Summary of Product Characteristics

1. Name of the medicinal product

Perkinil 5 Tablet

2. Qualitative and quantitative composition

Each Tablet contains Procyclidine Hydrochloride 5 mg.

Excipients with known effect

Lactose 44.740 mg
Sodium Methyl Hydroxybenzoate 0.04 mg
Sodium Propyl Hydroxybenzoate 0.02 mg
For a full list of excipients, see section 6.1

3. Pharmaceutical form

Tablet. A white round shaped slightly biconvex tablet having break line on one side and plain on other side.

4. Clinical particulars

4.1 Therapeutic indications

Perkinil is used for the adjunctive treatment of all forms of parkinsonian syndrome. It is mainly used for the symptomatic treatment of idiopathic (paralysis agitants), postencephalitic and arteriosclerotic parkinsonian. It is used to control troublesome extrapyramidal symptoms including pseudoparkinsonian, acute dystonic reactions and akathisia induced by neuroleptic drugs such as phenothiazine derivatives.

4.2 Posology and method of administration

Perkinil tablet is administered orally, preferably after meals. Parkinsonism: Initially 2.5 mg 3 times a day, then 5 mg 3 times a day and occasionally 5 mg at bed time. The dosage being adjusted as tolerated or until the total daily dose reaches 20 to 30 mg divided into 3 to 4 doses. Drug induced extrapyramidal symptom: Initially 2.5 mg 3 times a day. The dosage being increased by 2.5 mg increment per day as needed and tolerated.

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4.3 Contraindications

It should be given with caution in children and geriatric patients. It is advisable to be cautious in giving Procyclidine to patients with diarrhoea and cardiovascular disease, glaucoma, urinary retention, hepatic or renal impairment.

4.4 Special warnings and precautions for use

Since treatment is to be continued for an indefinite period, the patient should be carefully supervised over the long term. As with all anticholinergics the benefit/risk ratio should be assessed when prescribing procyclidine in patients with existing angle-closure (narrow angle) glaucoma or those considered to be predisposed to glaucoma. Cautious prescribing is also indicated in patients predisposed to obstructive disease of the gastrointestinal tract, those with urinary symptoms associated with prostatic hypertrophy and those with hypertension and cardiac disorders.

Tardive dyskinesia

In a proportion of patients undergoing neuroleptic treatment, tardive dyskinesias will occur. While anticholinergic agents do not cause this syndrome, when given in combination with neuroleptics, they may exacerbate the symptoms of tardive dyskinesia or reduce the threshold at which dyskinesias appear in patients predisposed to this abnormality. In such individual's subsequent adjustment of neuroleptic therapy or reduction in anticholinergic treatment should be considered.

Patients with mental health conditions

Patients with mental health conditions occasionally experience a precipitation of a psychotic episode when procyclidine is administered for the treatment of the extrapyramidal side effects of neuroleptics.

Older people

Older people, especially those on high doses of anticholinergics may be more susceptible to the adverse events associated with such therapy (see section 4.8). Specifically, older people may be particularly vulnerable to central nervous system disturbances such as confusion, impairment of cognitive function and memory, disorientation and hallucinations. These effects are usually reversible on reduction or discontinuation of anticholinergic therapy.

Impaired renal and hepatic function

There is no specific information available concerning the use of procyclidine hydrochloride in patients with impaired renal or hepatic function. However, since procyclidine is metabolised in the liver and excreted via the urine, care should be exercised when administering procyclidine to patients with impairment of renal or hepatic function.

Abrupt withdrawal

Procyclidine should not be withdrawn abruptly as rebound parkinsonian symptoms may occur. Abuse Procyclidine, along with other anticholinergic drugs, has the potential to be abused. Although the cases of abuse are rare, physicians should exercise caution in prescribing procyclidine to patients with symptoms that may not be genuine.

Lactose intolerance
Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Sodium Methyl Hydroxybenzoate and Sodium Propyl Hydroxybenzoate may cause allergic reactions (possibly delayed).

4.5 Interaction with other medicinal products and other forms of interaction
Monoamine oxidase inhibitors or drugs with anticholinergic properties, such as amantadine, memantine, antihistamines, phenothiazines, tricyclic and related antidepressants, clozapine, disopyramide and nefopam may increase the anticholinergic action of procyclidine.

The use of drugs with cholinergic properties, such as tacrine, may reduce the therapeutic response to procyclidine. Furthermore, drugs with anticholinergic properties may antagonise the effect of parasympathomimetic agents.

The concomitant use of procyclidine with some neuroleptics for the treatment of extrapyramidal symptoms has been associated with a reduction in neuroleptic plasma concentrations. However, this reduction is unlikely to be associated with a significant reduction in clinical effect.

Drugs with anticholinergic properties may decrease salivation causing dry mouth and, in theory, may reduce the absorption and therefore the therapeutic effect of sublingual or buccal nitrate tablets.

Anticholinergics, including procyclidine, may reduce the efficacy of levodopa by increasing gastric emptying time, resulting in enhanced gastric degradation.

The effect of anticholinergics such as procyclidine may antagonise the gastrointestinal effects of cisapride, domperidone and metoclopramide.

