Office of Nutritional Products
Labelling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740
20th September 2005

1940 5 OCT 28 P2:12
OCT 17

Dear Sir or Madam,

This letter serves as a 30 day notification pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994 (DSHEA), that
Boots Retail USA Inc. is using the following statements on the label or in the labelling of
Boots Detox 5 Day Plan Strawberry Flavour Dietary Supplement Total Body Cleanse,
consisting of;
Vials (x 5)
(dietary ingredients: Grape vine leaf extra (Vitis vinifera) 700mg and Pine bark extract (Pycnogenol) 30mg)

"Help combat the effects with this 5 day plan that helps re-energise your detoxifying organs to leave you feeling revitalised."

"Made from a blend of ingredients that target your detoxifying organs, the plan helps to flush away impurities from your body. The plan contains ingredients that battle against toxic substances and help protect from the dangers of free radicals."

"If your body needs a rest from the stresses of a modern hectic lifestyle then this 5 day plan will help combat over indulgence to remove impurities and re-energise".

These statements are accompanied by the required disclaimer. To the best of my knowledge, the information contained in this notice is complete and accurate and the company has substantiation that these statements are truthful and not misleading.

Sincerely,

APattie

Adèle Pattie
International Regulatory Affairs

Boots Retail USA Inc.,
Stamford,
CT 06901

2005-7018
AIMS

97S 0162 LET
16789

5 Day Plan

The Boots Detox product range works in harmony with your body to help flush away impurities and stimulate your body's natural detoxifying systems, leaving you purified and revitalised.

Do you need to detox?
Your body is designed to naturally flush out toxic substances. But a busy modern lifestyle can leave your system struggling to cope. Pollutants, pesticides, and other impurities can all find their way into the body. Help combat the effects with this 5 day plan to feel re-energised and revitalised.

Re-balancing and Harmonising
Made from a blend of ingredients that target your detoxifying organs, the plan helps to flush away impurities from your body. The plan contains ingredients that battle against toxic substances and help protect from the dangers of free radicals.

To Use: Each day for 5 days, add the contents of a vial to a quart or litre of water and drink the pleasant tasting supplement throughout the day.

Please refer to the enclosed booklet for further information about the simple dietary and lifestyle changes you can make to increase the effectiveness of this plan.

WARNING: Not recommended for children or during pregnancy. Store in a cool dry place away from children. Do not exceed stated daily intake.

Supplement Facts

Serving size 1 vial

Amount Per Serving		Contents % Daily Value
Grape vine leaf extract (Vitis vinifera)	700 mg	†
Pine bark extract (Pycnogenol)	30 mg	†

† Daily value not established

*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

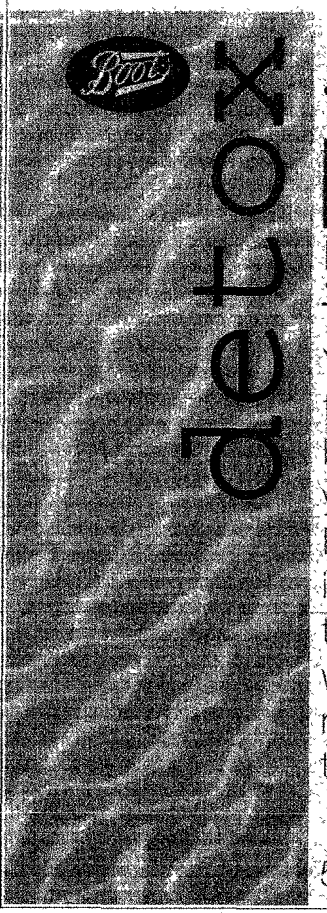
Other Ingredients: Water, Glycerol, Grape vine leaf extract (Vitis vinifera), Flavouring, Sodium citrate, Citric acid, Stabilise (Xanthan gum), Acacia, Pine bark extract (Pycnogenol), Sodium chloride, Preservative (Sorbic acid)

QJTX0

Mfd in the UK for BBI Ltd NG2 3AA, UK
Dist in USA by Boots Retail USA Inc. Stamford CT 06901
USA: Questions? 1-866-75-BOOTS
www.boots.com

