

## Consumer Medicine Information

### What is in this leaflet?

This leaflet answers some common questions about Dimetapp PSE Cough, Cold & Flu Day & Night Liquid Caps. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

### Keep this leaflet with the medicine.

You may need to read it again.

### What is Dimetapp PSE Cough, Cold & Flu Day & Night Liquid Caps used for?

Dimetapp PSE Cough, Cold & Flu Day & Night Liquid Caps have been developed specifically for adults and children 12 years of age and over.

Dimetapp PSE Cough, Cold & Flu Day & Night Liquid Caps combines the decongestant action of Pseudoephedrine with the antitussive action of the non-narcotic, centrally acting cough suppressant Dextromethorphan, the analgesic and antipyretic actions of Paracetamol and the antihistaminic action of Doxylamine.

The orange coloured daytime capsules provide non-drowsy, temporary relief from the symptoms of the common cold & flu: headaches, muscular aches, fever, body aches and pains, sore throat, stuffy noses and dry irritating coughs.

The blue coloured nighttime capsules temporarily relieve the symptoms of the common cold and flu: minor aches, pains, headache, muscular aches, sore throat and fever. It also relieves dry, irritating coughs due to minor throat and bronchial irritation, nasal and sinus congestion, runny nose, sneezing, itchy, watery eyes, and sinus pain.

### Before you take Dimetapp PSE Cough, Cold & Flu Day & Night Liquid Caps

#### When you must not take it

#### Do not take Dimetapp PSE Cough, Cold & Flu Day & Night Liquid Caps if you have an allergy to:

- any medicine containing paracetamol, dextromethorphan, pseudoephedrine and doxylamine succinate
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips tongue or other parts of the body
- rash, itching or hives on the skin.

#### Do not take this medicine if you are having an asthma attack.

#### Do not take this medicine if you:

- have very high blood pressure
- have severe coronary artery disease (heart disease caused by poor blood flow or narrowing of the blood vessels of the heart)
- are taking prescription medication for depression, psychiatric or emotional

conditions e.g. monoamine oxidase inhibitor (MAOI), selective serotonin reuptake inhibitor (SSRI) or for Parkinson's disease, or for 2 weeks after stopping the medication. If you are unsure if your prescription medication contains any of these drugs, ask a doctor or pharmacist before taking this product.

#### Do not take this medicine if you are pregnant or plan to become pregnant.

It may affect your developing baby if you take it during pregnancy. Your pharmacist or doctor will discuss the benefits and possible risks of taking the medicine during pregnancy.

#### Do not take this medicine if you are breastfeeding or plan to breastfeed.

It passes into the breast milk and there is a possibility that the baby may be affected.

#### Do not use this product in children under 12 years of age.

#### Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

#### If you are not sure whether you should start taking this medicine, talk to your pharmacist or doctor.

#### Before you start to take it

Tell your pharmacist or doctor if you have allergies to any other medicines, foods, preservatives or dyes.

#### Tell your pharmacist or doctor if you have or have had any of the following medical conditions:

- asthma
- chronic obstructive airways disease
- pneumonia
- any other respiratory (breathing) conditions
- liver or kidney disease
- high blood pressure
- overactive thyroid gland
- diabetes
- heart disease and poor blood flow in the blood vessels of the heart
- glaucoma
- prostate problems
- bladder problems
- epilepsy

#### Tell your pharmacist or doctor if you have a chronic cough.

This medicine may make your cough worse.

#### Tell your pharmacist or doctor if you have a condition that produces large amounts of mucus.

This medicine may make your condition worse.

#### If you have not told your pharmacist or doctor about any of the above, tell him/her before you start taking Dimetapp PSE Cough, Cold & Flu Day & Night Liquid Caps.

#### Taking other medicines

Tell your pharmacist or doctor if you are taking any other medicines, including any that you get without a prescription from

#### your pharmacy, supermarket or health food shop.

Some medicines and Dimetapp PSE Cough, Cold & Flu Day & Night Liquid Caps may interfere with each other.

These include:

- medicines used to treat depression, psychiatric or emotional conditions e.g. selective serotonin reuptake inhibitor (SSRI) or for Parkinson's disease
- monoamine oxidase inhibitors, a medicine used to treat depression, especially if taken within the last 14 days
- quinidine and amiodarone, medicines used to treat abnormal or irregular heart beat
- opioid analgesics used to treat pain
- medicines used to help you relax, sleep or relieve anxiety, such as sedatives
- alcohol
- Warfarin
- metoclopramide, a medicine used to control nausea and vomiting
- medicines used to treat epilepsy or fits
- chloramphenicol, an antibiotic used to treat ear and eye infections
- medicines used to treat heart conditions, high blood pressure
- medicines used to treat urinary tract infections and bladder problems
- medicines used to treat behavioural disorders
- phenylephrine, a medicine used to treat congestion
- appetite suppressants
- cholestyramine (Questran, Questran Lite)

These medicines may be affected by Dimetapp PSE Cough, Cold & Flu Day & Night Liquid Caps or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

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

### How to use Dimetapp PSE Cough, Cold & Flu Day & Night Liquid Caps

#### How much to use

#### For adults and children 12 years and over:

**DAYTIME:** Take 2 orange capsules orally with water, every 4-6 hours (morning, midday and afternoon) as necessary.

**NIGHTTIME:** Take 2 blue capsules orally with water at bedtime as necessary.

Each dose of Dimetapp PSE Cough, Cold & Flu Day & Night Liquid Caps should be taken at least 4-6 hours apart. Allow 4-6 hours between the daytime dose and nighttime dose.

Do not exceed 6 orange Day liquid capsules and 2 blue Night liquid capsules in 24 hours.

Do not exceed recommended dosage.

