

Prescription-based Medicine	
Class No.	119


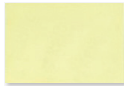


Newfezil Oral Dissolve Film

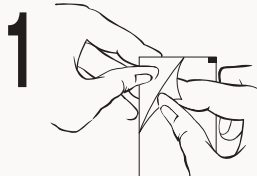
Newfezil ODF 10mg / 20mg

(Donepezil Hydrochloride)

● Drug Information

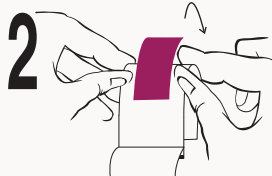
Product Name	Newfezil Oral Dissolve Film 5mg	Newfezil Oral Dissolve Film 10mg
Main Ingredient & Content	Donepezil Hydrochloride (Separate Provision) 5mg	Donepezil Hydrochloride (Separate Provision) 10mg
Shape	 Light pink rectangular oral dissolve film	 Light yellow rectangular oral dissolve film
Effectiveness	Treating symptoms of Alzheimer type dementia	
Usage & Dose	<p>Adult : Administer 5mg of Donepezil Hydrochloride once a day before sleeping at night. As the donepezil concentration is reached to its normal state at the 15th day after its administration and the frequency of adverse events may be influenced by the medicine's quantity increase speed, so the dose of 5mg donepezil should be administered for 4~6 weeks. After evaluating the medicine's clinical responses for this period, its dose can be increased up to 10mg. In case of increasing the dose to 10mg/day, carefully administer this medicine with concerning any GI(gastrointestinal) adverse event. The maximum dose of this medicine is 10mg.</p> <p>When the administration of this medicine is stopped, then its therapeutic effects are slowly reduced, and there is not any rebound effect resulting from the sudden stop of medicine's administration. This medicine is a type of oral dissolve film, so can be taken with melting it on the tongue without water.</p> <p>Women Patients over 85-years low and underweight : For these patients, there are a lot of adverse events, so it needs to carefully monitor them. For old, underweighted female patients, the dose/day should not be exceeded to 5mg.</p> <p>Children: This medicine has never been used on children.</p>	
Precautions	<p>1. Do not use this medicine on the following patients.</p> <ol style="list-style-type: none"> 1) Patients hypersensitive to the donepezil hydrochloride, the piperidine derivatives or an ingredient(s) of this medicine. 2) Pregnant women or women having the possibility to get pregnant and breast-feeding women. <p>2. Carefully administer this medicine to following patients</p> <ol style="list-style-type: none"> 1) Patients having heart diseases like the Sick Sinus Syndrome, the Intra-atrial or Intra-ventricular Conduction Disturbance. (Donepezil is possible to cause the bradycardia and arrhythmia.) 2) Patients administering a NSAID (non-steroid anti-inflammatory drug) or patients having a GI disease history. (Donepezil may exacerbate the patient's GI ulcer by accelerating the secretion of gastric acid and the movement of digestive duct.) 3) Patients having the asthma and obstructive pulmonary disease history (Donepezil may exacerbate the patient's symptoms by contracting of smooth muscle in bronchial tubes and accelerating the secretion of bronchial mucus.) 4) Patients having the EPS (extra pyramidal syndrome) (ex. Parkinson's disease, Parkinson's syndrome) (Donepezil is possible to trigger or exacerbate the disease symptoms by accelerating the activity of Cholinergic nerves in corpus striatum.) 	
How to Store	Store it in an airtight container in room temperature (1~30°C) away from moisture and sunlight.	
Expiration Date	36 months from the open date	
Packing Unit	1 Strips / 30 Strips / 60 Strips / 90 Strips	

● How to Take




1

Open the package.



2

Roll down the film strip.



3

Place it on tongue and let it dissolve in the mouth.

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