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Toxicological and clinical data for the tolerability and safety of Ginkgo biloba leaf extract

Sterlla Lyion*

Department of Toxicology, University of Southwest Research Institute, San Antonio, USA

Abstract

Ginkgo biloba is one of the most widely used herbal remedies in Europe and the US. It may be purchased in different types of formulations, but most of the clinical studies have been performed with the controlled G. biloba extract. Indications include Alzheimers disease, cardiovascular disease, dementia, memory loss, and cerebral ischemia. The pharmacological modes of action cover antioxidant effects, radical scavenging, inhibition of platelet activating factor, alterations in membrane fluidity (signal transduction), and inhibition of glucocorticoid synthesis. Due to the widespread and long-term use of G. biloba – about a million doses of EGb761® are sold per day – tolerability and safety are a crucial issue. Based on broad and long-term clinical use of G. biloba extracts, it is regarded as well tolerated in man.

Keywords: Cross matching Ginkgo biloba EGb761®, CAS 122933-57-7 Carcinogenicity Adverse drug reaction Clinical studies

Introduction

Importance of Ginkgo biloba extract

Extracts from Ginkgo biloba leaves have a long history, and today G. biloba is one of the most commonly used herbal medicinal products in Europe and in the US The extract taken most is the standardized extract EGb761®. G. biloba leaf extract is available as film-coated tablets, oral liquids, and injectable solutions. In Europe G. biloba extract is primarily regulated as herbal medicine, but in the US as a dietary supplement sold with health claims. G. biloba extract is used for diseases such as Alzheimer's disease, cardiovascular disease, dementia, memory loss, and cerebral ischemia [1] The pharmacological modes of action include antioxidant effects, radical scavenging, inhibition of platelet activating factor, alterations in membrane fluidity (signal transduction), and inhibition of glucocorticoid synthesis [2].

Components of G. biloba

A plant extract contains several chemical constituent types. Each component may possess different modes of action related to pharmacological and toxicological effects. Therefore, when assessing the risk of G. biloba leaf extract to humans a separate analysis of its components is necessary. Manufacturers produce G. biloba extracts in different ways. Depending on the production process, the components of the extract vary in quality and quantity. This may lead to remarkable differences in efficacy as well as toxicity profiles [3]. The pharmacologically active components include ginkgo ide B and quercetin. Ginkgo ide B has been shown to be effective, e.g., against ischemic brain injury Glycosylated forms of quercetin include rutin and quercetrin. Quercetin possesses antihypertensive, antithrombotic, anti-inflammatory, and anti-infectious effects as well as immunomodulatory activities [4].

Quercetin

Quercetin pre-treatment at 250 mg/kg, but not 10 or 50 mg/kg for 10 days increased rat hepatic CYP 1A2 and CYP 2E1 activities slightly. However, it had no effect on the activities of CYP 2D2, CYP 2C7, and CYP 2C11. Studies with rat liver homogenates showed that kaempferol is metabolized to quercetin by CYP 1A1, but not by CYP 1A2 or CYP 2B1. In rat hepatocytes quercetin and kaempferol have been shown to be extensively glucuronidated by the UDP-glucuronosyltransferase isoform UGT 1A9 Furthermore, after feeding rats a diet containing 1% wt/wt quercetin and 0.5% wt/wt flavones, a significant increase in the activity of UDP-glucuronosyltransferase was found in the liver and intestine [5]..

Pharmacokinetics of G. biloba leaf extract

G. biloba leaf extract is recommended to be administered at a dose of 120 mg two times per day or an 80 mg dose three times per day leading to a maximum recommended daily dose of 240 mg. It is generally agreed that flavonoid glycosides, quercetin, and kaemp- ferol are hydrolyzed in the small intestine by bacteria to aglycones. After absorption in the epithelium, the generated aglycones are conjugated with methyl-, sulfate-, or glucuronic acid groups. However, in rat plasma they may also be found as quercetin and kaempferol The microbial flora as well as the activity of conjugation enzymes vary between laboratory animals and humans leading to both qualitative and quantitative differences in the dose-related systemic exposure to free flavonoid aglycones. In contrast to flavonoid glycosides,terpene lactones are absorbed efficiently Thus, the relative variation on the systemic exposure of ginkgolides and bilobalide among different species is influenced by the activity of metabolism and excretion. No information is found on the absorption of flavonoids in mice [6].

Acknowledgement

None

Conflict of Interest

None

***Corresponding author:** Sterlla Lyion, Department of Toxicology, Univercity of Southwest Research Institute, SanAntonio, USA, Tel: 97336346610; E-mail: sterlla@elyio.com

Received: 02-May-2022, Manuscript No: tyoa-22-63057; **Editor assigned:** 04-May-2022, PreQC No. tyoa-22-63057 (PQ); **Reviewed:** 18-May-2022, tyoa-22-63057; **Revised:** 21-May-2022, Manuscript No: tyoa-22-63057 (R); **Published:** 25-May-2022, DOI: 10.4172/2476-2067.1000178.

Citation: Lyion S (2022) Toxicological and clinical data for the tolerability and safety of Ginkgo biloba leaf extract. Toxicol Open Access 8: 178.

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