### **SYMMETREL®**

#### **Consumer Medicine Information (CMI) summary**

The <u>full CMI</u> on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

## 1. Why am I taking SYMMETREL?

SYMMETREL contains the active ingredient amantadine hydrochloride. SYMMETREL is used to treat Parkinson's disease and to prevent infection from Influenza Type A ("the flu"). For more information, see Section 1. Why am <a href="Ltaking SYMMETREL?">Ltaking SYMMETREL?</a> in the full CMI.

# 2. What should I know before I take SYMMETREL?

Do not take if you have ever had an allergic reaction to SYMMETREL or any of the ingredients listed at the end of the CMI. Tell your doctor if you are allergic to any other medicines, foods, dyes, or preservatives.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding. You must not take SYMMETREL if you are pregnant or plan to become pregnant.

For more information, see Section 2. What should I know before I take SYMMETREL? in the full CMI.

## 3. What if I am taking other medicines?

Some medicines may interfere with SYMMETREL and affect how it works. A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

## 4. How do I take SYMMETREL?

- Take the capsule after a meal or snack.
- Swallow the capsule whole with a full glass of water.
   Do not chew, break, or crush the capsule.
- Your doctor will tell you how much SYMMETREL to take as it depends on factors like your condition, age, and overall health.

More instructions can be found in Section <u>4. How do I take SYMMETREL?</u> in the full CMI.

## 5. What should I know while taking SYMMETREL?

#### Things you should do

 Remind any doctor, dentist, surgeon, or pharmacist you visit that you are taking SYMMETREL.

	<ul> <li>Tell your doctor if your skin is burning more easily.</li> <li>Keep all your appointments.</li> </ul>
Things you should not do	<ul> <li>Do not stop taking this medicine suddenly or take more than your doctor tells you to.</li> <li>Do not give this medicine to someone else or allow yourself to run out of capsules.</li> </ul>
Driving or using machines	<ul> <li>SYMMETREL may cause dizziness, confusion, difficulty concentrating, impair your reactions, or cause blurred vision in some people. Be careful when undertaking any task that requires your attention.</li> <li>Children should avoid doing things like riding bicycles or climbing trees.</li> </ul>
Drinking alcohol	Do not drink alcohol while you are on

	treatment with SYMMETREL.
Looking after your medicine	<ul> <li>Store it in a cool dry place (below 30°C) away from moisture, heat, or sunlight.</li> <li>Do not store in the bathroom or near a sink, in the car or on a windowsill.</li> </ul>

For more information, see Section <u>5. What should I know while taking SYMMETREL?</u> in the full CMI.

## 6. Are there any side effects?

More common side effects: Skin changes (redness, itching, blotchy fishnet type pattern), feeling/being sick, more sweating, difficulty passing urine, tummy discomfort, appetite changes, dry mouth, nightmares, feeling sad, tired, anxious, light-headed, dizzy, or agitated; trouble focusing/sitting still, decreased impulse control, trouble sleeping. More serious side effects: wheezing, difficulty breathing, spreading rash or blisters on face, lips or hands, swelling of tongue or face (signs of an allergic reaction); experiencing things that are not there (hallucinations), uncontrollable movement (fits, seizures), stiff muscles/limbs; yellow skin/eyes (signs of liver problem), constantly sick with flu-like symptoms: chills/fever; vision loss, heart problems like rapid heart rate, feeling faint or disoriented/confused and difficulty speaking or slurred speech (possible signs of stroke).

For more information, including what to do if you have any side effects, see Section <u>6. Are there any side</u> <u>effects?</u> in the full CMI.

## **SYMMETREL** (Sym-me-trel)

**Active ingredient(s):** amantadine hydrochloride (A-MAN-ta-deen Hi-droh-clor-ride)

#### **Consumer Medicine Information (CMI)**

This leaflet provides important information about taking SYMMETREL. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking SYMMETREL.

#### Where to find information in this leaflet:

- 1. Why am I taking SYMMETREL?
- 2. What should I know before I take SYMMETREL?
- 3. What if I am taking other medicines?
- 4. How do I take SYMMETREL?
- 5. What should I know while taking SYMMETREL?
- 6. Are there any side effects?
- 7. Product details

## 1. Why am I taking SYMMETREL?

**SYMMETREL** contains the active ingredient amantadine hydrochloride. SYMMETREL is both an "antiparkinsonian agent" (treats the symptoms of "Parkinson's disease) and an "anti-influenzal

virostatic" (stops the activity) of Influenza Type A; the virus that causes "the flu" in your body.

SYMMETREL is used to treat adults with Parkinson's Disease. This occurs when chemicals in your brain responsible for sending messages ('neurotransmitters') are not in the right balance. Parkinson's disease causes shaking, trembling and uncontrolled movement because you may have too little "dopamine" and/or too much "acetylcholine" which makes it difficult to perform day-to-day tasks. SYMMETREL is either taken alone, or with other medicines to relieve these symptoms but is not a cure for this disease.

