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Toxicological Evaluation of Faforon Herbal: A Popular Stem Cell Product Marketed in Nigeria

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Abstract

Faforon herbal is a commercially marketed liquid preparation sold in Nigeria under the label of a "stem cell" product and promoted for the prevention or treatment of a wide range of conditions, including infections, fertility problems, and chronic diseases. These broad therapeutic claims have not been independently validated in peer-reviewed research, and regulatory bodies have separately raised general concerns about the marketing of unapproved stem cell-labeled products. Independent of these efficacy claims, this study evaluated the general toxicological safety profile of Faforon herbal using acute and repeated-dose oral toxicity testing in Wistar rats, following Organisation for Economic Co-operation and Development (OECD) test guidelines. In the acute toxicity phase, no mortality or overt signs of toxicity were observed at the limit dose of 5,000 mg/kg body weight, indicating an oral median lethal dose (LD50) greater than 5,000 mg/kg. In the 28-day repeated-dose phase, groups of six rats received distilled water (control) or Faforon herbal at 200, 1,000, or 2,000 mg/kg body weight daily. Body weight, relative organ weights, hematological indices, serum biochemistry, and liver and kidney histology did not differ significantly from control at the low and mid doses. At the highest dose (2,000 mg/kg), relative liver weight, alanine aminotransferase, and aspartate aminotransferase were significantly elevated relative to control ($p < .05$), and histology showed mild periportal hepatocyte vacuolation, while renal parameters and histology remained unaffected at all doses. These findings indicate a wide margin of safety for Faforon herbal at doses at and above typical recommended consumption levels, with mild, dose-dependent hepatic stress evident only at a substantially supratherapeutic dose. This toxicological safety assessment does not evaluate, and should not be interpreted as validating, the product's marketed regenerative or disease-specific therapeutic claims, which remain scientifically unsubstantiated and require separate, rigorous efficacy research.

Faforon herbal, toxicological evaluation, herbal safety, stem cell product, Wistar rats, OECD guidelines

Background

Faforon herbal is a liquid dietary supplement manufactured and distributed in Nigeria under a multilevel marketing model, promoted to consumers as a "stem cell" product claimed to rebuild damaged cells and address more than twenty distinct health conditions, ranging from anemia and infections to fertility problems, diabetes, and cancer. According to manufacturer product information, the preparation is formulated from an ethanol-water extraction of several plant materials, including Khaya grandifoliola, Boscia angustifolia, Sorghum bicolor, cocoa species, and Dialium guineense. These claims echo a broader pattern that regulatory bodies have flagged as a public health concern: the National Agency for Food and Drug Administration and Control has issued general safety alerts regarding products marketed under unapproved stem cell or exosome labeling, noting that such products are promoted with unsubstantiated claims regarding their capacity to prevent, treat, or cure disease (National Agency for Food and Drug Administration and Control, 2024). Notably, product registration with a national regulatory agency typically certifies manufacturing and basic safety standards rather than independently validating specific disease-treatment or cell-regenerative claims, a distinction that is frequently lost in commercial marketing of herbal products of this kind.

Independent of the validity of any specific therapeutic claim, the toxicological safety of a widely consumed herbal product is a distinct and answerable scientific question. Herbal preparations are commonly perceived by consumers as inherently safe by virtue of being "natural," yet a substantial toxicological literature demonstrates that plant-derived preparations can produce dose-dependent organ toxicity, particularly hepatic and renal effects, especially at high or prolonged exposure (Ernst, 2002; Saad et al., 2005). Systematic toxicological screening of medicinal plants and herbal formulations, following internationally recognized testing guidelines, provides an evidence base for safety that is independent of, and should not be confused with, evidence of therapeutic efficacy (Fennell et al., 2004). Despite widespread commercial availability of Faforon herbal, no independently conducted, peer-reviewed toxicological evaluation of the product appears in the published literature, creating a gap between its scale of consumer use and the evidence available to assess its safety.

Purpose of the Study

This study evaluated the acute and repeated-dose (28-day) oral toxicological profile of Faforon herbal in an albino rat model, assessing mortality, body and organ weight changes, hematological

indices, serum biochemistry, and liver and kidney histology, in order to establish an evidence-based safety profile independent of the product's marketed therapeutic claims.

Materials and Methods

Test Product and Experimental Animals

Faforon herbal was purchased directly from an authorized retail distributor in its original sealed commercial packaging and used without further modification. Thirty adult Wistar albino rats (140–180 g), comprising both sexes for the acute toxicity phase and males for the repeated-dose phase, were obtained from the university animal house, acclimatized for two weeks under standard laboratory conditions (12-hour light/dark cycle, 24 ± 2 °C, free access to feed and water), and handled in accordance with the National Research Council's (2011) Guide for the Care and Use of Laboratory Animals. The study protocol was approved by the institutional Animal Ethics Committee prior to commencement.

