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Case Report

Total Concentration of Edigalf Colloidal Sliver Life Water Submitted For Registration as Homeopathic Immune Care In Ghana.

Raphael Nyarkotey Obu, PhD, LLB

Nyarkotey College of Holistic Medicine, Holistic & Naturopathic Urology, Ghana

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Abstract: ***AIM:*** Toxicity of colloidal silver is an important issue in the medical sector. The product manufactured by Edigalf Services had been submitted to the FDA in Ghana for registration as homeopathic immunecare after animal studies. This current paper addresses the total concentration or power dose of the product colloidal silver life water. ***Method:*** In Addressing the FDA position on the total concentration of the said product submitted for registration. The Manufacturer reviewed the previous duration of usage from two weeks to be taken (15ml) three teaspoonful three times daily on the label previously submitted. The new reviews on the label have the duration for twelve days (12) only and to be taken one teaspoonful (5ml) daily. ***Result:*** From the calculation, the total concentration of the product, colloidal silver life water for twelve(12)days duration is 600mcg which still falls within the 'safe grade' of the Environmental Protection Agency(EPA)-IRIS Report-Silver. ***Conclusion:*** We report that, based on the total concentration or power dose for twelve (12) days, the product colloidal silver life water is within the acceptable grade of safety based on the Environmental Protection Agency (EPA)-IRIS Report on Silver.

Keywords: Total Concentration, Power dose, Safety, Silver water, Homeopathy, Immune care.

DISCUSSION

A recent case report by Naomi Mohan (2019), in a 19 year old female reported that the ingestion of a naturopathic drug, colloidal silver, caused vast leukocytoclastic vasculitis in one patient warranting hospitalization due to the extent of the disease. The report further concluded that, the symptoms resolved after discontinuation of colloidal silver ingestion. They further postulated that, due to the unknown safe ingestion concentrations and potential side effects, use of colloidal silver should be discouraged.

A similar case report in 2016 by Rezyk et al presented a patient with T cell lymphoma, who used silver colloidal as an alternative therapy for her condition, and subsequently developed pauci-immune crescentic glomerulonephritis. The authors suggested that, the silver deposition triggered a cellular immune-mediated process, potentially mediated by lymphomatous T cells directed at the glomerular basement membrane.

The 2007 Australian Adverse Drug Reactions Bulletin, Vol 26, No 5 published four reports of silver toxicity (argyria) following ingestion of homemade products containing colloidal silver (tiny particles of metallic silver suspended in liquid) prepared using a "colloidal silver generator":

- A 5 year old boy who ingested colloidal silver daily for several months developed grey discolouration of skin and tongue and abnormal hepatic function.
- An elderly man who drank colloidal silver daily for 6 months required hospital admission for debilitating fatigue accompanied by blue skin discolouration, dilated cardiomyopathy, amnesia and incoherent speech.
- An elderly man consuming liquid made using a "colloidal silver generator" over a 4 year period developed grey skin discolouration.
- An adult male ingesting homemade colloidal silver daily for 3 years and also applying it topically after shaving developed generalised skin discolouration.

***Corresponding Author:** Raphael Nyarkotey Obu **Email:** oburalph30@yahoo.co.uk

In each case, the plasma silver concentration was many times higher than in subjects not knowingly exposed to silver (background levels up to 2.3 µg/L have been reported.

Drug Concentration is the amount of a drug in a given volume of blood plasma, measured as the number of micrograms per milliliter. According to RA Ghiculescu(2008), "Therapeutic drug monitoring of concentrations of drugs in body fluids, usually plasma, can be used during treatment and for diagnostic purposes. The selection of drugs for therapeutic drug monitoring is important as the concentrations of many drugs are not clearly related to their effects. For selected drugs therapeutic drug monitoring aims to enhance drug efficacy, reduce toxicity or assist with diagnosis. Despite its apparent advantages, it has inherent limitations. Some large hospitals have services which provide support with drug monitoring and interpretation of results"

RA Ghiculescu(2008), further added that, When an effect, such as changes in blood pressure, pain or serum cholesterol is readily measured, the dose of a drug should be adjusted according to the response. Monitoring drug concentration is more useful when drugs are used to prevent an adverse outcome, for example, graft rejection or to avoid toxicity, as with aminoglycosides. A drug should satisfy certain criteria to be suitable for therapeutic drug monitoring. Examples include:

- narrow target range
- significant pharmacokinetic variability
- a reasonable relationship between plasma concentrations and clinical effects
- established target concentration range
- Availability of cost-effective drug assay.

Since the toxicity of colloidal silver water is of concerned to the public, the author of this article recommends manufacturers of the product to prescribe to their patients in a shorter duration for therapy.

According to Koch-Weser J 1981, measurement of serum concentrations is valuable only for drugs whose dosage should be individualized and whose therapeutic and toxic actions are not adequately quantifiable by clinical endpoints. The serum concentration of the drug and of important active metabolites must be accurately measurable, the relation between their concentrations in the serum and the intensity of therapeutic and toxic effects during clinical use must have been clearly defined, and serum levels must always be knowledgeably interpreted in conjunction with careful clinical observation and judgment. Measurements of serum drug concentrations are most often useful during prophylactic drug therapy, in patients with major pharmacokinetic disturbances, and when patients show unusual and unexplained sensitivity or resistance to therapy with a drug.