SYMMETREL is also used to prevent serious cases of only influenza Type A ("the flu") in patients aged 5 years or older where they may become very sick if they were to catch it and may or may not have been vaccinated. It does this by stopping the virus from creating new copies of itself. This medicine does not prevent or treat a cold or other types of flu.

# 2. What should I know before I take SYMMETREL?

#### **Warnings**

#### Do not take SYMMETREL if:

 You are allergic to amantadine, hydroxbenzoates, sulfites, or any of the ingredients listed at the end of this leaflet.

- You are pregnant or breastfeeding.
- The expiry date on the packaging has passed or if the packaging is damaged/shows signs of tampering.

Always check the ingredients to make sure you can take this medicine. You should talk to your doctor if you are prone to allergies including other medicines, food, dyes, and preservatives.

## Check with your doctor if you have:

- problems with your kidneys or liver
- seizures (uncontrollable fits)
- diagnosed mental illness or suicidal thoughts
- heart or circulation problems
- stomach ulcers (sores)
- low blood pressure
- glaucoma (increased pressure in the eyes)
- prostate problems (in men)
- persistent dry skin in the form of eczema
- have a history of addiction to gambling, sex or shopping

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6</u>. Are there any side effects?

## **Monitoring**

Your doctor will monitor your health and your behaviour closely throughout treatment. If you develop blurred vision for example, your doctor may refer you to an ophthalmologist (eye doctor) and they may recommend you stop taking it. It is important that you do not alter your dose or stop taking SYMMETREL unless your doctor tells you to as this could increase the chance of having unwanted effects.

## Changes to behaviour

SYMMETREL may make you unable to resist acting on impulses (urges) that you may or may not ordinarily do. This type of behaviour can include addictive gambling, excessive eating or spending, or heightened sex drive even if you have no prior history of these behaviours. Your doctor will want to monitor this.

#### Increased sensitivity of skin

SYMMETREL may cause your skin to be more sensitive than it normally is to the sun. For this reason, you should also avoid tanning beds and sunlamps.

When you are outside, ensure that you wear protective clothing that covers your skin and that you use a sunscreen of at least SPF 15+ to help prevent your skin from becoming red and blistered from sunburn.

#### **Pregnancy and breastfeeding**

You must not take SYMMETREL if you are pregnant or breastfeeding as it may harm your unborn baby. Check with your doctor if you are pregnant, think you may be pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed. The active ingredient in SYMMETREL (amantadine) passes into breast milk.

## Contraception

If you are a woman and you may become pregnant you must use an effective form of contraception (birth control) during treatment and for five days after your last dose of SYMMETREL.

#### Children and adolescents

Children under the age of five should not take SYMMETREL as there is not enough information that it is safe or effective in these patients.

## 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins, or supplements that you buy without a prescription from your pharmacy, supermarket, or health food shop.

Some medicines may interfere with SYMMETREL and affect how it works. This may include:

- other medicines for Parkinson's disease
- medicines used for mental conditions such depression, schizophrenia
- medicines that affect the nervous system (including those that make you calmer, relieve pain, or substances like alcohol)
- medicines for tummy cramps or spasms
- medicines used to treat high blood pressure (such as (hydrochlorothiazide and triamterene)

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect SYMMETREL.

## 4. How do I take SYMMETREL?

- Take the capsule after a meal or snack.
- Swallow the capsule whole with a full glass of water.
- Do not chew or crush the capsule.

#### How much to take

- Your doctor will tell you how many SYMMETREL capsules you need to take based on the condition that you have, your age, your overall health (in particular your kidney function) and what other medicines you may be taking.
- Follow the instructions provided and take SYMMETREL until your doctor tells you to stop.

#### **Parkinson's Disease**

- If you are taking SYMMETREL capsules because you have Parkinson's Disease, treatment is usually one capsule (100 mg) taken once a day.
- Your doctor may increase this to one capsule (100mg) taken twice a day, or higher doses depending on how you respond to treatment.
- You must not take more capsules than your doctor tells you to or stop taking this medicine suddenly regardless of how well you feel.

#### **Type A Influenza**

If you are taking SYMMETREL capsules because you have Type A influenza, treatment depends on your age and overall health.

#### Children aged 5 to 9 years:

Take only one capsule (100 mg) each day.

#### Children aged 10 or older:

Take one capsule (100 mg) twice daily.

#### Adolescents and adults up to age 65 years:

Take one capsule (100 mg) twice daily.

#### Adults over 65 years:

Take only one capsule (100 mg) each day.