Procyclidine may potentiate the vagolytic effects of quinidine. Anticholinergics may reduce the absorption of ketoconazole.

Exposure to high environmental temperature and humidity in association with a phenothiazine/anticholinergic drug regimen has rarely resulted in hyperpyrexia.

Daily administration of paroxetine increases significantly the plasma levels of procyclidine. If anticholinergic effects are seen, the dose of procyclidine should be reduced.

4.6 Fertility, pregnancy and lactation
The safe use of this drug in pregnancy, lactation or in women of childbearing age requires that the potential benefits be weighed against the possible hazards to the mother and child.

4.7 Effects on ability to drive and use machines
Adverse events of a neurological character such as blurred vision, dizziness, confusion and disorientation have been reported with procyclidine. Therefore, if affected, patients should be advised not to drive or operate machinery.

4.8 Undesirable effects
At usual dosage levels dryness of the mouth is generally the only adverse effect. Mydriasis, blurred vision and adverse G.I. effects (nausea, vomiting, epigastric distress, constipation) occur occasionally. An allergic reaction (e.g. rash) or muscular weakness may occasionally occur. High doses may cause vertigo and possibly confusion and hallucination. Adverse effect may usually be minimized by adjustment of dosage and administration after meal.

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 pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org/

4.9 Overdose
Symptoms and signs:
Symptoms of overdosage include stimulant effects such as agitation, restlessness and confusion with severe sleeplessness lasting up to 24 hours or more. Visual and auditory hallucinations have been reported. Most subjects are euphoric but the occasional patient may be anxious and aggressive. The pupils are widely dilated and unreactive to light. In recorded cases, the disorientation has lasted 1 to 4 days and ended in a recuperative sleep. Signs of CNS depression include somnolence, reduced consciousness and occasionally coma have been reported usually following very large overdoses. Tachycardia has also been reported in associated with cases of procyclidine overdose.

Treatment:

If procyclidine has been ingested within the previous hour or two (or possibly longer in view of its likely effects on gastric motility) then activated charcoal should be used to reduce absorption. Gastric lavage should only be considered if clinically appropriate. Other active measures such as the use of cholinergic agents or haemodialysis are extremely unlikely to be of clinical value although if convulsions occur, they should be controlled by injections of diazepam.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Anticholinergic agents; tertiary amines,
ATC Code: N04AA04

Mechanism of action Perkinil (Procyclidine Hydrochloride) is an antimuscarinic antiparkinsonian agent of relatively low toxicity. It is a synthetic tertiary amine. This drug exerts their antiparkinsonian effect by correcting the relative cholinergic excess which is thought to occur in parkinsonian as a result of dopamine deficiency. It is absorbed from G.I. tract and disappears rapidly from the tissues.

5.2 Pharmacokinetic properties

Absorption

Procyclidine is adequately absorbed from the gastrointestinal tract with a bioavailability of 75% and disappears rapidly from the tissue.

Biotransformation

No detailed information is available on the metabolic fate of procyclidine but very little of the parent compound is excreted in the urine unchanged. When given orally about one fifth of the dose is known to be metabolised in the liver, principally by cytochrome P450 and then conjugated with glucuronic acid. This conjugate has been detected in the urine.

Elimination

The relatively low clearance of 68 ml/min represents a predominantly metabolic change with a small first pass effect. The mean plasma elimination half-life after oral administration of procyclidine is approximately 12 hours.

5.3 Preclinical safety data

Fertility

A three-generation study in rats dosed at 40 mg/kg/day via the diet before and during pregnancy showed only that the number of viable pups was slightly decreased from the second mating. No other parameters were affected.

Teratogenicity

No teratogenic effects were seen in rats dosed subcutaneously with 10, 30 or 100 mg/kg/day on days 8 to 16 of pregnancy. Maternal bodyweight gain was

reduced at doses of 30 or 100 mg/kg/day, and a 10% reduction in foetal weight was seen at 100 mg/kg/day

Mutagenicity
Procyclidine was not genotoxic in in vitro bacterial mutation or mouse lymphoma assays.

Carcinogenicity
There are no data on the carcinogenic potential of procyclidine hydrochloride.

6. Pharmaceutical particulars

6.1 List of excipients

Lactose
Magnesium Stearate
Sodium Methyl Hydroxybenzoate
Microcrystalline Cellulose (PH 101)
Sodium Propyl Hydroxybenzoate Maize Starch

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 Years (36 Months)

6.4 Special precautions for storage

Store below 30°C. Protect from light and moisture. Keep all medicines out of reach of children

6.5 Nature and contents of container

Each box contains 100 tablets in blister pack.

6.6 Special precautions for disposal and other handling

No special requirements.

7. Marketing authorisation holder

Square Pharmaceuticals PLC.
Square Centre 48, Mohakhali C.A, Dhaka – 1212, Bangladesh.

8. Marketing authorisation number(s)

H2020/CTD7254/1106ER

9. Date of first authorisation/renewal of the authorisation

Date of first authorisation: 04 August 2020
Date of latest renewal: 17 July 2026

10. Date of revision of the text

17/06/2026