

12 May 2011

DOH-FDA Advisory
No. 2011- 004

SUBJECT: SAFETY ON THE OFF-LABEL USE OF GLUTATHIONE SOLUTION FOR INJECTION (IV)

WARNING TO THE PUBLIC:

The use of glutathione IV as a skin whitener is not approved by the FDA. The public is strongly warned to refrain from using glutathione for this purpose in light of potential harm associated with such use.

The alarming increase in the unapproved use of glutathione administered intravenously as a skin-whitening agent at very high doses is unsafe and may result in serious consequences to the health of users. There is inadequate safety documentation on the use of high doses of glutathione administered at 600 mg to 1.2 grams once weekly and even up to twice weekly. The only approved indication of the intravenous format of glutathione is as an adjunctive treatment to reduce neurotoxicity associated with cisplatin chemotherapy.

Adverse drug reactions resulting from the use of glutathione IV for skin whitening have been reported and include the following:

1. Reports of adverse drug reactions ranging from skin rashes to the serious and potentially fatal Steven Johnsons Syndrome and Toxic Epidermal Necrolysis.
2. Derangements in the thyroid function
3. Suspected kidney dysfunction potential resulting in kidney failure.
4. Severe abdominal pain in a patient receiving twice-weekly glutathione administered intravenously had been reported.

5. Incorrect technique in intravenous administration especially in association with administration by untrained persons can result in the following:
- a. Introduction of harmful microorganisms that can result in serious infections including potential fatal sepsis.
 - b. Injection of air can lead to embolus which is also potentially fatal.
 - c. Unsafe use of needles (recycling, sharing) can result in the transmission of hepatitis B and even HIV.
 - d. Counterfeiting of glutathione has been reported and may lead to use of non-sterile preparations which could lead to serious infections.

What is glutathione?

Glutathione is a compound naturally found in the body cells which is generated by the liver and participates in cellular and body functions such as antioxidant defense, metabolism and regulation. It is composed of the amino acids glutamine, glycine and cysteine. It is not normally required because it is abundant in foods such as fresh fruits and vegetables.

It may have the effect, although also disputed by many, of skin whitening by inactivating the enzyme tyrosinase which is necessary in melanin production and converts this pigment to the lighter phaeomelanin.

When administered orally, it is hydrolyzed by the gastric juices and further undergoes degradation by the liver enzyme and the resultant bioavailability is low. Intravenous administration delivers very high doses directly into the systemic circulation and may overload the renal circulation.


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