Patient Information Leaflet

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 is HERPECARE and what it is used for
2. What you need to know before you take HERPECARE.
3. How to take HERPECARE.
4. Possible side effects
5. How to store HERPECARE.
6. Contents of the pack and other information

1. What is HERPECARE and what it is used for

HERPECARE contains Cyproheptadine and cyproheptadine is a prescription medicine. Cyproheptadine may be used alone or with other medications.

Cyproheptadine belongs to a class of drugs called Antihistamines, 1st Generation.

It is not known if Cyproheptadine is safe and effective in children younger than 2 years.

2. What you need to know before you take HERPECARE.

Warnings

This medication contains cyproheptadine. Do not take it if you are allergic to cyproheptadine or any ingredients contained in this drug.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Centre immediately.

Contraindications

- Documented hypersensitivity

- Premature infants and neonates
- Nursing women
- Concomitant monoamine oxidase inhibitor therapy
- Narrow-angle glaucoma
- Stenosing peptic ulcer, pyloroduodenal obstruction
- Symptomatic prostatic hypertrophy
- Bladder neck obstruction
- Elderly, debilitated patient

Effects of Drug Abuse

- None

Short-Term Effects

- May cause central nervous system (CNS) depression, which may impair mental abilities; use caution when operating heavy machinery.
- Antihistamines may cause excitation in young children.

Long-Term Effects

- Risk of potentially fatal and irreversible interstitial pulmonary fibrosis if given over prolonged periods.

Cautions

- Elimination reduced renal insufficiency.
- Use with caution in cardiovascular disease, including high blood pressure (hypertension).
- Elderly patients: Avoid use in the elderly because of the high incidence of anticholinergic effects; may exacerbate existing lower urinary conditions or benign prostatic hyperplasia; if used, administer at the low end of the dosage range.
- May cause central nervous system (CNS) depression, which may impair mental abilities; use caution when operating heavy machinery.
- Use caution in cardiovascular disease, including hypertension and ischemic heart disease.

- Use with caution in patients with increased intraocular pressure, history of asthma or other chronic breathing disorders, or thyroid dysfunction.
- Non-anticholinergic antihistamines should be considered first for the treatment of allergic reactions in the elderly (Beers criteria).
- Antihistamines may cause excitation in young children.

Pregnancy and Lactation

- Cyproheptadine may be acceptable for use during pregnancy. Either animal studies show no risk but human studies are not available or animal studies showed minor risks and human studies were done and showed no risk.
- Cyproheptadine excretion in milk is unknown; its use is contraindicated while breastfeeding.

3. How to take HERPECARE

Dosages of Cyproheptadine:

Adult and Pediatric Dosage Forms and Strengths

Oral solution

2 mg/5 mL

Dosage Considerations – Should be Given as Follows

Although intended primarily for administration to children, the syrup is also used for administration to adults who cannot swallow tablets.

- Adults: 4 mg orally every 8 hours initially; maintenance: 4-20 mg/day, up to 32 mg/day divided every 8 hours between some patients; not to exceed 0.5 mg/kg/day
- Children under 2 years old: Safety and efficacy not established
- Children 2-6 years old: 2 mg orally every 8-12 hours; not to exceed 12 mg/day
- Children 7-14 years old: 4 mg orally every 8-12 hours; not to exceed 16 mg/day
- Alternatively, a total daily dose of 0.25 mg/kg or 8 mg/m²

Dosing Modifications

- Non-anticholinergic antihistamines should be considered first when treating allergic reactions (Beers Criteria)

- Advanced age is associated with reduced clearance and greater risk of confusion, dry mouth, constipation, and other anticholinergic effects and toxicity; use the lower end of dosage range (4 mg orally every 12 hours) for elderly patients, or administer less frequently
- Renal impairment: Elimination is reduced in renal insufficiency; administer lower doses, and monitor closely

Dosing Modifications

- Hepatic impairment: Give 75% of normal dose if transaminase levels are greater than 3 times the upper limit of normal (ULN) or bilirubin is 3.1-5 mg/dL
- Renal impairment: CrCl less than 10 mL/minute, give 75% of normal dose; CrCl greater than 10 mL/minute, give full dose

4. Possible side effects

Common side effects of cyproheptadine include:

- Abnormal facial movements (dyskinesia)
- Acute labyrinthitis
- Blurred vision
- Central nervous system (CNS) depression
- Chills
- Cholestasis
- Constipation
- Delirium
- Diarrhea
- Disturbed coordination/loss of coordination
- Dizziness
- Double vision
- Dry mouth, nose, and throat
- Early menses
- ECG changes (e.g., widened QRS)
- Eczema
- Euphoria

- Faintness
- Headache
- Hepatitis
- High blood pressure (hypertension)
- Impotence
- Increased sweating
- Increased urination
- Irritability
- Itching
- Lack of energy
- Liver failure
- Liver function abnormality
- Loss of appetite
- Low blood pressure (hypotension)
- Nausea
- Nervousness
- Numbness and tingling
- Palpitations
- Redness on exposed skin
- Restlessness or excitability (especially in children)
- Ringing in the ears (tinnitus)
- Sedation ranging from mild drowsiness to deep sleep (most frequent)
- Seizures
- Skin inflammation
- Skin rash
- Sleep problems (insomnia)
- Spinning sensation (vertigo)
- Stuffy nose
- Thickening of mucus in the nose/throat
- Tightness of chest
- Tired feeling

- Toxic psychosis
- Upset stomach
- Urinary retention
- Visual disturbances
- Vomiting
- Weakness
- Weight gain
- Wheezing
- Yellowing skin and eyes (jaundice) (rare)

Serious side effects of cyproheptadine include:

- Mental/mood changes (such as restlessness, confusion, hallucinations)
- Shaking (tremors)
- Difficult or painful urinating
- Fast/irregular heartbeats (arrhythmias) (e.g., extrasystole, heart block)

This document does not contain all possible side effects and others may occur. Check with your physician for additional information about side effects.

6. Contents of the pack and other information

What HERPECARE contains:

The active substance in HERPECARE is Cyproheptadine Hydrochloride Oral Solution.
HERPECARE is Brown coloured flavoured syrupy liquid.
The other ingredients are: Propylene Glycol USP, Sugar BP, Methyl Paraben BP, Propyl Paraben BP, Aspartame BP, Citric Acid Monohydrate BP, Flavour Mix Fruit IH, Calour Cammel IH, Purified water BP.

What HERPECARE looks like and contents of the pack

HERPECARE is Brown coloured flavoured syrupy liquid filled in 100 ml amber colour PET bottle sealed with plain golden colour pp cap.

Marketing Authorisation Holder and Manufacturer

Marketing Authorization Holder

M/s Uttaranchal Biotech Limited

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