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This document serves as reference information. Please ensure to read the information provided with the product.

[Keep this information leaflet with this medication and be sure to read it before taking the medication.]

# DREWELL®

Class ② OTC drug

**Sleeping 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 sleep rhythm has been disrupted by an irregular daily life

**DREWELL** taken orally at bedtime is most effective in relieving temporary sleeplessness symptoms, such as difficulty falling asleep and shallow sleep.

● **Active ingredient of DREWELL**

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

**DREWELL** is a medication formulated by application of the sleepiness-inducing effect of diphenhydramine hydrochloride.

● **Mechanism of sleepiness induction by DREWELL**

There are many histamine neurons called excitatory neurons in the posterior hypothalamus which are closely related to the sleep/wakefulness of the brain. Histamine released from the end portion of those neurons maintains and regulates wakefulness by exciting nerve cells in various parts of the brain, including the cerebral cortex. The active ingredient (diphenhydramine hydrochloride) of **DREWELL** suppresses histamine actions in the brain, exhibiting a sleep-inducing effect.



## ⚠️ 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 the risk of having some accidents.

● **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 take any of the following medications during the period of taking DREWELL:**

Other hypnotic sedatives, common cold medications, antipyretic-analgesic medications, antitussive-expectorant medications, oral medications containing antihistamines (e.g., oral rhinitis medications, motion sickness medications, 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 a previous bedtime dose, do not operate vehicles or machinery until such symptoms have disappeared.)

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

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

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



### Consultation

● **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) Elderly persons (Severe sleepiness may occur in elderly persons, and on the contrary, increased nervousness or such 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, prostatic hypertrophy



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- ② If any of the symptoms listed below develop after taking DREWELL, 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, swelling, itching
Gastrointestinal	Stomachache, nausea/vomiting, inappetence
Neuropsychiatric	Dizziness, headache, heaviness of head on awakening, daytime sleepiness, feeling uncomfortable, nervousness, temporary disturbance of consciousness (decreased attention, decreased wakefulness, impaired judgment, abnormal speech or behavior, etc.)
Cardiovascular	Palpitations
Urinary	Dysuria
Other	Malaise

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

Thirst, diarrhea

- ④ If there is no alleviation of sleeplessness symptoms 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, according to the table below, with cold or lukewarm water, once daily at bedtime when you have difficulty falling asleep or experience shallow sleep.

Age	Adults (aged 15 years or older)	Children under 15 years of age
Dose	2 tablets	× This medication must not be taken.

**<Precautions concerning Dosage and Administration>**

- (1) DREWELL must be used strictly in accordance with the specified dosage and administration.
- (2) If you take more than 2 tablets 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 at bedtime.
- (4) How to remove the tablet

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 tablet 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 tablet from the PTP sheet)

**Ingredients**

Diphenhydramine hydrochloride ..... 50 mg

in a total of 2 tablets

Excipients: Croscarmellose sodium, silicic anhydride, cellulose, lactose, hydroxypropyl cellulose, hypromellose, macrogol, magnesium stearate, talc, titanium oxide

**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**

**Inquiries should be made to the drugstore where you purchased the product or to the customer service office.**

Customer Service Office, SSP Co., Ltd. Phone: 0120-028-193

Opening hours: 9:00 to 17:30 (closed on Saturdays, Sundays, and Japanese public holidays)



Manufactured and Distributed by:

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