

# DREWELL® EX

Class ② OTC drug

**Sleep aid medication** for relief of the following symptoms due to temporary sleeplessness: Difficulty in falling asleep and/or shallow sleep

● For temporary sleeplessness in persons in any of the following conditions:

- Unable to sleep due to mental or emotional stress
- Unable to fall asleep because of increased nervousness despite fatigue
- Nocturnal awakening due to worrying
- Unable to fall asleep when the sleep rhythm has been disrupted by an irregular daily life



● Characteristics of DREWELL EX

- The active ingredient of DREWELL EX, "diphenhydramine hydrochloride," has excellent effects against symptoms such as difficulty in falling asleep and shallow sleep.
- DREWELL EX is a capsule-type formulation containing a liquid. One capsule is to be taken once daily at bedtime.
- This medication has a lavender aroma.



● Active ingredient of DREWELL EX

The active ingredient of DREWELL EX (diphenhydramine hydrochloride) is used widely to relieve skin itching and prevent allergic symptoms such as sneezing and nasal discharge, and the medication also has the effect of inducing sleepiness.

DREWELL EX is a medication formulated by utilizing the sleepiness-inducing effects of diphenhydramine hydrochloride.



## Precautions for Use



### Contraindications

If you do not follow the precautions exactly as listed below, your current symptoms may worsen, and you may be placed at increased risk of side effects or accidents.

① The following persons must not take this medication:

- (1) Women who are or may be pregnant
- (2) Children under 15 years of age
- (3) Persons suffering from chronic sleeplessness
- (4) Persons who have received a diagnosis of insomnia

② Do not use any of the following medications during the period of taking DREWELL EX:

Other hypnotic sedatives, common cold medications, antipyretic-analgesic medications, antitussive-expectorant medications, and oral medications containing antihistamines (e.g., oral rhinitis medications, motion sickness medications, and anti-allergic medications)

③ Do not operate vehicles or machinery after taking this medication.

(Drowsiness may occur, which could cause accidents. If sleepiness persists or malaise occurs during the day after taking the previous bedtime dose of DREWELL EX, do not operate vehicles or machinery until such symptoms have disappeared.)

④ Breast-feeding women are advised to not take DREWELL EX or stop breast-feeding if this medication is to be taken.

⑤ This medication must not be taken soon before or after alcohol intake.

⑥ Take DREWELL EX only when you have difficulty falling asleep or experience shallow sleep, and do not use this medication for a continuing period.



### Consultation

① The following persons should consult a physician, pharmacist, or registered salesperson before taking this medication:

- (1) Persons who are receiving any treatment from a physician
- (2) Older persons (severe sleepiness may occur in older persons, and conversely, increased nervousness or similar reactions may occur.)
- (3) Persons who have had any allergic reactions to drugs or other substances
- (4) Persons with the following symptom: Dysuria
- (5) Persons who have received a diagnosis of any of the following diseases: Glaucoma and prostatic hypertrophy



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®: Registered trademark

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**② If any of the symptoms listed below develop after taking DREWELL EX, they might be side effects of the medication. Stop taking this medication immediately and consult a physician, pharmacist, or registered salesperson, presenting this leaflet.**

Affected area	Symptoms
Skin	Rash/redness and itching
Gastrointestinal	Stomachache, nausea/vomiting, and inappetence
Neuropsychiatric	Dizziness, headache, heaviness of head on awakening, daytime sleepiness, uncomfortable feeling, nervousness, and temporary disturbance of consciousness (decreased attention, decreased wakefulness, impaired judgment, abnormal speech or behavior, etc.)
Cardiovascular	Palpitations
Urinary	Dysuria
Other	Malaise

**③ Any of the conditions mentioned below may occur after taking DREWELL EX. If such symptoms persist or worsen, stop taking this medication and consult a physician, pharmacist, or registered salesperson, presenting this leaflet.**

Thirst and diarrhea

**④ If symptoms of sleeplessness are not alleviated after taking 2 or 3 doses, stop taking this medication and consult a physician, pharmacist, or registered salesperson, presenting this leaflet.**

## Other Precautions

Sleepiness may persist or malaise may occur during the day following a previous bedtime dose.

### Indications

Relief of the following symptoms due to temporary sleeplessness: Difficulty in falling asleep and/or shallow sleep

### Dosage and Administration

Take a dose of DREWELL EX with cold or lukewarm water once daily at bedtime when you have difficulty falling asleep or experience shallow sleep, according to the table below.

Age	Adults (aged 15 years or older)	Children under 15 years of age
Dose	1 capsule	✗ This medication must not be taken.

#### < Precautions Concerning Dosage and Administration >

- (1) DREWELL EX must be taken strictly in accordance with the specified dosage and administration.
- (2) If you take more than one capsule at a time, you may experience unpleasant symptoms such as increased nervousness, and you may not be able to sleep.
- (3) Do not take this medication at times other than bedtime.
- (4) How to remove the capsule  
As shown in the illustration on the right, firmly press the raised portion of the press-through package (PTP) with a fingertip to push the capsule through the aluminum foil on the reverse side. (If the PTP sheet is mistakenly swallowed, its sharp edges may perforate the esophageal mucosa or lead to incidental events.)



(Illustration showing removal of the capsule from the PTP sheet)

### Ingredients

Diphenhydramine hydrochloride ..... 50 mg

Per capsule

Excipients: gelatin, D-sorbitol, medium chain triglyceride, povidone, macrogol, glycerin, benzyl alcohol, soy lecithin, and flavoring

### Precautions for Storage and Handling

- (1) Store in a dry, cool place away from direct sunlight.
- (2) Keep out of the reach of children.
- (3) Do not transfer the contents to another container (which may lead to drug misuse or changes in the quality of this product).
- (4) Do not take this medication after the expiration date.

Contact Information	<b>Inquiries should be made to the drugstore from where you purchased the product or to the customer service office.</b> Customer Service Office, SSP Co., Ltd. Phone: 0120-028-193 Opening hours: 9:00 to 17:00 (closed on Saturdays, Sundays, and Japanese public holidays)
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