Acute Oral Toxicity Study

Acute oral toxicity was assessed following the OECD Test No. 425 up-and-down procedure (Organisation for Economic Co-operation and Development, 2008b). Faforon herbal was administered as a single oral dose at the limit dose of 5,000 mg/kg body weight to fasted rats, which were then observed individually for mortality and signs of toxicity (changes in skin, fur, eyes, mucous membranes, respiratory, circulatory, autonomic, and central nervous system activity, and behavior patterns) at 30 minutes, 4 hours, and 24 hours post-dosing, and thereafter daily for 14 days.

Repeated-Dose 28-Day Oral Toxicity Study

The repeated-dose study followed the general design of OECD Test No. 407 (Organisation for Economic Co-operation and Development, 2008a). Twenty-four male rats were randomly assigned to four groups (n = 6): control (distilled water), low dose (200 mg/kg body weight, approximating the manufacturer-recommended daily consumption level scaled to rat body weight), mid dose (1,000 mg/kg, a fivefold multiple), and high dose (2,000 mg/kg, a tenfold multiple), administered orally once daily for 28 consecutive days. Body weight was recorded weekly. At the end of the study, animals were sacrificed under mild anesthesia; blood was collected for hematological and biochemical analysis, and liver and kidney were excised, weighed, and processed for histological examination.

Laboratory Analysis and Statistics

Hematological indices (packed cell volume, hemoglobin, white blood cell count) were determined using an automated hematology analyzer. Serum biochemistry (alanine aminotransferase [ALT], aspartate aminotransferase [AST], urea, and creatinine) was determined using standard enzymatic and colorimetric kits. Liver and kidney tissues were fixed in 10% neutral buffered formalin, processed routinely, stained with hematoxylin and eosin, and examined by light microscopy by an independent histopathologist blind to group assignment. Data were expressed as mean ± standard error of the mean (SEM) and analyzed by one-way analysis of variance (ANOVA), with Tukey's post hoc test used for pairwise comparisons where the overall F-test was significant, at $\alpha = .05$.

Results

Acute Toxicity

No mortality or overt signs of toxicity were observed in any animal within 24 hours or over the subsequent 14-day observation period following administration of Faforon herbal at the limit dose of 5,000 mg/kg body weight. Under OECD Test No. 425 classification criteria, this finding places the oral median lethal dose (LD50) above 5,000 mg/kg body weight, corresponding to the least hazardous globally harmonized classification category for acute oral toxicity.

Body and Organ Weights

Table 1 presents body weight, relative organ weights, and mortality across the 28-day repeated-dose study. Final body weight did not differ significantly across groups, and no mortality occurred in any group. Relative liver weight was significantly higher in the high-dose group relative to control ($p < .05$), while low- and mid-dose groups did not differ significantly from control. Relative kidney weight did not differ significantly across any group.

Table 1

Body Weight, Relative Organ Weights, and Mortality After 28 Days of Faforon Herbal Administration

Group	Final Body Weight (g)	Relative Liver Weight (%)	Relative Kidney Weight (%)	Mortality

Control	218 ± 6[a]	2.84 ± 0.09[a]	0.68 ± 0.03[a]	0/6
Low dose (200 mg/kg)	221 ± 7[a]	2.89 ± 0.10[a]	0.69 ± 0.03[a]	0/6
Mid dose (1,000 mg/kg)	215 ± 6[a]	3.02 ± 0.11[a]	0.71 ± 0.03[a]	0/6
High dose (2,000 mg/kg)	206 ± 7[a]	3.38 ± 0.14[b]	0.74 ± 0.04[a]	0/6

Note. Values are mean ± SEM (n = 6) except mortality, expressed as number of deaths/group size. Means within a column not sharing a superscript letter differ significantly at $p < .05$ (Tukey's test).

Hematological and Biochemical Findings

Table 2 presents hematological and biochemical parameters at day 28, alongside typical reference ranges for the species. Hematological indices, urea, and creatinine did not differ significantly across groups and remained within normal reference ranges at all doses. ALT and AST were significantly elevated in the high-dose group relative to control ($p < .05$), with the mid-dose group showing an intermediate, non-significantly elevated value; the low-dose group did not differ from control on any parameter. Notably, even the elevated high-dose ALT and AST values remained within, or only marginally above, the upper bound of the typical reference range for this species.

Table 2

Hematological and Biochemical Parameters After 28 Days of Faforon Herbal Administration

Parameter	Control	Low Dose	Mid Dose	High Dose	Ref. Range
PCV (%)	45.1 ± 1.2[a]	46.0 ± 1.1[a]	44.6 ± 1.3[a]	42.8 ± 1.4[a]	39–49
Hb (g/dL)	14.8 ± 0.4[a]	15.0 ± 0.4[a]	14.5 ± 0.5[a]	13.9 ± 0.5[a]	12–17
WBC (×10⁹/L)	7.6 ± 0.5[a]	7.8 ± 0.6[a]	8.0 ± 0.6[a]	8.6 ± 0.7[a]	5–12
ALT (U/L)	38.4 ± 2.1[a]	40.1 ± 2.3[a]	44.6 ± 2.6[ab]	58.2 ± 3.4[b]	20–61
AST (U/L)	84.2 ± 3.8[a]	87.5 ± 4.0[a]	94.1 ± 4.3[ab]	116.7 ± 5.6[b]	59–247

Urea (mg/dL)	28.6 ± 1.5[a]	29.4 ± 1.6[a]	30.1 ± 1.7[a]	32.0 ± 1.9[a]	15–40
Creatinine (mg/dL)	0.62 ± 0.04[a]	0.64 ± 0.04[a]	0.66 ± 0.05[a]	0.71 ± 0.05[a]	0.4–1.2

Note. Values are mean ± SEM (n = 6). Means within a row not sharing a superscript letter differ significantly at $p < .05$ (Tukey's test). PCV = packed cell volume; Hb = hemoglobin; WBC = white blood cell count; ALT = alanine aminotransferase; AST = aspartate aminotransferase. Reference ranges are approximate typical values for healthy adult Wistar rats.

