Package leaflet: Information for the user

Pharmaton[®] Capsules

Read all of this leaflet carefully before you start taking Pharmaton[®] Capsules because it contains important information for you to get the best results.

- Keep this leaflet. You may need to use it again.
- Ask your pharmacist if you need more information or advice.
- Talk to your pharmacist or doctor if you develop new symptoms or if your symptoms get much worse or have not shown any sign of improvement over 4 weeks.
- If a side effect occurs and gets troublesome, or seems serious to you, or if you experience a side effect not listed in this leaflet, please tell your pharmacist or doctor.

In this leaflet:

- 1. What Pharmaton[®] Capsules are and what they are used for.
- 2. Before you take Pharmaton[®] Capsules.
- 3. How to take Pharmaton[®] Capsules.
- 4. Possible side effects.
- 5. How to store Pharmaton[®] Capsules.
- 6. Further information.

1. WHAT PHARMATON® CAPSULES ARE AND WHAT THEY ARE USED FOR

Pharmaton[®] Capsules are a multivitamin, mineral and ginseng supplement. Each capsule contains standardised Ginseng extract G115[®] with Vitamins A, B group, C, D, E, Nicotinamide, Folic acid, Biotin, and minerals Iron, Calcium, Copper, Magnesium, Zinc, and Selenium.

See Section 6 (Further information) for a complete list of the ingredients and quantities in each capsule.

Pharmaton[®] Capsules are for:

- Relief of daily fatigue associated with a busy, hectic lifestyle. Symptoms of daily fatigue include temporary periods of exhaustion (for example caused by stress), tiredness and a feeling of weakness or lack of vitality.
- Ill-balanced or deficient nutrition, where needed to prevent or treat symptoms of vitamin and mineral deficiency.

Pharmaton[®] Caspules contains Ginseng G115[®] which works by enhancing mental and physical performance, and through the combined action with vitamins and minerals on the basic metabolic processes.

Pharmaton[®] Capsules are suitable for adult men and women but not for children.

More information about daily fatigue

Daily fatigue is associated with a busy, hectic lifestyle, and symptoms may include:

- Lack of energy
- Increase in rest requirements
- Energy not restored even after sleep
- Decreased mental and physical performance
- Lethargy
- Lack of concentration

Lifestyle changes that may help to overcome daily fatigue include:

Healthy eating

- Regular exercise, such as a midday stroll
- Take time out to allow for relaxation
- Prioritise work loads, instead of cramming too much into one day
- Delegate tasks at work and home
- Find new ways to deal with stress
- Learn to say no when there are too many demands on personal time
- · Reduce the intake of alcohol, caffeine, and cigarettes

2. BEFORE YOU TAKE PHARMATON[®] CAPSULES

Do not take Pharmaton[®] Capsules if:

- You are allergic to any of the ingredients listed in Section 6 of this leaflet
- You have severe problems with your kidneys
- You have high iron levels, or a condition such as "haemochromatosis", which is caused by a problem that may run in your family
- You have problems with high levels of Vitamin A or D in your body
- You have problems with high levels of calcium in your blood or urine
- Do not take this medicine if any of the above applies to you.

If you are not sure, talk to your pharmacist or doctor before taking this medicine.

Warnings and precautions

Pharmaton[®] Vitality Capsules contains 150 micrograms biotin per capsule. If you are about to undergo laboratory testing you must tell your doctor or the laboratory personnel that you are taking or have recently taken Pharmaton[®] Vitality Capsules, because biotin may affect results of such tests. Depending on the test, the results may be falsely elevated or falsely low due to biotin. Your doctor may ask you to stop taking Pharmaton[®] Vitality Capsules before performing laboratory tests. You should also be aware that other products that you may take, such as multivitamins or supplements for hair, skin, and nails could also contain biotin and affect the results of laboratory tests. Please inform your doctor or the laboratory personnel, if you are taking such products.

Taking other medicines

The following medicines should not be taken with Pharmaton[®] Capsules:

• Vitamin A derivatives called "retinoids" (prescribed to treat acne), or Vitamin D treatment

Before taking Pharmaton[®] Capsules you should tell your pharmacist or doctor if you are taking any of the following medicines:

- Medicines to thin the blood called "anticoagulants" such as warfarin. This is because your doctor will need to monitor your blood before you start or stop taking Pharmaton[®] Capsules
- Levodopa (used to treat Parkinson's disease)
- Antihypertensives (medicines used to lower your blood pressure)
- Depressants or stimulants which act on the central nervous system
- Tetracycline antibiotics such as tetracycline, doxycline, minocycline

Food, drink, vitamin and mineral supplements

It is important not to take too much Vitamin A, D, or iron. You should consider your daily intake of all vitamins and minerals taking into account all sources including food and drinks.

Pregnancy and breast-feeding

Pharmaton[®] Capsules contain Vitamin A.

Do not take this medicine if you are pregnant or are likely to become pregnant as large doses of vitamin A may harm the baby, especially if used during the first three months of pregnancy.