27-53-200
Excitation Date

5 000167 084375



5 Day Plan

Strawberry flavour

DIETARY SUPPLEMENT

TOTAL BODY CLEANSE

Your body is designed to naturally flush out toxic substances. But a busy modern lifestyle can leave your system struggling to cope. Pollutants, pesticides and other impurities can all find their way into the body. Help combat the effects with this 5 day plan that helps re-energise your detoxifying organs to leave you feeling revitalised.*

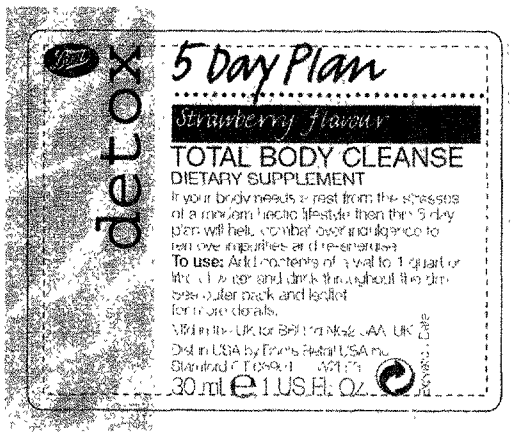
5 x 30 ml ℮ 1 US Fl. Oz. Vials

Artwork Ref:	Version No.:	Comp Code:	QCNZ9	Purchase Order No.:	406/4700011304
HL8333	2	Item Code:	27-53-200	Category Manager:	Richard Thornhill

VAL
Jupiter Design
Ruddington Manor
Manor Park
Ruddington
Nottingham
NG11 6DS
JUPITER

Date:	08/07/05	File Name:	HL8333/VAL/QJTX0/Detox5DaySlStr
Packaging Technologist:	Ian Beadle	Print Process:	Screen
Charge Code:	30008	Printer:	ACL

Packaging Team Approval:
Cutter Guide ☐ Colour Separation ☐
Printability ☐ Environment ☐
Signed.



Artwork Ref:	Version No.:	Comp Code:	WZLE3	Purchase Order No.:	406/4700011304
HL8334	2	Item Code:	27-53-200	Category Manager:	Richard Thornhill

Jupiter Design
Ruddington Manor
Manor Park
Ruddington
Nottingham
NG11 6DS
JUPITER
Switchboard 0115 984 200
ISDN 0115 984 6651
Fax 0115 984 4210
artwork@jupiterdesign.co.uk

Artwork Dispatch

1 ISDN ☐ CD ☐ FTP ☐ My Jupiter ☐
Date _____ Vs ____ Artworker ____

Flag if dispatched more than once

2 ISDN ☐ CD ☐ FTP ☐ My Jupiter ☐
Date _____ Vs ____ Artworker ____

3 ISDN ☐ CD ☐ FTP ☐ My Jupiter ☐
Date _____ Vs ____ Artworker: ____

4 ISDN ☐ CD ☐ FTP ☐ My Jupiter ☐
Date _____ Vs ____ Artworker ____

5 ISDN ☐ CD ☐ FTP ☐ My Jupiter ☐
Date _____ Vs ____ Artworker ____

6 ISDN ☐ CD ☐ FTP ☐ My Jupiter ☐
Date _____ Vs ____ Artworker ____

Date:	08/07/05	File Name:	HL8334-VAL-WZLE3-Detox5DayPlStr
Packaging Technologist:	Ian Beadle	Print Process:	Flexo
Charge Code:	30008	Printer:	Fields
Artworkers:	LW/FR	Repro House:	TBA
Profile Ref: (dimensions if required):	62 x 50		
Substrate:	PPr	Substrate Colour:	White
Barcode M/F:	n/a	Truncated to:	XXmm
Software Used:	Illustrator 10		

PLEASE NOTE THAT THE BARCODE HAS BEEN CREATED WITH ZERO BAR WIDTH REDUCTION. IF YOU REQUIRE ANY OTHER PLEASE REPLACE. NOT FOR ACTUAL COLOUR, COLOUR LASER COPY ONLY. GRIPS AND BLEEDS NEED TO BE ADDED.