Histopathological Findings

Table 3 summarizes histopathological findings. Hepatic and renal architecture in the control, low-dose, and mid-dose groups were essentially normal, with only occasional mild sinusoidal congestion noted in the mid-dose liver sections. In the high-dose group, hepatic sections showed mild periportal hepatocyte vacuolation and scattered focal congestion, consistent with the biochemical elevation in ALT and AST observed in this group, though overall lobular architecture remained preserved and no evidence of necrosis was observed. Renal histology was unremarkable across all groups, including the high-dose group, consistent with the absence of significant change in urea or creatinine.

Table 3

Histopathological Findings in Hepatic and Renal Tissue After 28 Days of Faforon Herbal Administration

Group	Hepatic Histology	Renal Histology
Control	Normal hepatocyte cords, intact central vein and sinusoids	Normal glomerular and tubular architecture
Low dose (200 mg/kg)	Normal architecture, comparable to control	Normal architecture, comparable to control
Mid dose (1,000 mg/kg)	Normal architecture with occasional mild sinusoidal congestion	Normal architecture, comparable to control
High dose (2,000 mg/kg)	Mild periportal hepatocyte vacuolation and scattered focal congestion; overall lobular architecture preserved	Normal architecture, comparable to control

Note. Findings represent qualitative consensus assessment by an independent histopathologist blind to group assignment, based on hematoxylin and eosin-stained sections.

Discussion

This study found that Faforon herbal produced no mortality or overt toxicity at the acute limit dose of 5,000 mg/kg, placing it in the least hazardous acute oral toxicity classification category, and that repeated daily administration for 28 days was not associated with significant adverse hematological, biochemical, or histological findings at doses at or moderately above (up to fivefold) the manufacturer-recommended consumption level. This pattern indicates a wide margin of safety for the product under typical or even moderately excessive consumption patterns. At a substantially supratherapeutic dose (tenfold the recommended level), however, significant elevation of hepatic enzymes and mild histological evidence of hepatocyte stress emerged, without corresponding renal effects, indicating that the liver is the more sensitive target organ for this preparation at high exposure.

This dose-dependent hepatic signal at high exposure, in the absence of adverse effects at lower doses, is broadly consistent with the toxicological literature on herbal preparations generally, in which many botanicals demonstrate a favorable safety margin at customary use levels but can produce measurable organ stress when consumed well beyond recommended amounts (Adeneye et al., 2006; Ernst, 2002; Gbadamosi & Okolosi, 2013). The absence of necrosis or renal involvement even at the highest dose tested suggests the observed hepatic changes reflect an adaptive or mild-stress response rather than severe organ injury within the exposure range and duration examined here.

It is important to distinguish the scope of this study from the product's marketing claims. This toxicological evaluation addresses only the general safety of Faforon herbal with respect to mortality, organ weight, hematology, biochemistry, and histology under controlled laboratory conditions; it does not test, and cannot be interpreted as supporting, the product's marketed claims regarding stem cell regeneration or the prevention or treatment of specific diseases, claims that remain scientifically unsubstantiated in the peer-reviewed literature and that regulatory bodies have separately identified as a category of concern in herbal product marketing more broadly (National Agency for Food and Drug Administration and Control, 2024). Consumers and clinicians should not interpret a favorable toxicological safety profile as evidence of therapeutic efficacy for any specific condition.

This study is limited by its reliance on a single batch of a commercially sourced product whose exact composition may vary across production batches, a 28-day exposure duration that cannot address chronic or long-term safety, and testing in male rats only for the repeated-dose phase, which does not address potential sex-specific or reproductive effects. Future research should include chronic (90-day or longer) toxicity testing, evaluation across multiple product batches, sex-disaggregated analysis, and independent, rigorously controlled efficacy trials addressing the product's specific marketed health claims.

Conclusion

Faforon herbal demonstrated a favorable acute and short-term repeated-dose toxicological safety profile in this rat model, with an oral LD50 greater than 5,000 mg/kg and no significant adverse effects at doses up to fivefold the recommended consumption level, though mild hepatic enzyme elevation and histological change emerged at a tenfold supratherapeutic dose. These findings support a reasonable margin of safety for the product at typical consumption levels but underscore the need for continued regulatory surveillance, chronic toxicity testing, and, separately, independent efficacy research, given that the product's broad marketed therapeutic and stem cell-regenerative claims remain scientifically unsubstantiated and fall outside the scope of this toxicological safety assessment.

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