

## CONSUMER MEDICINE INFORMATION

### What is in this leaflet

This leaflet answers some common questions about APPESE.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking APPESE against the benefits they expect it will have for you.

**If you have any concerns about taking this medicine, talk to your doctor or pharmacist.**

Keep this leaflet with your medicine. You may need to read it again.

### What APPESE is used for

APPESE is used to treat restless legs syndrome.

Restless legs syndrome is a condition in which a sense of uneasiness, restlessness, and itching often accompanied by twitching and pain is felt in the legs and sometimes arms when sitting or lying down, especially in bed at night. The only relief is walking or moving the affected limbs, which often leads to problems sleeping at night time.

Restless legs syndrome is thought to be due to a deficiency in the body of dopamine, a naturally occurring body chemical.

APPESE belongs to a group of medicines called non-ergoline, dopamine agonists. APPESE works by having a similar effect on the body as dopamine, therefore it makes up for the dopamine shortage in restless legs syndrome. This in turn relieves the discomfort

and reduces the involuntary limb movements that disrupt night time sleep.

APPESE is not recommended for use in children or adolescents (under the age of 18), as there have been no studies of its effects in this age group).

APPESE is available only with a doctor's prescription.

There is no evidence that APPESE is addictive.

### Before you take APPESE

#### *When you must not take it*

**Do not take APPESE if you are allergic to medicines containing ropinirole or any of the ingredients listed at the end of this leaflet.**

**Do not take APPESE if you are pregnant or intend to become pregnant.**  
APPESE may affect your developing baby if you take it during pregnancy.

**Do not take APPESE if you are breastfeeding.**  
APPESE passes into breast milk and may affect your baby.

**Do not take APPESE if the expiry date (Exp.) printed on the pack has passed.**

**Do not take APPESE if the packaging is torn or shows signs of tampering.**

#### *Before you start to take it*

**Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.**

**Tell your doctor if you have, or have had, any medical conditions, especially the following:**

- liver problems
- kidney problems
- heart problems
- blood pressure problems
- mental disorders
- Neuroleptic-induced Akathisia (restlessness or difficulty keeping still, caused by medicines to treat mental disorders. This is a separate condition to restless legs syndrome).

**If you have not told your doctor about any of the above, tell them before you start taking APPESE.**

#### *Taking other medicines*

**Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.**  
Some medicines may be affected by APPESE, or may affect how well it works. These include:

- fluvoxamine, a medicine to treat depression
- neuroleptics, medicines to treat mental disorders
- metoclopramide, a medicine used to treat nausea or vomiting
- theophylline, a medicine used to treat breathing difficulties
- ciprofloxacin, an antibiotic
- hormone replacement therapy (HRT).

**If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.**

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking APPESE.

If you start smoking or give up smoking while taking APPESE, your doctor may also need to adjust your dosage.

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## How to take APPESE

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### *How much to take*

The starting dose is 0.25 mg once daily. After two days your doctor may increase your dose to 0.5 mg once daily for the remainder of your first week of treatment. After the first week, your doctor may continue to increase your dose gradually.

Your doctor may increase or decrease the amount that you are taking to give you the maximum benefit from the medicine. People generally experience benefit from taking 2mg of APPESE a day. However, some people need to take more or less than this amount.

**Follow all directions given to you by your doctor and pharmacist carefully.**

### *How to take APPESE*

**Take APPESE once a day. APPESE is usually taken just before bedtime, but can be taken up to 3 hours before going to bed.**

**Swallow tablet(s) whole with a glass of water. You can take APPESE with or without food.** Taking APPESE with food may decrease the occurrence of nausea (feeling sick) which is a possible side effect of APPESE.

### *Use in children and elderly patients*

APPESE is not recommended in children under the age of 18 years.

Elderly patients should follow the dosing instructions from your doctor or pharmacist.

### *If you forget to take APPESE*

**Do not take an extra dose. Wait until the next day and take your normal dose then.**

**Do not try to make up for the dose that you missed by taking more than one dose at a time.**

**If you have missed taking APPESE for more than a few days, consult your doctor for advice on restarting APPESE.**

### *How long to take APPESE for*

**Keep taking your APPESE for as long as your doctor tells you to.** It may take a number of weeks for APPESE to work.

**Do not stop taking APPESE even if you begin to feel better.** For best effect APPESE must be taken regularly.

**Do not stop taking APPESE, or change the dose without first checking with your doctor.**

### *If you take too much APPESE (overdose)*

**Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much APPESE. Do this even if there are no signs of discomfort or poisoning.** You may need urgent medical attention.