Colours: P5195c; P Cool Gray 11c; P 194c; Varnish

Artwork Comments:

XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX

Jupiter Design Artwork Sign Off (if external): _____ Date: / /

Packaging Team Approval:
Cutter Guide ☐ Colour Separation ☐
Printability ☐ Environment ☐
Signed: _____
Date: _____

NPI & D Approval:
Text ☐ Medical ☐
Legal ☐ Range Consistency ☐
Signed: _____
Date: _____

Category Team Approval:
Barcode ☐ Range Consistency ☐
Item Code ☐ Text ☐
Signed: _____
Date: _____

Supplier Approval:
Cutter Guide ☐ Text ☐
Printability ☐ Production Codes/Lot Area ☐
Signed: _____
Date: _____

www.boots.com

08/01 002088 PJTT5

detox

Your pocket guide

The hows and whys, the benefits and the results. An easier, more natural way to look and feel better. This booklet contains comprehensive help and advice on the detox process. Everything from the nutritional and lifestyle changes you can make, through to why the simplest of things – like laughing more – can help. Hopefully its contents will answer many of your questions and at the same time give you advice on how to make detoxing a treat rather than a chore.

RANGE detox | PAGE NO 16 & 1

Trinity Graphic Limited

CUSTOMER & CONTACT	DESCRIPTION				COLOURS
BCM	Detox Leaflet Amends				Cyan, Magenta, Yellow, Black
CUSTOMER ORDER No.	ACCOUNT EXECUTIVE		OPERATOR		
To Follow	A. Champbell		Gareth Prate		
TRINITY WORKS No.	DATE	PROOF	LABEL SIZE	SCREEN	
68244	1/6/04	No.2	77 x 77	150#	Total No. of Colours 4

PROG: 1 | Q.C.I.D.

Hawthorn Avenue, Hull HU3 5JD Tel: 01482 227431 Fax 01482 223152 ISDN: 01482 585886 E-Mail: trinitvg@globalnet.co.uk

Approved
Ian Beadle
09 SEP 04

Detox. How, why, what?

Pollutants, exhaust fumes, alcohol, smoke and pesticides are all everyday parts of 21st century life, and are all capable of contributing to the impurity build-up within our bodies. An increased exposure to these impurities can often leave you feeling less than 100% – lacking in energy and vitality, and can reduce your body's ability to digest food and eliminate waste. Detoxing is an excellent way to give your body a spring clean – reducing the level of excess waste and impurities built-up by everyday living. By watching what you eat and drink and with a few simple lifestyle changes, you should soon start to see and feel the benefits in both your body and mind.

RANGE	PAGE NO
detox	2 & 3

Trinity Graphic Limited

CUSTOMER & CONTACT	DESCRIPTION				COLOURS
BCM	Detox Leaflet Amends				Cyan, Magenta, Yellow, Black
CUSTOMER ORDER No.	ACCOUNT EXECUTIVE		OPERATOR		
To Follow	A. Champbell		Gareth Prate		
TRINITY WORKS No.	DATE	PROOF	LABEL SIZE	SCREEN	
68244	1/6/04	No.2	?? x ??	150#	Total No. of Colours 4

