Phazix®
Pill Swallowing Gel

Assessing the Safety of Phazix® Pill Swallowing Gel

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Introduction

An estimated 37% of adults experience difficulties swallowing pills.[1] The prevalence of swallowing impairment increases with age and its associated loss of function.[2,3] Care providers have addressed this issue by crushing medication and mixing it with a variety of substances (e.g., juice, foods such as applesauce, thickeners).[4] However, these substances can interfere with absorption rates, and pill crushing is associated with patient and care-provider risks.[5-8]

Phazix® Pill Swallowing Gel has no known effect on drug dissolution rates[9] and can be used in place of food, juice, or thickeners as mixing vehicles to facilitate swallowing of whole pills.[10] Though composed entirely of common food ingredients, Phazix is classified by the U.S. Food and Drug Administration (FDA) and the European Commission (EC) as a Class 1 medical device. This is because it is intended to assist a patient perform a specific function[11] and it does not achieve its intended purpose through chemical action.[12] Roughly a teaspoon (~5 ml) of Phazix is typically used to facilitate swallowing of medication.

Phazix ingredients

By order of volume, Phazix is composed of these well-documented food ingredients:

1. Water
2. Sucrose (sugar), for sweetening
3. Maltodextrin, a thickener
4. Carrageenan (seaweed extract), a stabilizer
5. Potassium sorbate, a preservative
6. Citric acid, a pH regulator
7. Natural flavor

Phazix, a gluten-free product, contains no dairy products, grains, nuts, or other substances identified by the FDA as major food allergens.[13] A safety data sheet containing other common allergens confirmed not to be found in Phazix is available at Phazix.com/faq. Phazix users with allergies, or their care providers, should review the ingredients listed on Phazix packaging.

Table 1 contains all Phazix ingredients, how they are categorized by the FDA in CFR 21, their specific FDA listing, and comments. According to the FDA, "substances generally recognized as safe" (GRAS) are generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of their intended use.[14]

Table 1. FDA listings for Phazix ingredients

Ingredients	CFR 21 category	CFR 21 listings	Comments
Sucrose, maltodextrin, citric acid	Direct food substances affirmed as generally safe	§184.1854 §184.1444 §184.1033	All 184.1 substances are GRAS
Carrageenan	Food additives permitted for direct addition to food for human consumption	§172.620	FDA 172.620: "the food additive carrageenan may be safely used in food." Carrageenan has Acceptable Daily Intake (ADI) recommendations (see below).
Potassium sorbate	Substances generally recognized as safe	§182.3640	The FDA considers potassium sorbate a GRAS substance (182.3640). Potassium sorbate has Acceptable Daily Intake (ADI) recommendations (see below).

Acceptable Daily Intake (ADI) recommendations: carrageenan and potassium sorbate

Acceptable Daily Intake (ADI) is an estimate of the amount of a food additive that can be ingested on a daily basis over a lifetime without appreciable risk to health. ADI is usually given as a range of milligrams (mgs) per kilogram (kg) of bodyweight (bw) per day. ADI levels are established by first determining the lowest no-observed-adverse-effect level (NOAEL) in animals and building in a large safety factor for humans.[15]

The leading international authority for establishing ADIs is the Joint FAO/WHO Expert Committee on Food Additives (JECFA). However, national regulatory authorities (e.g., the FDA and EC) may commission further reviews and analyses of food substances at the request of clinicians, researchers, or consumer advocates. The EC currently works via the European Food Safety Authority (EFSA), the successor of the Scientific Committee on Food (SCF).

JECFA has established an ADI for potassium sorbate (E202), widely used as a preservative in food products, of 25mg/kg bw.[16] The SCF ADI value for carrageenan (E407), a seaweed extract commonly used as a food stabilizer, is 75 mg/kg body bw.[17] JECFA considers carrageenan safe for humans albeit requiring additional considerations for use in infant formulae (JECFA found concentrations of up to 1000 mg/liter "not of concern" in infant formulae).[18] In 2019, the FDA reviewed and confirmed that carrageenan may be safely used in food.[19]

The carrageenan used in food (E407) should not be confused with other carrageenan products which are not safe for use in food (e.g., poligeenan or degraded carrageenan). Recent clinical literature continues to support the safety of E407 in food.[20]

Assessment of general safety

Based on the ADIs and expert opinion referenced above, the manufacturer recommends that Phazix not be used in children under the age of two and has assessed the general safety (toxicity) of Phazix by examining the amount (mg) of carrageenan and potassium sorbate in: a) a typical daily dose of Phazix (15ml, based on one teaspoon of Phazix used three times per day), and b) hypothetical intake of an entire 150ml container of Phazix at once.

Table 2 contains the results of these two scenarios on ADI and NOAEL for a child weighing 12kg (26.5 pounds) and an adult woman weighing 60kg (132 pounds). It should be noted that ADI assumes consumption over a lifetime, and that occasional daily intake exceeding ADI is not considered dangerous within prescribed NOAEL limits.[15]

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Table 2. ADI and NOAEL for daily Phazix use and hypothetical overexposure

	Carrageenan		Potassium sorbate	
	Child (12 kg)	Adult (60 kg)	Child (12 kg)	Adult (60 kg)
ADI (mg/kg)*	75		25	
ADI amount (mg)	900	4500	300	1500
Phazix typical daily use (mL)	15ml			
Amount consumed (mg)	106		121	
ADI%	11.8%	2.4%	40.4%	8.1%
Phazix overexposure (mL)†	150ml			
Amount consumed (mg)	1060		1212	
ADI%	118%	24%	404%	81%
NOAEL (mg)‡	9000	45,000	4080–6000	15,000
NOAEL%	11.8%	2.4%	20%–30%	8%

* EC (carrageenan) and JECFA (potassium sorbate) † 10 times typical daily intake ‡ Garnered from several sources. Manufacturer data on file

Summary

Pill-swallowing problems are common among healthcare patients. Crushing and/or mixing of medication with foods, juices, or thickeners to ease swallowing is a common practice but should be avoided. Phazix, which facilitates pill swallowing, is composed of ingredients commonly used in food products. All of these ingredients are considered to be safe for human consumption by the Joint FAO/WHO Expert Committee on Food Additives (JECFA), U.S Food and Drug Administration, and the European Commission. Even an accidental intake of a large (150ml) quantity of Phazix falls well below the NOAEL threshold for young children.

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