#### In elderly patients with impaired kidney function:

If you are over 65 years of age or have reduced kidney function, your doctor may reduce your dose or ask you to take SYMMETREL capsules less frequently than patients with normal kidney function.

## <u>In elderly patients WITHOUT impaired kidney</u> function:

Do not take more than 100 mg daily unless prescribed by your doctor.

You must not take more capsules than your doctor tells you to regardless of how well you feel or whether you think it is working.

#### When to take SYMMETREL

SYMMETREL should be taken at about the same time every day, as directed by your doctor. This will have the best effect and helps you remember to take it.

#### **Parkinson's Disease**

- Adults up to the age of 65 years old: For the first week, take your medicine (one 100 mg capsule) once daily. After the first week of treatment, depending on how you respond, your doctor may suggest you take one capsule (100 mg) twice daily.
- Adult over 65 years old: Take only one capsule (100 mg) per day.

### Type A influenza

SYMMETREL capsules should be taken soon as possible after exposure to the flu virus in accordance with the below:

- Children aged 5-9: Take only one capsule (100 mg) daily.
- Children aged 10 and older & adults to 65 years:
   Take one capsule (100 mg) twice each day
- Adults over 65 years old: Take only one capsule (100 mg) daily.
- People with reduced kidney function due to increasing age or kidney disease: Take as directed by your doctor as you may be reduced to one capsule (100 mg) every 2 to 7 days to help prevent side effects.
- If side effects occur: your doctor may reduce your dose to one capsule (100 mg) daily.

### How long to take SYMMETREL

#### **Parkinson's Disease**

- You may need to take SYMMETREL for a long time to control your symptoms.
- You must not change your dose or stop taking SYMMETREL unless you doctor tells you to.
- If your doctor tells you to stop taking SYMMETREL then they may gradually reduce your dose before taking you off treatment completely.

#### Type A Influenza

- Keep taking Symmetrel for at least 10 days, ideally as soon as you are exposed to the virus.
- Sometimes it may be necessary to keep taking it until the outbreak of influenza is over.

#### If you forget to take SYMMETREL

- SYMMETREL should be taken regularly at about the same time each day.
- If you miss your dose at the usual time and it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.
   Otherwise, take the dose as soon you remember and then go back to taking it as you normally would.
- Do not take a double dose to make up for the dose you missed. This may increase the chance of you getting an unwanted side effect.

## If you take too much SYMMETREL

If you think that you have taken too much SYMMETREL you may need urgent medical attention.

#### You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning. Patients over the age of 65 years or patients who have a problem with their kidneys are at a higher risk of this.

Some of the symptoms of an overdose may include stiffness or unusual muscle movements, seizures (fits), vomiting, difficulty breathing, fast or irregular heartbeat, seeing or hearing things that are not there and losing consciousness.

# 5. What should I know while taking SYMMETREL?

## Things you should do

- Keep all your doctor's appointments so that your progress and overall health can be checked.
- Take SYMMETREL exactly as your doctor tells you to.
- Be careful when getting up from a sitting or lying position. You can help manage the light-headed/dizzy feelings by getting up slowly and flexing leg muscles and wiggling your toes to get the blood flowing. When getting out of bed, dangle your legs over the side for a minute or two before standing up.
- Tell your doctor if your skin becomes red or blistered (like a sunburn).
- Tell your doctor if you have been having urges to gamble, shop or are experiencing a higher than normal sex drive (libido) that is difficult to resist.

 Remind any doctor, dentist, surgeon, or pharmacist you visit that you are taking SYMMETREL.

## Call your doctor straight away if you:

- Become pregnant or think you may become pregnant
- Experience vision loss or blurred vision. Your doctor may refer you to an eye doctor (ophthalmologist) who may recommend you stop taking SYMMETREL.
- Experience confusion, disorientation, hallucinations, nausea, vomiting, accelerated breathing, irregular heartbeat, movement disorders, or seizures

## Things you should not do

- Do not take more SYMMETREL than your doctor has told you to take.
- Do not stop taking this medicine suddenly without talking to your doctor.
- Do not allow yourself to run out of capsules where you may not have access to a pharmacy (such as weekends, public holidays or while on holidays)
- Do not give this medicine to someone else.

## **Driving or using machines**

Be careful before you drive or use any machines or tools until you know how SYMMETREL affects you. SYMMETREL may cause dizziness, confusion, difficulty concentrating, impair your reactions, or cause blurred vision in some people. Be careful when doing something that requires your attention.

Children should avoid doing things like riding bicycles or climbing trees.

## **Drinking alcohol**

## Do not drink alcohol while you are on treatment with SYMMETREL.

Taking SYMMETREL with alcohol could make you more dizzy or lightheaded than usual. If this medicine makes you feel light-headed, dizzy, or faint, be careful when getting up from a sitting or lying position.

