CANTHEX CAPSULES

1. Generic Name

Alpha Lipoic Acid, Biotin, Chromium polynicotinate and Zinc Capsules.

2. Qualitative and quantitative Composition:

Each Hard Gelatin Capsule Contains:

Alpha Lipoic Acid IP (as granule form)......200 mg

Biotin IP......5 mg

Chromium Polynicotinate......200 mg

Zinc Sulphate Monohydrate IP......25 mg

The Excipient used are Microcrystalline Cellulose Powder, Croscarmellose Sodium, Collodial Silicon Dioxide, Polyplasdone, Sodium Lauryl Sulphate and Orange /White colour.

3. Dosage form and strength

Dosage form: Capsule

Strength: Alpha Lipoic Acid (200 mg), Biotin (5 mg), Chromium Polynicotinate (200 mg) and Zinc Sulphate Monohydrate (25 mg).

4. Clinical particulars

4.1 Therapeutic indication

As a Nutraceuticals it is formulated with specific ingredients to resolve dark patches on neck, armpits, knuckles and other skin folds

4.2 Posology and method of administration

Posology

As directed by physician

Method of administration

Orally

4.3 Contraindications

It is contraindicated in persons who have shown hypersensitivity to Alpha Lipoic Acid, Biotin, Chromium polynicotinate, Zinc or any of its ingredients.

4.4 Special warnings and precautions for use

Talk to your doctor before taking CANTHEX, if you:have stomach or intestinal ulcers, heart, liver or kidney disease or any other medical conditions

4.5 Drugs interactions

No data available.

4.6 Use in special populations (such as pregnant women, lactating women, paediatric patients, etc.)

<u>Pregnancy</u>

It is not known whether Canthex Capsule is safe for use during pregnancy. Hence, it is better to consult your doctor before taking this medicine.

Breast-feeding

It is not known whether Canthex Capsule is safe for use while breastfeeding. Hence, it is better to consult your doctor before taking this medicine.

Use in children

Canthex Capsule is not recommended for use in children below 18 years as the safety and efficacy data are not established.

4.7 Effects on ability to drive and use machines

CANTHEX will usually not affect your ability to drive and use machines

4.8 Undesirable effects

CANTHEX may cause nausea, vomiting, stomach upset, headache, skin rashes or other allergic reactions, although not everybody gets them.

Reporting of adverse reactions

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 any point of contact of Torrent Pharma available at: https://www.torrentpharma.com/index.php/site/info/adverse event reporting By reporting side effects, you can help provide more information on the safety of this medicine.

4.9 Overdose

No data available.

5 Pharmacological properties

5.1 Pharmacodynamic properties

NA

5.2 Pharmacokinetic properties

NA

6 Nonclinical properties

6.1 Animal Toxicology or Pharmacology

NA

7 Description

Alpha Lipoic Acid:

Alpha Lipoic Acid is 1,2-Dithiolane -3-Pentanoic acid; 1,2- Dithiolane-3-valeric acid. The empirical formula is $C_8H_{14}O_2S_2$ and its molecular weight is 206.3 g/mol. The structural formula is:

Biotin:

Biotin is 1H-Thieno [3,4-d]imidazole-4-pentanoic acid. Hexahydro-2-oxo-, [3aS-(3a α , 4 β ,6a α)]; (3aS,4S,6aR)- Hexahydro-2-oxo-1H-thieno[3,4-d]imidazole-4-valeric acid. The empirical formula is $C_{10}H_{16}N_2O_3S$ and its molecular weight is 244.3 g/mol. The structural formula is:

Chromium Polynicotinate:

Chromium Polynicotinate is chromium(3+);pyridine-3-carboxylate. The empirical formula is $C1_8H_{12}CrN_3O_6$ and its molecular weight is 418.3 g/mol. The structural formula is:

Zinc Sulphate Monohydrate:

Zinc Sulphate Monohydrate empirical formula is $ZnSO_4,H_2O$ and its molecular weight is 179.5g/mol. The structural formula is:

CANTHEX CAPSULES:

Alpha Lipoic Acid, Biotin, Chromium polynicotinate and Zinc Capsules are Orange/White coloured '0'Size hard gelatin capsule filled with yellow colour granular powder. The Excipient

used are Microcrystalline Cellulose Powder, Croscarmellose Sodium, Collodial Silicon Dioxide, Polyplasdone, Sodium Lauryl Sulphate and Orange /White colour.

8 Pharmaceutical particulars

8.1 Incompatibilities

Not applicable

8.2 Shelf-life

Do not use later than date of expiry.

8.3 Packaging information

CANTHEX CAPSULES is available in pack of 30 & 60 Capsules

8.4 Storage and handing instructions

Do not store above 30°C. Store protected from light and moisture.

Keep out of reach of children.

Appropriate overage are added to compensate the loss on storage.

9. Patient Counselling Information

Ask the patients to inform the treating physicians in case of any of the below:

- Have any allergies
- Are pregnant or plan to become pregnant
- Are breastfeeding or plan to breastfeed
- Have any serious illness
- Are taking any medicines (prescription, over-the-counter, vitamins, or herbal products)

10 Details of manufacturer

Safetab Life Science,

Plot No.: A-67 to 72,

PIPDIC Electronic Park,

Thirubuvanai, Puducherry – 605 107.

11 Details of permission or licence number with date

Mfg. Licence. No.:07 22 1907 Issued on: 11.01.2023

12. Date of revision

NA

MARKETED BY



TORRENT PHARMACEUTICALS LTD.

Torrent House, Off Ashram Road,

Ahmedabad-380 009, INDIA

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