SUMMARY OF PRODUCT CHARACTERISTICS

NAME OF THE MEDICINAL PRODUCT: IB TONIC

Composition and Active Ingredients

I.b. Tonic is composed of the following active ingredients:

- Ferric Ammonium Citrate 200Mg
- Vitamin B1 2Mg
 Vitamin B2 1Mg

Overview

I.b. Tonic is used for <u>Iron deficiency anemia</u>, Thiamine deficiency, Neurological disorders, Heart problem, Eye disorders, Migraine headache, Hyperhomocysteinemia and other conditions. I.b. Tonic may also be used for purposes not listed in this medication guide.

I.b. Tonic contains Ferric Ammonium Citrate, Vitamin B1 and Vitamin B2 as active ingredients.

I.b. Tonic works by producing blood cells and platelets in the body; metabolizing carbohydrate thus maintains normal growth; maintaining many tissues of the body to prevent vitamin B2 deficiency;

Detailed information related to I.b. Tonic's uses, composition, dosage, side effects and reviews is listed below.

Uses

<u>l.b. Tonic</u> is used for the treatment, control, prevention, & improvement of the following diseases, conditions and symptoms:

- Iron deficiency anemia
- Thiamine deficiency
- Neurological disorders
- Heart problem
- Eye disorders
- Migraine headache
- Hyperhomocysteinemia
- I.b. Tonic may also be used for purposes not listed here.

Side-effects

The following is a list of possible side-effects that may occur from all constituting ingredients of I.b. Tonic. This is not a comprehensive list. These side-effects are possible, but do not always occur. Some of the side-effects may be rare but serious. Consult your doctor if you observe any of the following side-effects, especially if they do not go away.

- Gastrointestinal problems
- Stomach pain
- Black stools
- Restlessness
- Itching of skin
- Difficulty in swallowing
- Coughing
- Difficulty in breathing
- Sweating
- Feeling of warmth
- Mild tenderness or hardening at the injection site
- Breathing problems

- Low blood pressure
- Rashes
- Feeling sick
- Swelling of face, lips and eyelids
- Allergic reactions
- Skin irritation
- Weakness
- Swelling of lips
- Swelling of face and tongue
- Diarrhea
- I.b. Tonic may also cause side-effects not listed here.

If you notice other side-effects not listed above, contact your doctor for medical advice. You may also report side-effects to your local food and drug administration authority.

Precautions

Before using I.b. Tonic, inform your doctor about your current list of medications, over the counter products (e.g. vitamins, herbal supplements, etc.), allergies, pre-existing diseases, and current health conditions (e.g. pregnancy, upcoming surgery, etc.). Some health conditions may make you more susceptible to the side-effects of the drug. Take as directed by your doctor or follow the direction printed on the product insert. Dosage is based on your condition. Tell your doctor if your condition persists or worsens. Important counseling points are listed below.

- Breastfeeding
- Difficulty in breathing
- Hives
- Pregnant
- Pregnant, planning to become pregnant or breastfeeding

Interactions with I.b. Tonic

If you use other drugs or over the counter products at the same time, the effects of I.b. Tonic may change. This may increase your risk for side-effects or cause your drug not to work properly. Tell your doctor about all the drugs, vitamins, and herbal supplements you are using, so that you doctor can help you prevent or manage drug interactions. I.b. Tonic may interact with the following drugs and products:

- Arsenic trioxide
- Chloramphenicol
- Phenobarbital
- Probenecid
- Riboflavin
- Sodium Succinate
- Tricyclic antidepressants
- Trisenox

When not to use I.b. Tonic

Hypersensitivity to I.b. Tonic is a contraindication. In addition, I.b. Tonic should not be used if you have the following conditions:

- Allergic reactions
- Hypersensitivity

Other important Information on I.b. Tonic

Missing a dose

In case you miss a dose, use it as soon as you notice. If it is close to the time of your next dose, skip the missed dose and resume your dosing schedule. Do not use extra dose to make up for a missed dose. If you are regularly missing doses, consider setting an alarm or asking a family member to remind you. Please consult your doctor to discuss changes in your dosing schedule or a new schedule to make up for missed doses, if you have missed too many doses recently.

