyls, alkanes and alkenes. Of these, lipid hydroperoxides, are known in sufficient or very high concentrations could be toxic by altering cell membranes. Acted upon by glutathione peroxidase, they are reduced to their corresponding alcohols.

10 PREGNANCY AND LACTATION

Do not recommend using OMNIVIR on the pregnant or lactating women.

11 DOSAGE AND DIRECTIONS FOR USE

To power Omnivir, plug to the mains switch and press on/off button.

Select either LOW or HIGH function to start using the Omnivir.

After selecting the right function, please wait for the oxygen/ozone level to reach at least 95% before administering and also check if there is water in the humidifier before administering.

When ready, insert the gas tube or balloon, 5 to 8cm into the rectum and start the dosage. Hold all the gas in the rectum during the dosage and hold for a further ten (10) minutes after the dosage to allow all the medicine to be absorbed.

NB: Please refer to the Installation Manual for more information on set-up

Recommended doses and dosage schedules for fighting HIV/AIDS.

Persons below 15 years

Dosage: 350ml

Dosage duration: 7 minutes

Dosage Level Function: LOW

Persons between 15 and 79 years

Dosage: 750ml

Dosage duration: 15 minutes

Dosage Level Function: HIGH

Persons over 80 years

Dosage: 350ml

Dosage duration: 7 minutes

Dosage Level Function: LOW

NB: When administering the gas, hold all the gas inside the rectum and hold for a further 10 minutes after the machines shuts down to allow all the medicine to penetrate into the body.

All patients should use the Omnivir twice or three time a day for maximum efficacy.

Route of Administration

OMNIVIR is administered by insufflations through the rectum.

12 SIDE EFFECTS AND SPECIAL PRECAUTIONS

(i) Oxygen/Ozone mixture toxicity depends on the inspired flow rate, ozone concentration in the mixture and the duration of the dosage. Chronic high overdose may lead to dizziness, nausea, coughing, malaise, fatigue and mild headaches .

NB: To minimise risk of overdose, the flow rate of Omnivir is fixed and the dosage durations are preset for both young persons, adults and elderly.

(ii) Normally breathing low doses/level of ozone as available in the atmosphere or in sanitized offices is harmless, but breathing higher doses could lead into burning of the mucus in the lungs which leads to nausea like feeling, dry coughing continuously and asthma like feeling.

iii) Any fire or spark is highly dangerous in the presence of increased oxygen and ozone concentration. Avoid oil or grease as this may spark and start a violent fire.

(iv) Omnivir is electric powered so do not use the machine in water or when wet or raining as this might cause fire.

(v) Care should be taken in the handling and use of medical oxygen and ozone.

(vi) Avoid administering oxygen/ozone mixture if the purity concentration level is below 95% as ozone produced from non-medical oxygen (air) is toxic because of the nitrogen oxides, nitrites, nitric acids, sulphur dioxides and other compounds formed.

(vii) OMNIVIR is not a substitute for your prescribed medication, please do not discontinue your prescribed medicines.

13 KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT.

Symptoms of oxygen/ozone overdose could include nausea, dizziness, malaise, fatigue, mild headaches and irritation or burning sensation on the rectum lining.

To treat some of these symptoms of overdose, take antioxidants e.g. Vitamin C. Drinking pure orange or grapefruit juice also helps to ease the symptoms.

14 IDENTIFICATION

The name "OMNIVIR" shall be stencilled on the front of the machine. Its rectangular box enclosure shall be made from a HDPE, whilst the humidifier and all tubes and pipes made from the ozone resistant Teflon and Silicone.

The Omnivir machine shall be CE marked.

The Omnivir gas mixture is a humid colourless gas.

15 PRESENTATION

A heat shrink seal shall be fitted to every Omnivir, confirming that the machine has passed quality control for oxygen and ozone purity, electrical safety and leak test.

A unique batch reference and item number shall be printed on the Omnivir.

Every Omnivir will come with a user guide/manual to be kept by the user for proper usage and maintenance.

16 STORAGE INSTRUCTIONS

Avoid fuel, oil, grease, or any other readily combustible substances to come into contact with both the machine and the oxygen/ozone mixture.

Do not leave the mains switch on after use.

Do not store in bathroom

Always keep the humidifier fitted into the machine.

Do not keep in the fridge/freezer.

Keep out of reach of children.

17 REGISTRATION NUMBER

18 Name and Business Address of the Holder of the Certificate of Registration.

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19 DATE OF PUBLICATION OF THE PACKAGE INSERT

26 May 2008