For the use only of a Registered Medical Practitioners

Cyproheptadine Hydrochloride, Tricholine Citrate & Sorbitol Solution Syrup

PEP-ON

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1. NAME OF THE MEDICINAL PRODUCT

Cyproheptadine Hydrochloride, Tricholine Citrate & Sorbitol Solution Syrup

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains
Cyproheptadine Hydrochloride IP…….. 2 mg
Tricholine Citrate……275 mg
Sorbitol Solution (70%) IP……..……..2 g
Flavoured syrupy base……...q.s.

3. PHARMACEUTICAL FORM

Syrup for oral administration

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Pep-on Syrup is used as appetite enhancer.

4.2 Posology and Method of Administration

ORAL

Adult: 5ml tid for 15 days

4.3 Contraindications

Hypersensitivity to any of the components of the formulation.

Hypersensitivity to Pep-on Gold Syrup is a contraindication. In addition, Pep-on Syrup should not be used if you have the following conditions:

- Angle-closure glaucoma
- stenosing peptic
- Bladder neck obstruction
- Cyproheptadine and other drugs of similar chemical structure
- Elderly or debilitated patients
- Monoamine oxidase inhibitor therapy
- Newborn or premature infants

4.4 Special Warnings and Precautions for Use

Before using this drug, 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. Dosage is based on your condition. Tell your doctor if your condition persists or worsens.

Important counselling points are listed below.

- Urine retention
- Prostate hypertrophy or impassable urine pathways
- Avoid drinking alcohol as it can increase certain side effects
- Consult your doctor before taking this medicine if you are pregnant
- Do not drive or operate heavy machinery
- Do not start or continue the drug without consulting
- Do not take this medicine while you are breastfeeding
- If you are allergic to it or any of the other ingredients

Special precautions:

Patient with Cardiovascular disease including HTN and ischaemic heart disease, increased intraocular pressure, asthma or other chronic breathing disorders, thyroid dysfunction. Pregnancy.

4.5 Interaction with Other Medicinal Products and Other Forms of Interaction

May have additive effects with CNS depressants e.g. hypnotics, sedatives, tranquilizers, antianxiety agents.

Potentially Fatal: MAOIs prolong and intensify the anticholinergic effects of antihistamines.

4.6 Fertility, Pregnancy and Lactation

Either animal-reproduction studies have not demonstrated a foetal risk but there are no controlled studies in pregnant women or animal-reproduction studies have shown an adverse effect (other than a decrease in fertility) that was not confirmed in controlled studies in women in the 1st trimester (and there is no evidence of a risk in later trimesters).

4.7 Effects on Ability to Drive and Use Machines

Patient may experience drowsiness, dizziness, hypotension or a headache as side-effects when using Pep-on Syrup. The patient should not drive a vehicle if using the medicine. The patients are also advised not to drink alcohol with medicine as alcohol intensifies drowsiness side-effects. Please check for these effects on your body when using Pep-on Syrup. Always consult with your doctor for recommendations specific to your body and health conditions.

4.8 Undesirable Effects

Confusion, disturbed coordination, dizziness, excitation, euphoria, hallucinations, headache, hysteria, insomnia, irritability, nervousness, restlessness, sedation, seizure, sleepiness, tremor, vertigo, hypotension, palpitation, tachycardia, abdominal pain, anorexia, increased appetite, constipation, diarrhoea, nausea, vomiting, xerostomia, difficult urination, urinary retention, urinary frequency, blurred vision, diplopia, tinnitus, acute labyrinthitis, nasal congestion, pharyngitis, thickening bronchial secretion, paraesthesia, hepatitis, cholestasis, hepatic failure, jaundice, angioedema, photosensitivity, rash, urticaria, fatigue, chills, diaphoresis.

4.9 Overdose

Cyproheptadine

Possible symptoms and signs: Nervous System depression to stimulation, atropine-like (e.g. dry mouth, fixed, dilated pupils, flushing) and GI symptoms.

Management: Induce vomiting w/ syrup of ipecac. If unable to vomit, perform gastric lavage followed by activated charcoal. Saline cathartics may be useful for quick dilution of bowel content by osmosis. Vasopressors may be used for hypotension.

5. PHARMACOLOGICAL PROPERTIES

5.1 Mechanism of Action: Cyproheptadine is a sedating antihistamine with antimuscarinic, serotonin antagonist and calcium channel blocking properties. It competes w/ histamine for H1-receptor sites on effector cells in the gastrointestinal tract, blood vessels and respiratory tract.