The goal of therapeutics is to achieve a desired beneficial effect with minimal adverse effects. When a medicine has been selected for a patient, the clinician must determine the dose that most closely achieves this goal. Pharmacodynamics governs the concentration-effect part of the interaction, whereas pharmacokinetics deals with the dose-concentration part (Holford & Sheiner, 1981). The pharmacokinetic processes of absorption, distribution, and elimination determine how rapidly and for how long the drug will appear at the target organ.

On the other hand, the bioavailability is the ***amount of unchanged drug that reaches the systemic circulation***. In that regard it pertains to how colloidal silver particles are absorbed into the bloodstream after being ingested. We know that silver nanoparticles are absorbed in the first few feet of the small intestine and their presence can be measured using atomic absorption/emission spectroscopy beginning about 15 minutes after ingestion.

Bioavailability only concerns the amount of drug (or other substance) that reaches systemic circulation; it does not have anything to do with the ability of the substance to be metabolized by the body. It does not have anything to do with the substance being water soluble or combining with biological tissue. These are important to remember because so much has been written that claims that silver nanoparticles are not bioavailable, when clearly any such statement is false. If they were not bioavailable, they would not enter the bloodstream.

The physicochemical properties of a drug govern its absorptive potential, but the properties of the dosage form (which partly depend on its design and manufacture) can largely determine drug bioavailability. Differences in bioavailability among formulations of a given drug can have clinical significance. Thus, the concept of equivalence among drug products is important in making clinical decisions. **Chemical equivalence** refers to drug products that contain the same compound in the same amount and that meet current official standards; however, inactive ingredients in drug products may differ. **Bioequivalence** refers to chemical equivalents that, when administered to the same person in the same dosage regimen, result in equivalent concentrations of drug in blood and tissues. **Therapeutic equivalence** refers to drug products that, when administered to the same person in the same dosage regimen, provide essentially the same therapeutic effect or toxicity. Bioequivalent products are expected to be therapeutically equivalent.

Therapeutic problems (e.g., toxicity, lack of efficacy) are encountered most frequently during long-term therapy when a patient who is stabilized on one formulation is given a nonequivalent substitute (as for

digoxin or phenytoin).Sometimes therapeutic equivalence may be achieved despite differences in bioavailability. For example, the therapeutic index (ratio of the maximum tolerated dose to the minimum effective dose) of penicillin is so wide that moderate blood concentration differences due to bioavailability differences in penicillin products may not affect therapeutic efficacy or safety. In contrast, bioavailability differences are important for a drug with a relatively narrow therapeutic index. The physiologic characteristics and comorbidities of the patient also affect bioavailability. Absorption rate is important because even when a drug is absorbed completely, it may be absorbed too slowly to produce a therapeutic blood level quickly enough or so rapidly that toxicity results from high drug concentrations after each dose.

True silver colloids reach the bloodstream ***unchanged*** in form meaning they are truly bioavailable. Ionic silver does not reach the bloodstream *unchanged* because the *silver ions are converted into silver chloride* which means ionic silver products are less bioavailable than true colloidal silver products.

Silver is a noble metal and in its elemental state (metallic, not ionic) does not readily combine to form compounds. The biological activity of metallic silver nanoparticles does not require that the silver combine with biological material in the body. Its action is one of being a catalyst, and as such it remains unchanged from its original form (silver nanoparticles).

Silver nanoparticles, which are the predominant form of silver in true colloidal silver products, do not dissolve nor are they metabolized in the human body. They enter the body as silver nanoparticles, they circulate in the bloodstream and then leave the body and always remain as silver nanoparticles. They perform their catalytic action while in the form of silver nanoparticles; their effectiveness being determined by their particle surface area.

Days	CONCENTRATION(PPM	Teaspoonful once daily
1	10ppm	50mcg
2	10ppm	50mcg
3	10ppm	50mcg
4	10ppm	50mcg
5	10ppm	50mcg
6	10ppm	50mcg
7	10ppm	50mcg
8	10ppm	50mcg
9	10ppm	50mcg
10	10ppm	50mcg
11	10ppm	50mcg
12	10ppm	50mcg
		Total concentration/power dose for 12 days(600mcg)

Fig 1. Illustrates the total concentration/power dose of colloidal silver life water manufactured by Edigaf falls within the 'safe grade' level by the EPA-IRIS Report on silver for twelve days (12)

CONCLUSION

From the literature reviews, colloidal silver products if not well used or monitored could pose a health danger to patients. Hence, the author of this paper advises manufactures and prescribers to always do monitor their patients. Also they should prescribe the products in a shorter duration for therapeutic purposes. The Total concentration or power dose of this product submitted to the FDA in Ghana for registration is 'Safe' for therapeutic usage in a shorter duration of 12 days.

Conflict of Interest

None

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