Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Dekinet

Tablet

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 2 mg of biperiden hydrochloride.

Excipients with known effect: Each tablet contains about 38 mg of lactose.
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet
Almost white scored tablet, marked D/2.
The tablet can be divided into equal doses.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

All types of Parkinson's disease.

4.2 Posology and method of administration

Posology

Parkinsonism
Dosage should be individualized. Begin with 1/2 a tablet twice daily, and gradually increase to 1 tablet, 3-4 times daily. Then decrease continuously to the lowest dosage regimen which adequately controls the symptoms.

Drug-induced Extrapyramidal Symptoms
The oral dosage is 1 tablet, 1-3 times daily.

Special populations

Elderly
Elderly patients, particularly those with cerebral lesions of a vascular or degenerative nature, may exhibit increased sensitivity even to therapeutic doses of the drug. Cautious dosing is recommended. Chronic use may predispose geriatric patients to glaucoma.

Paediatric population
Safety and effectiveness of use in children have not been established.

Method of administration
Oral use.

Dekinet should be taken with a small amount of food to avoid gastric irritation.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

Dekinet is contra-indicated in the presence of untreated narrow-angle glaucoma, mechanical stenoses in the gastrointestinal tract, paralytic ileus, megacolon, prostatic adenoma and diseases that can lead to perilous tachycardia.

4.4 Special warnings and precautions for use

Dekinet should only be used with caution in the elderly, and in patients with thyrotoxicosis, cardiac failure, tachycardia, prostatic adenoma or patients who show an increased tendency to convulsions.

Central excitation effects are frequently seen in patients with symptoms of a cerebral deficiency and can necessitate a decrease in the dosage (see Sections 4.2, 4.8). There have been reports of temporarily reduced REM sleep (sleeping phase with rapid eye movements), characterised by an increase in the time needed to reach this stage and a percentage decrease in the length of this phase in the total sleep (see Section 4.8).

The dose should be gradually changed not abruptly; the treatment should be initiated or discontinued gradually.

Excipients
This medicine contains lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interactions

The administration of Dekinet in combination with other anticholinergic, psychotropic drugs, antihistamines, antiparkinsonian drugs and antispasmodics can potentiate the CNS and peripheral side effects. The concomitant intake of quinidine may potentiate the anticholinergic effect (especially AV conduction).

The concurrent administration of levodopa and Dekinet may potentiate dyskinesia. Generalised choreic movements have been reported in Parkinson's disease following concurrent administration of carbidopa/levodopa and Dekinet (biperiden). Tardive dyskinesia induced by neuroleptics may be intensified by Dekinet. Parkinsonian symptoms in the presence of existing tardive dyskinesia are occasionally so serious as to mandate continued anticholinergic therapy.

The effect of metoclopramide and compounds with similar activity on the gastrointestinal tract is attenuated by anticholinergics such as Dekinet.

As with all other drugs acting on the central nervous system, the consumption of alcohol should be avoided under Dekinet therapy.

4.6 Fertility, pregnancy and lactation

Dekinet should only be used during pregnancy or lactation if considered essential by the physician. There is no information available on animal reproductive studies and no reports of use during pregnancy or lactation in human.

4.7 Effects on ability to drive and use machines

Dekinet may cause drowsiness. Patients being treated should not drive or operate machinery unless it has been shown not to affect physical or mental ability.

4.8 Undesirable effects

Side-effects may occur particularly at the beginning of treatment and if the dosage is increased too quickly (see Section 4.2). Due to the unknown number of users, the percentage frequency of spontaneously recorded side-effects cannot be determined exactly.

The following frequencies are used as the basis in the evaluation of side-effects:
Very common (≥1/10)
Common (≥1/100 to <1/10)
Uncommon (≥1/1,000 to <1/100)
Rare (≥1/10,000 to <1/1,000)
Very rare (<1/10,000)
Not known (cannot be estimated from the available data)

Infections and infestations
Not known: Parotitis.

Immune system disorders
Very rare: Hypersensitivity.

Psychiatric disorders
Rare: In higher doses excitement, agitation, fear, confusion, delirious syndromes, hallucinations, sleeplessness.
Central excitation effects are frequently seen in patients with symptoms of a cerebral deficiency and can necessitate a decrease in the dosage.
There have been reports of temporarily reduced REM sleep (sleeping phase with rapid eye movements), characterised by an increase in the time needed to reach this stage and a percentage decrease in the length of this phase in the total sleep.
Very rare: Nervousness, euphoria.

Nervous system disorders
Rare: Fatigue, dizziness and disturbance of memory.
Very rare: Headache, dyskinesia, ataxia and speaking disorder, increased disposition to cerebral seizures and convulsions.

Eye disorders
Very rare: Disturbance of accommodation, mydriasis, and photosensitivity. Closed-angle glaucoma might occur (controlling of intraocular pressure).

Cardiac disorders
Rare: Tachycardia
Very rare: Bradycardia. A fall in blood pressure may occur following parenteral administration.

Gastrointestinal disorders
Rare: Dryness of mouth, nausea, gastric disorder.
Very rare: Constipation

Skin and subcutaneous tissue disorders
Very rare: Reduced perspiration, allergic rash.

Musculoskeletal and connective tissue disorders
Rare: Muscle twitching.

Renal and urinary disorders
Very rare: Voiding disorders, especially in patients with prostate adenoma (dose reduction), more seldom: urinary retention.

General disorders and administration site conditions
Rare: Drowsiness.

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. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form https://sideeffects.health.gov.il

4.9 Overdose

Symptoms:

The symptoms of overdose are anticholinergic effects such as mydriasis, dryness of mucous membranes, flushing, rise in heart rate, reduction of bowel motility, reduction in ureter and bladder tone, increased temperature, excitation, confusion, clouding of consciousness and/or hallucinations. In severe overdose, cardiac and respiratory depression may occur.

Treatment:

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

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Anti-parkinson drugs, anticholinergic agents, biperiden.
ATC code: N04AA02. Tertiary amines.
Dekinet is an anticholinergic agent with a marked effect on the central nervous system which is important for its therapeutic application and, unlike atropine, has weak peripheral vegetative effects.

5.2 Pharmacokinetic properties

In a 15-day pharmacokinetic study, Richens et al (1988) measured the following parameters in young healthy volunteers and elderly male patients:

	Study day 1		Study day 15	
	Young Volunteers	Elderly Patients	Young Volunteers	Elderly Patients
MEANS				
Cmax (ng/ml)	4.34	7.24	2.46	4.20
tmax (h)	0.9	1.6	0.8	1.6
$t_{1/2}$ (h)	14.2	30.2	24.5	38.5
AUC (ng/ml)	28.6	78.7	20.9	98.8

5.3 Preclinical safety data

None.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Corn starch, lactose, microcrystalline cellulose, calcium phosphate dibasic dihydrate, povidone 25, talc micronized, magnesium stearate.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

Blister packs. Boxes of 30 tablets.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 REGISTRATION HOLDER

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Revised in February 2022 according to MOHs guidelines.