

Biperiden HCI

Akidin

2 mg Tablet ANTI-PARKINSONISM

FORMULATION:

Each tablet contains:

Biperiden HCI, USP. 2 mg

PRODUCT DESCRIPTION:

Biperiden HCI (Akidin) 2 mg is a white, oval-shaped tablet with score on one side and plain on the other.

INDICATIONS:

Biperiden HCI (Akidin) is used in the management of Parkinsonian syndromes, including rigidity and tremor. It is also used for extrapyramidal symptoms such as dyskinesia, akathisia and parkinsonism caused by neuroleptics and similarly acting drugs.

CLINICAL PHARMACOLOGY:

Pharmacodynamics:

Biperiden HCI (Akidin) is a centrally acting anticholinergic drug responsible for its therapeutic effect and has weak peripheral effects compared to Atropine.

Pharmacokinetics:

Biperiden is readily absorbed from the gastrointestinal tract. It undergoes extensive first-pass metabolism, hence its bioavailability is only 30%. Its elimination half-life is about 20 hours.

DOSAGE AND ADMINISTRATION:

Treatment of Biperiden HCI (Akidin) is usually given with small incremental doses, depending on the therapeutic effect and side effects. Cautious dosing is necessary in elderly patients, especially those with symptoms of organic brain disease. There have been limited experience in pediatric use of the drug product.

Parkinsonism:

Adults: The initial dose is 1 mg (1/2 tablet) in two divided dose. The dose may be adjusted to 2 mg (1 tablet) daily up to a maximum dose of 16 mg (8 tablets) daily. The total daily dose must be given evenly throughout the day.

Drug-induced Extrapyramidal Symptoms

Adults: 1 to 4 mg may be given to patient in one to four divided doses concomitantly given with neuroleptics depending on the severity of the symptoms.

Children 3 – 15 years of age: 1 to 2 mg may be given to patient in one to three divided doses.

Or as prescribed by a physician.

CONTRAINDICATIONS:

This product is contraindicated in patients with prostatic enlargement, in whom it may lead to urinary retention, those with paralytic ileus or pyloric stenosis and ulcerative colitis. It should not also be given to patients with narrow-angle glaucoma and myasthenia gravis. It is contraindicated to patients with diseases that may lead to perilous tachycardia.

WARNINGS AND PRECAUTIONS:

Biperiden HCI (Akidin) should be used with caution in children and elderly, and in patients with diarrhea, thyrotoxicosis, heart failure, tachycardia, prostatic adenoma, and to those with high risks of convulsions.

Increases in dosage and transfer to other forms of treatment should be gradual and should not be withdrawn abruptly.

PREGNANCY AND LACTATION:

There are no controlled studies in human and animals regarding pregnancy and lactation, thus, the use of Biperiden HCl (Akidin) is not recommended during pregnancy unless necessary and advised by a physician.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES:

Biperiden HCI (Akidin) may cause drowsiness; thus, patients are not recommended to drive or use machineries.

ADVERSE FEFECTS:

Psychiatric disorders: anxiety, euphoric mood, agitation, confusion, delirium, and hallucinations.

Nervous System disorders: dizziness, fatigue, ataxia, memory impairment, and dyskinesia.

Eve disorders: mydriasis, cycloplegia, photophobia,

Skin disorder: dryness of skin

Immune System disorder: hypersensitivity
Cardiac disorders: tachycardia, bradycardia
Gastrointestinal disorders: constipation, dry mouth
Renal and Urinary disorders: urinary retention

"For suspected adverse drug reaction, report to FDA: www.fda.gov.ph.

Seek medical attention immediately at first sign of any adverse drug reaction."

DRUG INTERACTIONS:

Concomitant use of Biperiden HCI (Akidin) with other anticholinergic psychotropic drugs, antihistamines, antiparkinsonian drugs and antispasmodics increases the CNS and peripheral side effects. Anticholinergic effect is enhanced when it is administered with Quinidine.

Concomitant use of Levodopa with Biperiden HCI (Akidin) may exacerbate parkinsonian symptoms including dyskinesia. Administration of neuroleptic drugs with Biperiden HCI (Akidin) may intensify tardive dyskinesia. Parkinsonian symptoms in the presence of existing tardive dyskinesia are occasionally so serious as to mandate continued anticholinergic therapy.

Anticholinergics, such as Biperiden HCI (Akidin), reduce the effect of Metoclopramide and compounds with similar activity on the gastrointestinal tract.

Alcohol intake should be avoided when taking Biperiden HCl (Akidin).

OVERDOSE AND TREATMENT:

Anticholinergic effects are the symptoms of overdosage of Biperiden HCI (Akidin). These include dryness of mucous membranes, flushing, mydriasis, tachycardia, constipation, urinary retention, increased temperature, excitation, confusion, and hallucinations. In severe cases of overdosage, cardiac and respiratory depression may occur.

Gastric lavage and emesis should be considered. Acetylcholinesterase inhibitors are the recommended antidote. Vital signs should be closely monitored and appropriate supportive measures should be taken. Artificial ventilation, reduction of fever, and application of bladder emptying catheter may be necessary. In the event of cardiac depression, a cardiac stimulant drug, such as Dobutamine, may be considered.

CAUTION:

Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

STORAGE CONDITION:

Store at temperatures not exceeding 30°C.

Keep out of reach of children.

AVAILABILITY:

Registration No.: DRP-7715

Date of First Authorization: April 2016 / Renewal of Authorization: March 2019

Date of Revision: September 2018

Manufactured for: MEDCHOICE CNS PHARMA CORPORATION

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