ISO 9001 UKAS

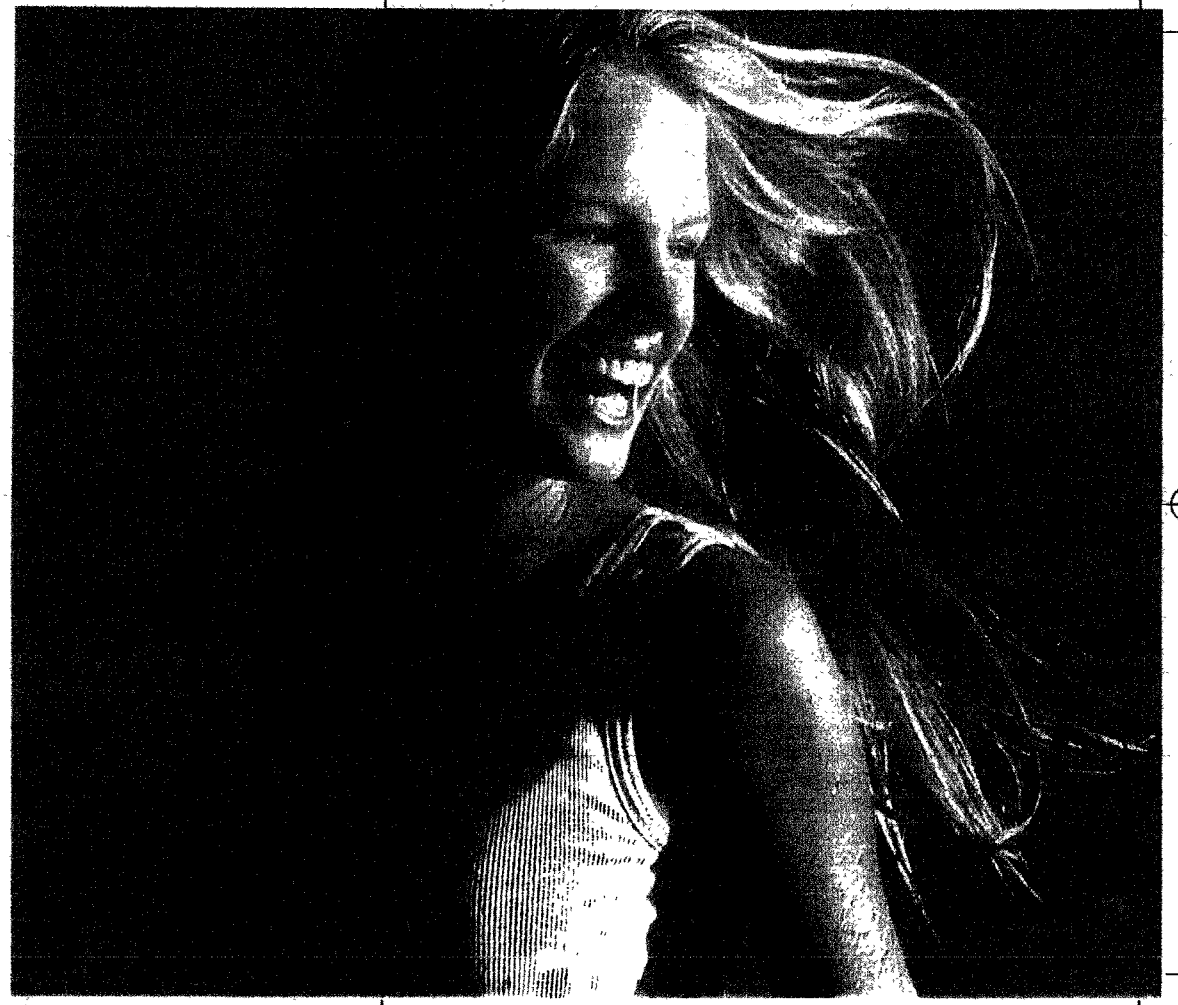
PROG	Q.C.I.D.
1	

Hawthorn Avenue, Hull HU3 5JD Tel: 01482 227431 Fax 01482 223152 ISDN: 01482 585886 E-Mail: trinityg@globalnet.co.uk

Approved
Ian Beadle
09 SEP 04

The benefits of detoxing

Differences between individuals, in terms of metabolism and the patterns of previous lifestyle, will affect the degree to which you will be able to feel the benefits of detoxing, but there is little doubt that you will experience some beneficial changes.
As the impurity build-up is flushed away you will feel re-energised and revitalised as your body's systems are optimised. As your internal impurity levels reduce this can lead to clearer skin, healthier looking hair and increased energy levels. Detoxing is part of a healthier approach to life, rather than a diet programme. However the change in lifestyle may mean that weight loss is a side effect. What's more, abstaining from some of your
usual bad habits can be the first steps to cutting down or giving up.