5.2 Pharmacokinetic properties

Absorption: Cyproheptadine is well absorbed from the GI tract. Time to peak plasma concentration: 6-9 hr.

Metabolism: Cyproheptadine is almost completely metabolised principally to the quaternary ammonium glucuronide conjugate. Undergoes aromatic ring hydroxylation, N-demethylation and heterocyclic ring oxidation.

Excretion: Via urine as conjugates (approx 40%) and faeces (2-20%). Elimination half-life: Approx 16 hr (metabolites).

6. Non clinical properties

6.1 Animal Toxicology or Pharmacology

Carcinogenesis, Mutagenesis, Impairment of Fertility Long-term carcinogenic studies have not been done with cyproheptadine. Cyproheptadine had no effect on fertility in a two-litter study in rats or a two generation study in mice at about 10 times the human dose.

Cyproheptadine did not produce chromosome damage in human lymphocytes or fibroblasts in vitro; high doses (10-4M) were cytotoxic. Cyproheptadine did not have any mutagenic effect in the Ames microbial mutagen test; concentrations of above 500 mcg/plate inhibited bacterial growth

7. Description:

A light brown coloured clear syrupy liquid having characteristic flavour.

8. Pharmaceutical Particulars

8.1 Incompatibities:

NA.

8.2 Shelf-life

30 Months

8.3 Packaging information:

200 ml in bottle.

8.4 Storage and handling instructions:

Store protected from light at a temperature not exceeding 30°C.

9. Patient Counselling Information

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. What Pep-on syrup is and what it is used for
2. What you need to know before you taking Pep-on syrup
3. How to take Pep-on syrup
4. Possible side effects
5. How to store Pep-on syrup

What Pep-on is and what it is used for?

Pep-on Syrup is an appetite enhancer i.e., it stimulates appetite.

What you need to know before you take Pep-on syrup

- **Do not take Pep-on syrup**

If you are allergic to any of the other ingredients of this medicine

- **Warnings and precautions**

Before using this drug, 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.).

Do not exceed the recommended dose. If symptoms persist, consult your doctor.

- **Are there any effects on Driving?**

You may experience drowsiness, dizziness, hypotension or a headache as side-effects when using Pep-on Syrup. You should not drive a vehicle if using the medicine. You are also advised not to drink alcohol with medicine as alcohol intensifies drowsiness side-effects. Always consult with your doctor for recommendations specific to your body and health conditions

- **Are there any pregnancy warnings?**

This medicine does not cause any harm to the fetus, but there is no scientific evidence to certify it. Hence, it is best to consult a doctor before consuming it during pregnancy. It is best to be administered orally.

- **Is it habit forming?**

No habit forming tendencies were reported.

- **Are there any breast-feeding warnings?**

This medicine is not recommended for use in women who are breast-feeding as it can cause side effects for the baby. Consult your doctor before taking this medication.

How to take Pep-on syrup

Take this medicine in the dose and duration as advised by your doctor. Check the label for directions before use. Measure it with a measuring cup and take it by mouth. Shake well before use. It may be taken with or without food, but it is better to take it at a fixed time.

If you take more Pep-on syrup than you should

Contact your doctor immediately if an overdose is suspected. Symptoms of overdose may include dizziness, restlessness, and confusion. Supportive measures like gastric lavage might be initiated based on the severity of symptoms.

If you forget to take Pep-on syrup

Take the missed dose as soon as you remember. If it is almost time for the next scheduled dose, then the missed dose can be skipped.

Possible side effects

Confusion,
dizziness,
hallucinations,
headache,
irritability,
nervousness,
restlessness,
sleepiness,
tremor,
vertigo,
Increased heart rate

How to store Pep-on syrup

Do not use this medicine after the expiry date, which is stated on the carton and the blisters after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects to pvglobal@alkem.com. By reporting side effects you can help provide more information on the safety of this medicine

10. Details of manufacturer:

Made in India by:

ALKEM

ALKEM LABORATORIES LTD.
At: Village-Thana, Tehsil-Baddi,
Distt.-Solan,
Himachal Pradesh-173 205.
H.O.: ALKEM HOUSE
Senapati Bapat Marg,
Lower Parel, Mumbai-400 013.
To report a product query & adverse drug event,
Please reach us at-pvglobal@alkem.com

11. Details of permission or license number with date:

M.L.No. L/MNB/05/103 dated 14/06/2005 valid till 13/06/2025.

12. Date of Revision:

30/10/2020.