7.1% Chlorhexidine Digluconate for Umbilical Cord Care Standard Information for Patient Information Leaflet

Background

7.1% chlorhexidine digluconate for umbilical cord care (the chlorhexidine product) has been scaled up globally over the past few years, and the product is now being manufactured by a few pharmaceutical companies in low- and middle-income countries (LMICs). Additional pharmaceutical companies in LMICs are expected to start manufacturing and supplying 7.1% chlorhexidine digluconate in the near future in order to provide increased and consistent availability of the product.

The Chlorhexidine Working Group (CWG) created this document for manufacturers of the chlorhexidine product, or for implementing organizations who will develop patient information leaflets, in order to help them provide easily understandable, accurate, and consistent product information to users. This document does not constitute a legal interpretation of the requirements for patient information leaflets. The CWG recommends that those developing patient information leaflets consult drug regulatory authorities in the countries where they plan to market the product in order to obtain specific requirements on drug labeling and patient information leaflets.

Patient Information Leaflets:

Drug labeling is broadly defined as "all labels, and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article". Drug labeling must be provided along with pharmaceutical products, and drug regulatory authorities in each country regulate such labels. In the U.S., for example, the United States Food and Drug Administration (USFDA) regulates information that must be included in drug labeling and requires that drug manufacturers obtain approval from USFDA. Drug labeling includes labels affixed to the outer and immediate container, prescribing information, labels on physician or direct-to-consumer samples, and patient information leaflets or package inserts found inside boxes.

Labeling requirements for prescription drugs differ from those of non-prescription drugs (e.g., over-the-counter drugs). A "package insert", which is typically found inside the box of a prescription drug, is intended to provide healthcare professionals with the information they need to properly prescribe drugs. On the contrary, an insert that is found inside a box of an over-the-counter drug is called a "patient information leaflet" and it is directed to consumers to ensure that consumers can:

- Diagnose the underlying condition
- Determine whether the drug is appropriate for them
- Self-administer the product safely and effectively
- Avoid potential serious consequences
- Recognize when to see a physician or seek emergency assistance

Regulatory authorities in a number of countries have so far provided “over-the-counter designation” to the chlorhexidine product in order to utilize retail channels so that it will reach as many possible newborns as possible. In addition, mothers and their family members and relatives, in addition to healthcare professionals, apply the product to newborns. Considering these factors, we are providing standard information to be included in a patient information leaflet, as required for an over-the-counter drug, in **Table 1**.

The information described below generally follows USFDA guidelines. However, the information that must be provided for an over-the-counter drug might be different from one country to another. In addition, if the chlorhexidine product is authorized to be marketed as a prescription drug, different drug labeling will likely be required. It would therefore prudent to consult the drug regulatory authority in each country where the product will be marketed.

The Chlorhexidine Working Group

This material represents a collaborative effort of the Chlorhexidine Working Group (CWG). The CWG is a group of organizations committed to advancing chlorhexidine for umbilical cord care. For more information about chlorhexidine for umbilical cord care, please visit the chlorhexidine technical resource page on the Healthy Newborn Network site: http://www.healthynewbornnetwork.org/page/chlorhexidine-umbilical-cord-care-resource-page

Table 1. Standard information on 7.1% chlorhexidine digluconate for umbilical cord care (as an over-the-counter drug)

Title	Description	Standard Information
Active ingredient(s)	The product's active ingredients, including the amount in each dosage unit	7.1% chlorhexidine digluconate (equivalent to 4% chlorhexidine)
Purpose(s)	The purpose of the product	Topical antiseptic
Uses (Indications)	The uses, indication for use, for the product.	To prevent umbilical cord infection in newborns. [Note: 7.1% chlorhexidine digluconate has been evaluated in clinical trials and has been proven to be safe and effective for its intended use for umbilical cord care. It has not been evaluated as a hand sanitizer, pre-surgical hand washing, or for any other purpose.]
Warning(s)	Warnings specific to the product, including when the product should not be used under any circumstances, and when it is appropriate to consult with a doctor or pharmacist. This section also describes side effects that could occur and substances or activities to avoid.	For external use only. Do not inject. Do not swallow. Keep out of the eyes and ears. If chlorhexidine comes into contact with the eyes, wash out promptly and thoroughly with water. Seek advice from healthcare professional if you see redness or other signs of skin irritation.
Dosage instructions	When, how, and how often to take the product.	***For countries that adopt a single application:*** Wash hands and use clean thread and a clean cutting instrument to tie and cut the umbilical cord. Apply immediately after cutting the cord. Apply to the tip of the cord, the stump, and around the base of the stump. Wash hands after use. ***For countries that adopt a multi-day application:*** Wash hands and use clean thread and a clean cutting implement to tie and cut the umbilical cord. Apply immediately after cutting the cord. Apply to the tip of the cord, the stump, and around the base of the stump. Repeat the application once daily through the first week of life or until the cord falls off, whichever occurs earlier. Wash hands after each use.
Contraindications		This product should not be handled by anyone with a known history of hypersensitivity to chlorhexidine or to any of the excipients in this formulation
Adverse effects		**Immune system disorders:** hypersensitivity and anaphylaxis (frequency unknown) **Skin and subcutaneous tissue disorders:** allergic skin reactions such as erythema and skin irritation (frequency unknown)
Other information	Storage conditions, sodium content (if any) etc.	Keep the container tightly closed. [Note: This information applies if the primary container is a tube or bottle. Other information should be included if different types of containers other than tubes or bottles are used.] Store in a relatively cool area, away from direct sunlight. [Note: Include specific maximum temperature for storage based on stability data.]
Other information	The product's inactive ingredients, which is important information that can help consumers avoid ingredients that might cause an allergic reaction.	[Depends on the formulation.]