Package leaflet: Information for user

Pharmaton® Capsules

Boehringer Ingelheim

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 do not show any sign of improvement.
- If a side effect occurs and gets troublesome, or seems serious, or if you experience any 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. They contain standardised Panax ginseng extract G115® Pharmaton with Vitamins A, B group, C, D, E, Nicotinamide, Folic acid, Biotin and minerals Iron, Calcium, Copper, Manganese, 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® Capsules work by enhancing mental and physical performance through the combined action of Ginseng G115®, 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 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.

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
- Tetracycline antibiotics such as tetracycline, doxycline, minocycline
- Levodopa (used to treat Parkinson’s disease)

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 these vitamins and minerals taking into account all sources including food and drinks.

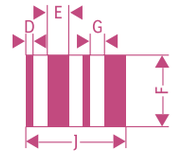
Pregnancy and breast-feeding

Pharmaton® Capsules contain Vitamin A and D. Do not take this medicine if you are pregnant, trying to get pregnant or 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 are intolerant or cannot digest lactose do not take Pharmaton® Capsules
- If you are allergic to any of the other ingredients in Pharmaton® Capsules listed in Section 6, do not take this medicine

File information		Mandatory in	
		TD	Printfile
Issue date of TD:	17.04.2014	Yes	Yes
PPM SKU:	P016275	No	Yes
PPM SKU version:	005	No	Yes
Issue date of artwork:	02.05.2014	No	Yes
Print colors:	PAN 287	No	Yes
Mat. No. Pack. Site:	4770017103-005	No	Yes
Min. font size:	8 pt		
Legend case version:	V4.0 01/OCT/2012 (please do not change or remove it)		



MASS D 0,5 mm
MASS E 1,5 mm
MASS G 1,0 mm

Example Technical information control code

Technical information					
a = Batch No.		b = Expiry date			
c = Manufacturing date		d = Price/Sample/Clinic			
Technical colors					
BI-Diecut-Legendcase		Free area		Gluepoints	

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 do not show any sign of improvement.

Adults

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

Children

Do not give these capsules to children.

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)
- Feeling dizzy
- Stomach pains

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Malta

ADR Reporting
The Medicines Authority
Post-Licensing Directorate
203 Level 3, Rue D'Argens
GŻR-1368 Gżira

Website: www.medicinesauthority.gov.mt
e-mail: postlicensing.medicinesauthority@gov.mt

5. HOW TO STORE PHARMATON® CAPSULES

Do not store above 25°C. Keep the bottle tightly closed, in a dry place.
Keep out of the sight and reach of children.
Do not take the 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.

6. FURTHER INFORMATION

What Pharmaton® Capsules contains

Each soft capsule contains the following active ingredients:

Active ingredient	Supplement Name	Amount of Supplement per capsule
Standardised Panax ginseng extract G115® Pharmaton	Ginseng G115®	40 mg
Vitamin A concentrate (oily form) synthetic	Vitamin A	800 micrograms RE
Colecalciferol	Vitamin D	200 IU
All-rac-α-Tocopheryl acetate	Vitamin E	10 mg α-TE
Ascorbic acid	Vitamin C	60 mg
Thiamine mononitrate	Vitamin B_1	1.4 mg
Riboflavin	Vitamin B_2	1.6 mg
Nicotinamide	Vitamin B_3	17.8 mg NE
Pyridoxine hydrochloride	Vitamin B_6	2 mg
Folic acid	Folic acid	100 micrograms
Cyanocobalamine	Vitamin B_{12}	1 microgram
Biotin	Vitamin B_7	150 micrograms
Calcium hydrogen phosphate, (anhydrous)	Calcium	100 mg
Dried Iron sulphate	Iron	10 mg
Manganese sulphate, monohydrate	Manganese	2.5 mg
Dried Magnesium sulphate	Magnesium	10 mg
Zinc sulphate monohydrate	Zinc	1 mg
Copper sulphate, dried	Copper	2 mg
Sodium selenite, dried	Selenium	50 micrograms
Lecithin	Lecithin	100 mg

RE = retinol equivalent, α-TE = tocopherol equivalent, NE = niacin equivalent

The capsules also contain the following inactive ingredients: rapeseed oil, arachis (peanut) oil, ethyl vanillin (flavouring), gelatin, hard fat, triglycerides (medium chain), glycerol, iron oxide red and black (E172 - colourings), lactose monohydrate, colloidal anhydrous silica, All-rac-α-tocopherol, butylated hydroxyanisol and butylated hydroxytoluene

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 /Importer responsible for batch release

The Marketing Authorisation Holder and Importer/Manufacturer responsible for batch release of Pharmaton® Capsules is:

Aldox Ltd, School Street, Tarxien, Malta.

This leaflet was revised in May 2014.

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