RANGE detox PAGE NO 4 & 5

Trinity Graphic Limited

CUSTOMER & CONTACT	DESCRIPTION				COLOURS
BCM	Detox Leaflet Amends				Cyan Magenta Yellow Black
CUSTOMER ORDER No.	ACCOUNT EXECUTIVE		OPERATOR		
To Follow	A. Champbell		Gareth Prate		
TRINITY WORKS No.	DATE	PROOF	LABEL SIZE	SCREEN	
68244	1/6/04	No.2	?? x ??	150#	Total No. of Colours 4

PROG	Q.C.I.D.
1	

Hawthorn Avenue, Hull HU3 5JD Tel: 01482 227431 Fax 01482 223152 ISDN: 01482 585886 E-Mail: trinityg@globalnet.co.uk

Approved
Ian Beadle
09 SEP 04

How detoxing works

Detoxing is a way of removing excess waste and impurities from your body. The impurities we pick up in our everyday lives are carried around the body in our blood. They are carried to the liver, where they are filtered and converted into compounds that other organs are able to process and expel. When detoxing you should include elements for all the major organs involved in processing impurities. The Boots Detox range works in harmony with your body, helping the organs flush away impurities.

From plans for your whole body to products that target specific detoxifying organs, such as the skin, and the digestive system, our range can help both improve and supplement the cleansing process. Whilst our products will help to detoxify your body, the lifestyle changes described in this booklet will ensure that you get the most benefit from the time that you are investing. What's more, our products are designed to not only be effective, but also pleasant, and in some cases are decadently pampering, while still contributing to your detox. Sticking to the healthy lifestyle may not seem so bad when you can treat yourself to our gently warming face mask.

Our range contains plans and kits that will help you carry out a head to toe detox. They contain ingredients that target all the major detoxifying organs to give a general overhaul of your purifying processes.

Trinity Graphic Limited

CUSTOMER & CONTACT	DESCRIPTION				COLOURS
BCM	Detox Leaflet Amends				Cyan Magenta Yellow Black
CUSTOMER ORDER No.	ACCOUNT EXECUTIVE		OPERATOR		
To Follow	A. Champbell		Gareth Prate		
TRINITY WORKS No.	DATE	PROOF	LABEL SIZE	SCREEN	
68244	1/6/04	No.2	77 x 77	150#	Total No. of Colours 4

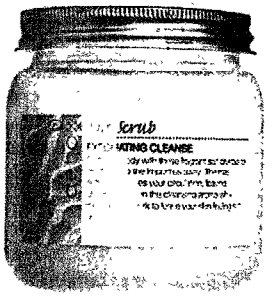
PROG 1 Q.C.I.D.

Approved
Ian Beadle
09 SEP 04

Detox your skin and circulation

The major internal organs involved in removing toxins from your body are your lungs, liver, kidneys and digestive system. You breathe out impurities when you exhale, so deeper breathing is beneficial. By optimising your digestive process you will expel impurities more quickly and maximise your ability to absorb nutrients. The range contains specific products to help with this. Your kidneys are also important – drinking lots of water is the best way of helping them.

detox



RANGE	PAGE NO
detox	8 & 9

CUSTOMER & CONTACT	DESCRIPTION		COLOURS
BCM	Detox Leaflet Amends		Cyan, Magenta, Yellow, Black
CUSTOMER ORDER No.	ACCOUNT EXECUTIVE	OPERATOR	
To Follow	A. Champbell	Gareth Prate	
TRINITY WORKS No.	DATE / PROOF / LABEL SIZE / SCREEN		
68244	1/6/04 / No.2 / 77 x 77 / 150#		Total No. of Colours 4

PROG	Q.C.I.D.
1	

Trinity Graphic Limited
Hawthorn Avenue, Hull HU3 5ID Tel: 01482 227431 Fax 01482 223152 ISDN: 01482 585886 E-Mail: trinitym@globalnet.co.uk

Approved
Ian Beech
09 SEP 04

The Essentials While Detoxing

Whilst our Detox range is undoubtedly a great way to aid the detoxifying process, there are many other things you can make part of your daily routine to help maximise the effects.

Drink more fluids
You should aim to drink at least 1.5 litres (3 pints) of fluids a day, preferably water. This will help flush your system and rehydrate your body.

Change your diet
A change to a more balanced, healthier diet can work wonders for your system and can also result in weight loss and increased energy levels. As a general rule, eat and drink natural, fresh produce.