Do not take this medicine if you are breast-feeding

Important information about the ingredients

- Pharmaton[®] Capsules contain peanut oil (also known as arachis oil). If you are allergic to peanut or soya, do not take Pharmaton[®] Capsules
- Pharmaton[®] Capsules contain a small amount of lactose.
- If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Pharmaton[®] Capsules
- If you are allergic to any of the other ingredients in Pharmaton[®] Capsules listed in Section 6, do not take this medicine.

3. HOW TO TAKE PHARMATON[®] CAPSULES

Follow the instructions printed in this leaflet. Talk to your pharmacist or doctor if you develop new symptoms or if your symptoms get much worse or have not shown any sign of improvement over four weeks.

Adults

- Take one capsule each day
- It is recommended to take the capsule in the morning with food
- Swallow the capsule whole with water

Children

Do not give these capsules to children.

How long to take Pharmaton[®] Capsules for

- Start by taking Pharmaton[®] Capsules for 4 weeks.
- If, after 4 weeks treatment, you are starting to feel better, you may continue to take Pharmaton[®] Capsules for up to 12 weeks.
- The usual course of treatment is 8 to 12 weeks.
- After 12 weeks, talk to a doctor if you would like to continue taking Pharmaton[®] Capsules. The doctor may wish to investigate your symptoms further.

If you take more Pharmaton[®] Capsules than you should

 If you overdose on this medicine you should talk to a doctor or go to a hospital straight away. Take the medicine pack with you

If a child accidentally swallows Pharmaton[®] Capsules

- Keep out of the reach and sight of children. This product contains iron which could be fatal to a child that takes too much.
- If a child accidentally swallows a capsule, talk to a doctor or go to a hospital straight away. Take the medicine pack with you.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Pharmaton[®] Capsules can cause side effects in some people, but these are usually mild.

The following side effects may happen with this medicine:

Common – affects fewer than 1 in 10 people:

- Nausea (feeling sick), vomiting (being sick)
- Headache

Uncommon – affects fewer than 1 in 100 people:

• Diarrhoea

Unknown – some side effects are recorded so rarely that their frequency is not known:

- Hypersensitivity reactions including rash and pruritus (itching)
- Severe allergic reaction (anaphylactic reaction)
- Feeling dizzy
- Stomach pains
- Insomnia

The side effects nausea, vomiting, stomach pains and diarrhoea are less likely to happen if you take the capsules with food.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance Earlsfort Terrace IRL – Dublin 2 Tel: +353 1 6764971

Fax: +353 1 6762517 Website: www.hpra.ie e-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE PHARMATON[®] CAPSULES

Do not store above 25°C. Keep the bottle tightly closed to protect from moisture. Keep out of the sight and reach of children.

Do not use Pharmaton[®] Capsules after the expiry date which is stated on the carton and bottle label after EXP. The expiry date refers to the last day of the month.

The capsules also contain the following ingredients: rapeseed oil, arachis (peanut) oil, ethyl vanillin (flavouring), hard fat, triglycerides (medium chain), lactose monohydrate and colloidal anhydrous silica.

The capsule shell contains gelatin, glycerol and iron oxide red and black (E172 - colouring).

6. FURTHER INFORMATION

What Pharmaton[®] Capsules contains

Each soft capsule contains the following active ingredients:

Active ingredient	Supplement name	Amount of supplement per capsule	RDA
Panax Ginseng extract G115 [®]	Ginseng G115 [®]	40 mg	*
Vitamin A concentrate (oily form), synthetic	Vitamin A	2667 IU	100%
Cholecalciferol concentrate (oily form)	Vitamin D	200 IU	100%
all-rac-α-Tocopheryl acetate	Vitamin E	10 mg	83%
Ascorbic acid	Vitamin C	60 mg	75%

Thiamine mononitrate	Vitamin B1	1.4 mg	127%
Riboflavin	Vitamin B2	1.6 mg	114%
Nicotinamide	Vitamin B3	18 mg	112%
Pyridoxine hydrochloride	Vitamin B6	2 mg	142%
Folic acid	Folic acid	100 mcg	50%
Cyanocobalamin	Vitamin B12	1 mcg	40%
Biotin	Vitamin B7	150 mcg	300%
Anhydrous dibasic calcium phosphate	Calcium	100 mg	12.5%
Dried ferrous sulphate	Iron	10 mg	71%
Dried magnesium sulphate	Magnesium	10 mg	2%
Zinc sulphate monohydrate	Zinc	1 mg	10%
Copper sulphate, dried	Copper	2 mg	200%
Sodium selenite	Selenium	50 mcg	91%
Lecithin	Lecithin	100 mg	*

RDA = Recommended Daily Amount

* No RDA available

Recommended Daily Allowance (RDA) refers to the amount of each vitamin and mineral that a healthy individual should consume each day in order to stay fit. During temporary periods of exhaustion, the daily intake of vitamins and minerals (and Ginseng G115[®]) from one capsule of Pharmaton[®] Capsules has been clinically proven to provide relief from tiredness and lack of vitality.

What Pharmaton[®] Capsules look like and contents of the pack

Pharmaton[®] Capsules are a dark brown opaque soft gelatin capsule. They are available in packs of 30 and 100 capsules.

Marketing Authorisation Holder:

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