Do not give this medicine in children under 12 years of age.

Dimetapp PSE Cough, Cold & Flu Day & Night Liquid Caps should not be used for more than few days at a time except on medical advice.

A persistent cough may be a sign of a serious condition. If symptoms do not improve within 7 days (or within 48 hours in the case of children), tend to recur, or are accompanied by rash, persistent headache, fever that lasts more than 3 days, or if new symptoms occur, patients should consult a doctor.

*If you forget to take it*

If it is almost time for your next dose, skip the dose you missed and take the next dose when you are meant to. Otherwise, use it as soon as you remember and then go back to using Dimetapp PSE Cough, Cold & Flu Day & Night Liquid Caps as you would normally.

**Do not use a double dose to make up for the dose that you missed.**

This may increase the chance of you getting an unwanted side effect.

*If you use too much (overdose)*

Stop use and immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) or go to the nearest hospital straight away, if you think that you or anyone else may have used too much Dimetapp PSE Cough, Cold & Flu Day & Night Liquid Caps. Do this even if there are no signs of discomfort or poisoning. Keep this telephone number handy.

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While you are using Dimetapp PSE Cough, Cold & Flu Day & Night Liquid Caps

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*Things you must do:*

If anyone in the family becomes pregnant and happens to use Dimetapp PSE Cough, Cold & Flu Day & Night Liquid Caps, tell your doctor or pharmacist immediately.

If you are about to be started on any new medicine tell your doctor, dentist or pharmacist that you are using Dimetapp PSE Cough, Cold & Flu Day & Night Liquid Caps.

*Things you must not do:*

**Adults:**

**Do not take this product for more than few days at a time unless your doctor tells you to.**

**Children:**

**Do not take this product for more than 48 hours unless your doctor tells you to.**

*Things to be careful of:*

Do not drive or operate machinery until you know how this product affects you. This product may cause dizziness in some people and therefore may affect alertness. The blue night capsule may cause drowsiness in some people.

**Alcohol warning:** If you generally consume 3 or more alcohol containing drinks per day, you should consult your doctor for advice on when and how you should take this product or any other paracetamol containing product.

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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 whilst using Dimetapp PSE Cough, Cold & Flu Day & Night Liquid Caps.**

Dimetapp PSE Cough, Cold & Flu Day & Night Liquid Caps may have unwanted side effects in a few individuals. All medicines can have side effects. Ask for the advice of your doctor or pharmacist if you have any concerns about the effects of using this medicine.

**Tell your doctor or pharmacist if you notice any of the following side effects and they worry you:**

- nervousness
- shaking (tremor)
- spinning sensation (vertigo)
- headache
- faster heart rate (tachycardia)
- high blood pressure (hypertension)
- drowsiness
- dizziness
- sleeplessness (insomnia)
- nausea (feeling sick)
- vomiting
- dryness of the mouth
- blurred vision
- rash (including urticaria)

The above list includes the more common side effects of your medicine. They are usually mild.

**If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:**

- excitation
- extreme confusion
- nervousness and anxiety
- irritability
- rectal bleeding
- restlessness
- severe nausea and vomiting
- shortness of breath, wheezing or difficulty breathing
- sudden abdominal pain
- swelling of the face, lips, tongue or other parts of the body
- skin rashes, itching or hives on the skin
- urine retention
- severe skin reactions including skin reddening, blisters or rash

The above list includes serious side effects that may require medical attention. These side effects are rare.

**Tell your pharmacist or doctor if you notice anything that is making you feel unwell.**

Other side effects not listed above may also occur in some people.

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After using Dimetapp PSE Cough, Cold & Flu Day & Night Liquid Caps

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## Storage

**Keep Dimetapp PSE Cough, Cold & Flu Day & Night Liquid Caps in a cool dry place where the temperature stays below 25°C.**

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

Heat and dampness can destroy some medicines.

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

*Disposal*

**After the expiry date has passed any unused Dimetapp PSE Cough, Cold & Flu Day & Night Liquid Caps should be returned to your pharmacist so that it can be disposed of safely.**

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## Product description

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*What it looks like*

The daytime capsule is an oval, clear orange, soft gelatin capsule.

The nighttime capsule is an oval, clear blue, soft gelatin capsule.

*Ingredients*

**Each orange coloured DAY capsule contains:**

**Dextromethorphan hydrobromide, 10mg  
Pseudoephedrine hydrochloride, 30mg  
Paracetamol, 300mg**

**The orange coloured DAY capsule also contains the following inactive ingredients:**

- Macrogol 400
- Propylene glycol
- Povidone
- Gelatin
- Glycerol
- Sorbitol
- Sunset Yellow FCF CI15985
- Water - purified

**SUGAR FREE GELATIN CAPSULES**

**Each blue coloured NIGHT capsule contains:**

**Dextromethorphan hydrobromide, 10mg  
Pseudoephedrine hydrochloride, 30mg  
Paracetamol, 300mg**

**Doxylamine Succinate, 6.25mg**

**The blue coloured NIGHT capsule also contains the following inactive ingredients:**

- Macrogol 400
- Propylene glycol
- Povidone
- Gelatin
- Glycerol
- Sorbitol
- Brilliant blue FCF CI42090
- Water - purified

**SUGAR FREE GELATIN CAPSULES.**

*Name and Address*

For all enquiries please contact:

Pfizer Australia Pty Limited  
Level 17, 151 Clarence Street,  
Sydney, New South Wales, 2000  
AUSTRALIA

Australia 1800 555 057  
or visit: [www.dimetapp.com.au](http://www.dimetapp.com.au)

**Dimetapp PSE Cough, Cold & Flu Day & Night Liquid Caps - AUST R 58352**

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08 September 2005

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