Good detoxifying foods include:
Fruit – fresh or dried, Vegetables – preferably raw or steamed, Nuts, pulses and seeds, Fish, Brown rice, Wholemeal bread, Olive, walnut or sesame oil, Garlic, Herbal teas, Fruit juice – preferably not made from concentrate, Vegetable juice

Things to avoid or moderate
Dairy products (difficult to digest), processed or convenience food, artificially sweetened food, tea, coffee and alcohol (dehydrates your body), candy and chocolate

If possible you should also try to stop smoking and avoid smoky environments.

RANGE detox PAGE NO 10 & 11

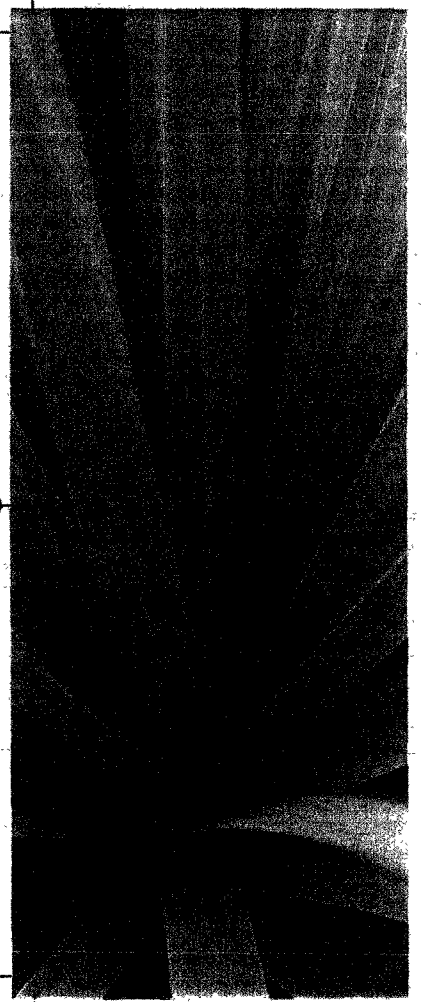
Trinity Graphic Limited

CUSTOMER & CONTACT	DESCRIPTION				COLOURS
BCM	Detox Leaflet Amends				Cyan Magenta Yellow Black
CUSTOMER ORDER No.	ACCOUNT EXECUTIVE		OPERATOR		
To Follow	A. Champbell		Gareth Prate		
TRINITY WORKS No.	DATE	PROOF	LABEL SIZE	SCREEN	
68244	1/6/04	No.2	77 x 77	150#	Total No. of Colours 4

PROG	Q.C.I.D.
1	

Hawthorn Avenue, Hull HU3 5JD Tel: 01482 227431 Fax: 01482 223152 ISDN: 01482 595096 E-Mail: [illegible]

Approved
Ian Beadle
09 SEP 04



Take the Holistic Approach

Exercise
One of the best ways of enhancing the detoxifying process is to take some form of regular exercise. Anything from visiting the gym to walking the dog will help improve both your circulation and metabolic rate and get internal organs working.

Deep breathing
Taking deep breaths can help to expel impurities from your lungs. You should try breathing deeply for at least 5 minutes every day.

Improve your environment
Your home or office can be as prone to impurities as the outside. Green plants are an excellent way of removing airborne pollutants, and ionisers, humidifiers and oil burners are all great ways of improving the atmosphere.

Potential side effects

When detoxing you may experience certain minor side effects. These often depend on your lifestyle prior to detoxification. For example, someone who usually drinks a lot of coffee may experience mild headaches as their body adjusts to the change in caffeine levels.

Common side effects
Mild headaches – caused by your body learning to live without chemicals such as alcohol, sugar and caffeine. These usually appear on day 2 or 3 of the detox and can last for up to 24 hours. Drink lots of fluid and make time for relaxation.

Spots – The skin is the body's biggest organ of elimination, so the appearance of spots during a detox is not uncommon. They can appear as early as day 3 and can last throughout the detox process – drinking plenty of water will help.

Increased bowel movements – this is completely normal and is a sure sign that your body is starting to cleanse itself.