Overdosage of I.b. Tonic

- Do not use more than prescribed dose. Taking more <u>medication</u> will not improve your symptoms; rather they may cause poisoning or serious side-effects. If you suspect that you or anyone else who may have overdosed of <u>l.b. Tonic</u>, please go to the emergency department of the closest hospital or nursing home. Bring a medicine box, container, or label with you to help doctors with necessary information.
- Do not give your medicines to other people even if you know that they have the same <u>condition</u> or it seems that they may have similar <u>conditions</u>. This may lead to overdosage.
- Please consult your physician or pharmacist or product package for more information.

Storage of I.b. Tonic

- Store <u>medicines</u> at room temperature, away from heat and direct light. Do not freeze <u>medicines</u> unless required by package insert. Keep <u>medicines</u> away from children and pets.
- Do not flush medications down the toilet or pour them into drainage unless instructed to do so. <u>Medication</u> discarded in this manner may contaminate the environment. Please consult your pharmacist or doctor for more details on how to safely discard <u>I.b. Tonic</u>.

Expired I.b. Tonic

Taking a single dose of expired <u>I.b. Tonic</u> is unlikely to produce an adverse event. However, please
discuss with your primary health provider or pharmacist for proper advice or if you feel unwell or sick.
Expired drug may become ineffective in treating your prescribed conditions. To be on the safe side, it is
important not to use expired drugs. If you have a <u>chronic illness</u> that requires taking medicine
constantly such as heart condition, seizures, and life-threatening allergies, you are much safer keeping
in touch with your primary health care provider so that you can have a fresh supply of unexpired
medications.

1. Name of the medicinal product

IB TONIC

2. Qualitative and quantitative composition

Each 5ml contains

Ferric Ammonium Citrate 200.00mg
Thiamine Hydrochloride 2.00 mg
Riboflavin Sodium Phosphate 1.00 mg

3. Pharmaceutical form

Oral Liquid

4. Clinical particulars

4.1 Therapeutic indications

Oral prophylactic and therapeutic treatment of vitamin B complex and iron deficiency.

4.2 Posology and method of administration

Prophylactic

Adults and elderly

One teaspoonful three times daily

Therapeutic

Children

2 to 5 year, half teaspoonful two times daily

up to 12 years, one teaspoonful two times daily

Adults and elderly

Two to three 5ml spoonfuls three times daily

Or as prescribed by a doctor

4.3 Contraindications

Known sensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

No special warnings.

4.5 Interaction with other medicinal products and other forms of interaction

The pyridoxine hydrochloride may reduce the effectiveness of levodopa.

4.6 Pregnancy and lactation

Considered safe in the recommended dose.

4.7 Effects on ability to drive and use machines

None stated

4.8 Undesirable effects

None known

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard.

4.9 Overdose

Not applicable.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Ferric ammonium citrate: is used to treat iron deficiency anemia in adults with chronic kidney disease who are *not* on dialysis.

Thiamine Hydrochloride (Vit B1): A water soluble vitamin. It is a co-enzyme for carbohydrate metabolism.

Riboflavine Sodium Phosphate (Vit B2): A water soluble vitamin converted in the body to flavine mononucleotide and flavine adenine dinucleotide and then involved as co-enzymes in oxidative and reductive metabolic processes.

5.2 Pharmacokinetic properties

All the actives are water soluble vitamins. Quantities in excess of the bodies requirements are excreted either unchanged or as metabolites, mainly in the urine but to a lesser extent also in the faeces.

5.3 Preclinical safety data

None stated

6. Pharmaceutical particulars

6.1 List of excipients

Butyl Hydroxybenzoate, Disodium Edetate, Dilute Hydrochloric Acid, Ethyl Hydroxybenzoate, Methyl Hydroxybenzoate, Propyl Hydroxybenzoate, Propylene Glycol, Soluble Orange Oil Flavour, Sorbitol Solution 70% (non-crystallising), Purified Water

6.2 Incompatibilities

None known

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store between 4°C and 25°C. Protect from light.

6.5 Nature and contents of container

150ml Glass bottle.

Cap White PP28 TE CR with EPE/PE/AL/PET Wad

6.6 Special precautions for disposal and other handling

None stated

7. Marketing authorisation holder

Wallace Manufacturing Chemists Ltd.

Wallace House

51-53 Stert Street

Abingdon

Oxfordshire OX14 3JF

United Kingdom

8. Marketing authorisation number(s)

PL 0400/5049R

- 9. Date of first authorisation/renewal of the authorisation
- 5th March 1998
- 10. Date of revision of the text

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