#### Looking after your medicine

Keep your medicine in the container it came in until it is time to take it. Follow the instructions on the carton on how to take care of your medicine properly.

Store it in a cool dry place (below 30°C) away from moisture, heat, or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

Keep it where young children cannot reach it.

## When to discard your medicine

You may discard your medicine when it is empty, your doctor tells you that you do not need to take it anymore, or if it is out of date.

## Getting rid of any unwanted medicine

If your doctor tells you that you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

#### Less serious side effects

Less serious side effects	What to do
Changes to behaviour or mood  • Desire to gamble a lot	Speak to your doctor if you have any of these less serious side effects and they worry you.

#### Less serious side effects | What to do Increased sex drive/ If you are over 65 years interest old, you should be especially careful while Uncontrollable shopping/ spending taking this medicine. Report any side effects Binge eating or promptly to your doctor. compulsive overeating. Feeling anxious, SYMMETREL can nervous, agitated, or cause confusion or depressed (sad) disorientation, especially in older people. Your **Tummy problems** family or carer should be Constipation made aware of this. Diarrhoea Vomiting (being sick) Indigestion Nausea (feeling sick) **General well-being** Sweating a lot Feeling weak or shaky Feeling restless or tired Problems paying attention Poor sleep, nightmares Hair loss Feeling dizzy/lightheaded

Dry mouth

Less serious side effects	What to do
Skin problems	
<ul> <li>Skin that looks like sunburn - redness, itching, blistering</li> <li>Purple or blotchy skin that looks like a fishnet pattern.</li> </ul>	
Kidney problems	
<ul> <li>Difficulty passing urine or unable to stop passing urine.</li> <li>Swelling of feet or lower legs due to fluid buildup</li> <li>Eye problems</li> </ul>	
Blurred vision	

## **Serious side effects**

Serious side effects	What to do
Signs of an allergic reaction  • Sudden and spreading skin changes including an angry, itchy, or red rash, hives, swelling/	Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Serious side effects	What to do
blisters on the lips, mouth, or tongue  • Shortness of breath, wheezing, trouble breathing  Heart and circulation problems	
<ul> <li>Fast or irregular heartbeat</li> <li>Feeling disoriented, confused, fainting and sudden drop in body temperature.</li> <li>Difficulty speaking, slurred speech (possible signs of stroke).</li> <li>Liver problems</li> </ul>	
<ul> <li>Yellow skin or eyes</li> </ul>	
General well-being	
<ul> <li>Hallucinations (seeing, hearing, or feeling things that are not there)</li> <li>Abnormally highlevel of energy, erratic behaviour (mania)</li> </ul>	
Movement problems	
Stiff or rigid muscles	

Serious side effects	What to do
<ul> <li>Uncontrollable movement (fits, seizures)</li> </ul>	
Eye problems	
<ul> <li>Sudden vision loss</li> </ul>	
Infections	
<ul> <li>Being sick constantly with flu-like symptoms (chills, fever, sore throats, aching joints, swollen glands, or sores in the mouth.</li> <li>Very low body temperature (below 35°C); especially in children</li> </ul>	

## Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

## Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at <a href="https://www.tga.gov.au/reporting-problems">www.tga.gov.au/reporting-problems</a>. By reporting side

effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

## 7. Product details

This medicine is only available with a doctor's prescription.

Symmetrel capsules contain 100 mg of amantadine hydrochloride.

#### What SYMMETREL contains

Active ingredient (main ingredient)	amantadine hydrochloride.
Other ingredients (inactive ingredients)	<ul> <li>rape seed oil</li> <li>lecithin</li> <li>a wax blend composed of yellow beeswax, hydrogenated, and partially hydrogenated soya oils</li> <li>sodium ethyl hydroxybenzoate</li> <li>sodium propyl hydroxybenzoate</li> <li>gelatin</li> </ul>

	<ul> <li>glycerol</li> <li>iron oxide red</li> <li>Karion 83 (a mixture of sorbitol, mannitol, and hydrolysed starch in water)</li> <li>titanium dioxide</li> <li>white, edible branding ink</li> </ul>
Potential allergens	SYMMETREL contains hydroxbenzoates and sulfites. It does not contain sucrose, gluten, tartrazine, or any other azo dyes.

Do not take this medicine if you are allergic to any of these ingredients.

#### What SYMMETREL looks like

SYMMETREL capsules are soft brown gelatin capsules, marked "GEIGY" on one side and "GB" on the other. Each bottle contains 100 capsules (AUST R 11057).

#### Who distributes SYMMETREL

NOVARTIS Pharmaceuticals Australia Pty Limited ABN 18 004 244 160 54 Waterloo Road Macquarie Park NSW 2113

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This leaflet was prepared in March 2024.

(CMI sym080420c\_v2 is based on the PI sym080420i).