A furry tongue – Again a sure sign that the body is removing impurities.
Use a mouthwash or try scraping your tongue with a toothbrush.

Lulls in energy during the first few days – Your body will be used to instant energy snacks. It will take a few days to adjust to the more gradual energy release replacements. These side effects should be minor in nature, and only last for a few days.

Why not try detoxing with a friend?
It's a great way to overcome any potential pitfalls and gain the extra resolve that's sometimes needed to stick it out.

Trinity Graphic Limited

CUSTOMER & CONTACT	DESCRIPTION				COLOURS
BCM	Detox Leaflet Amends				Cyan Magenta Yellow Black
CUSTOMER ORDER No.	ACCOUNT EXECUTIVE		OPERATOR		
To Follow	A. Champbell		Gareth Prate		
TRINITY WORKS No.	DATE	PROOF	LABEL SIZE	SCREEN	
68244	1/6/04	No.2	?? x ??	150#	Total No. of Colours 4

ISO 9001 UKAS

PROG	Q.C.I.D.
1	

Hawthorn Avenue, Hull HU3 5JD Tel: 01482 227431 Fax 01482 223152 ISDN: 01482 585886 E-Mail: trinityg@globalnet.co.uk

Approved
Ian Beadle
09 SEP 04

Did you know?

Laughing helps – a good laugh not only gives your internal organs a workout, it also reduces stress levels – an important factor in detoxification.

Cold showers can help you detox – they increase your circulation and kick-start lymph flow.

Many aromatherapy oils have cleansing properties that can help with detox, for example juniper, lemon grass and rosemary.

Frequently asked questions

Q. How often should I detox?
A. Everyone's lifestyle and metabolism is different. It will depend on your impurity intake, and your body's natural efficiency at detoxing. When you have detoxed you will feel clearer and re-energised. As impurities start to build up again this feeling will lessen. It's then time to detox again!

Q. When should I detox?
A. We recommend that you detox when you feel you need it. For example, after prolonged periods of over-indulgence, or before a big event so that you look and feel your best e.g. summer holidays. It is best not to detox when you are experiencing a hectic time at work or socially. Coping with the change in lifestyle can be time consuming until you are familiar with it.

Q. Who shouldn't detox?
A. Anyone who is pregnant or breastfeeding should not detox. We also do not recommend detoxing for children. Check the individual products in the range for warnings that are specific to that product.

Q. Where can I get further information?
A. There are numerous books, magazine articles and internet sites that offer detox advice – some of which is conflicting, and some even dangerous. Anything that sounds extreme is probably best avoided. Take care to use reputable sources only.

Q. Which plan should I do?
A. It depends! The 5 day plan is more suitable if you want to boost your body's detoxifying systems to get a quick result, particularly in reducing the impurity build-up in your liver. The 28 day plan builds up over time, so the benefits are more gradual but more thorough. Changes to a more healthy lifestyle will have become ingrained if you do them for a month – leading to less impurity exposure in the future.

Q. Can I take both plans at once?
A. We do not recommend that you do both plans at once. You may wish to do the 28 day plan the first time, and then when you next feel the need, do a 5 day detox.

Q. Will I be hungry?
A. Just because you are detoxing, it is no reason to deprive yourself of food, providing you eat natural and fresh produce.

RANGE detox PAGE NO 14 & 15

Trinity Graphic Limited

CUSTOMER & CONTACT	DESCRIPTION				COLOURS
BCM	Detox Leaflet Amends				Cyan Magenta Yellow Black
CUSTOMER ORDER No.	ACCOUNT EXECUTIVE		OPERATOR		
To Follow	A. Champbell		Gareth Prate		
TRINITY WORKS No.	DATE	PROOF	LABEL SIZE	SCREEN	
68244	1/6/04	No.2	?? x ??	150#	Total No. of Colours 4

ISO 9001 UKAS

PROG	Q.C.I.D.
I	

Hawthorn Avenue, Hull HU3 5JD Tel: 01482 227431 Fax: 01482 221152 ISDN: 01482 505086 DX: [illegible]

Approved
Ian Beadle
09 SEP 04