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## While you are taking APPESE

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### *Things you must do*

**Before starting any new medicine, tell your doctor or pharmacist that you are taking APPESE.**

**Tell all the doctors, dentists and pharmacists who are treating you that you are taking APPESE.**

**Tell your doctor if, for any reason, you have not taken your medicine exactly as directed.**

Otherwise, your doctor may think that it was not working as it should and change your treatment unnecessarily.

**If you become pregnant while taking APPESE, tell your doctor immediately.**

### *Things you must not do*

**Do not use APPESE to treat any other conditions unless your doctor tells you to.**

**Do not give APPESE to anyone else, even if they have the same condition as you.**

### *Things to be careful of*

**Be careful driving or operating machinery until you know how APPESE affects you.**

APPESE may cause drowsiness in some people, especially at the start of treatment. If this occurs, do not drive, operate machinery or do anything else that could be dangerous.

In addition, some people may very rarely fall asleep suddenly without any apparent warning of sleepiness. **If you feel excessive daytime sleepiness (somnolence) or fall asleep suddenly without feeling sleepy, you must not drive or operate machinery until your doctor says you can. Make sure you know how APPESE affects you before you drive a car or operate machinery.**

**As with other drugs of this type, it is best to avoid alcohol while you are taking APPESE.**

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## Side effects

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking APPESE.**

Like all other medicines, APPESE may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

**Do not be alarmed by this list of possible side effects.**

You may not experience any of them.

**Ask your doctor or pharmacist to answer any questions you may have.**

**Tell your doctor if you notice any of the following and they worry you:**

- dizziness
- feeling drowsy
- nausea
- vomiting
- fatigue, either mental or physical
- abdominal pain
- fainting
- nervousness.

APPESE can reduce blood pressure which may make you feel dizzy or faint especially when standing up from a sitting or lying position.

Very rarely APPESE can cause excessive daytime somnolence (drowsiness) and sudden sleep onset episodes where patients fall asleep suddenly without apparently feeling sleepy. If you feel extremely tired during the day or fall asleep suddenly without warning you should see your doctor as soon as possible.

**Tell your doctor immediately if you notice any of the following:**

- wheezing, swelling of the lips/mouth, difficulty breathing, hayfever, lumpy rash (hives) or fainting. These could be symptoms of an allergic reaction.

**Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.**

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## After using APPESE

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### Storage

**Keep APPESE where children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

**Keep your tablets in the pack until it is time to take them.**

If you take the tablets out of the pack they may not keep well.

**Keep your tablets in a cool dry place where the temperature stays below 25°C.**

**Do not store APPESE or any other medicine in the bathroom or near a sink.**

**Do not leave APPESE in the car or on window sills.**

Heat and dampness can destroy some medicines.

### Disposal

**If your doctor tells you to stop taking APPESE, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.**

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## Product description

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### What it looks like

APPESE comes in 4 strengths of tablets:

- APPESE 0.25 - White to off-white, pentagon shaped tablet with 'RI' over '25' on one side and '>' on the other side
- APPESE 0.5 - Yellow, pentagon shaped tablet with 'RI' over '50' on one side and '>' on the other side
- APPESE 1 - Green, pentagon shaped tablet with 'RI' over '1' on one side and '>' on the other side

- APPESE 2 - Pink, pentagon shaped tablet with 'RI' over '2' on one side and '>' on the other side

Each pack contains 12 tablets (0.25 mg only) or 28 tablets (0.5 mg, 1 mg and 2 mg).

### Ingredients

The active ingredient in APPESE is ropinirole (as ropinirole hydrochloride).

- each APPESE 0.25 tablet contains 0.25 mg of ropinirole
- each APPESE 0.5 tablet contains 0.5 mg of ropinirole
- each APPESE 1 tablet contains 1 mg of ropinirole
- each APPESE 2 tablet contains 2 mg of ropinirole.

The tablets also contain:

- lactose
- microcrystalline cellulose
- croscarmellose sodium
- magnesium stearate
- Opadry II 85F18378 White (0.25 mg only)
- Opadry II 85F62505 Yellow (0.5 mg)
- Opadry II 85F61303 Green (1 mg only)
- Opadry II 85F64712 Pink (2 mg only).

*The tablets do not contain gluten, sucrose, tartrazine or any other azo dyes.*

### Supplier

Sigma Pharmaceuticals (Australia) Pty Ltd  
96 Merrindale Drive  
Croydon Vic 3136  
Tel: 03 - 9839 2800

Australian registration numbers:  
APPESE 0.25 - AUST R 140830  
APPESE 0.5 - AUST R 140833  
APPESE 1 - AUST R 140834  
APPESE 2 - AUST R 140835

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