### **Consumer Medicine Information**

#### What is in this leaflet

This leaflet answers some common questions about Symmetrel.

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

The information in this leaflet was last updated on the date listed on the final page. Some more recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine. You can also download the most up to date leaflet from www.novartis.com.au.

Those updates may contain important information about the medicine and its use of which you should be aware.

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

If you have any concerns about this medicine, ask your doctor or pharmacist. Keep this leaflet with the medicine.

You may need to read it again.

## What Symmetrel is used for

Symmetrel capsule has two very different uses:

- 1. to treat the symptoms of Parkinson's disease
- 2. to prevent a type of influenza ("the flu") caused by Type A influenza virus.

## Parkinson's Disease

This is caused by a disturbance in the balance of two substances, dopamine and acetylcholine, that the brain uses to send signals to other parts of the body.

Symmetrel helps to fix the imbalance of too little dopamine and/or too much acetylcholine; and to relieve the symptoms, such as shaking of the limbs, stiffness and slowness of movement which make it difficult to perform usual tasks.

Symmetrel can be used alone or with other medicines to treat this condition.

### Type A influenza virus

Symmetrel is usually used for people who could become very ill if they get the flu infections (for example, people who have a serious illness such as lung disease or diabetes). Usually these people will have been vaccinated (had a flu shot). But if, for some reason, they have not been vaccinated, Symmetrel can be given.

Symmetrel is only used to prevent Type A influenza. It will not help once you have the flu. This medicine cannot prevent or treat colds, other types of flu not caused by Type A virus, or other viral infections.

# Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another purpose.

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

It is not habit-forming.

There is not enough information to recommend this medicine for children under five years of age.

# Before you take Symmetrel

# When you must not take it Do not take Symmetrel if you have ever had an allergy to:

- amantadine hydrochloride (the active ingredient in Symmetrel) or
- to any of the other 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 Symmetrel if you are pregnant.

It may affect your unborn baby if you take it while you are pregnant.

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

In that case, return it to your pharmacist.

Before you start to take it

Tell your doctor if you have any of the following health problems or medical conditions:

- · kidney or liver disease
- seizures (fits)
- a mental disorder
- · heart disease or circulation problems
- stomach ulcers
- · low blood pressure
- increased pressure in the eyes (glaucoma)
- prostate trouble
- recurring skin problems (eczema)

Your doctor may want to take special precautions if you have any of the above conditions.

# Tell your doctor if you are breast-feeding.

The active ingredient in Symmetrel passes into the breast milk and could affect your baby. Your doctor can discuss with you the risks and benefits of breast-feeding while you are taking this medicine.

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

Your doctor will want to know if you are prone to allergies.

Ask your doctor for advice if you think you may be allergic, if you have ever had any unusual sensitivity, rash or other possible signs of allergy.

If you have not told your doctor about any of these things, tell him/ her before you take Symmetrel.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop. Some medicines and Symmetrel may interfere with each other. These include:

- · other medicines for Parkinson's disease
- medicines for depression or other mental disorders
- other medicines that affect the nervous system (e.g. medicines to help you sleep or calm you down, pain relievers, alcohol)
- medicines for abdominal or stomach cramps or spasms
- some combination diuretics (water or fluid pills) used to treat high blood pressure (hydrochlorothiazide and triamterene)

You may need to take different amounts of your medicines or to take different medicines while you are taking Symmetrel. Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Symmetrel.

If you have not told your doctor about any of these things, tell him/ her before you start taking this medicine.

### How to take Symmetrel

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

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

These instructions may differ from the information contained in this leaflet.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

How much to take

Follow your doctor's instructions on how many Symmetrel capsules to take.

This is important as there are two different ways to take this medicine, depending on whether you are being treated for Parkinson's disease or for Type-A influenza.

# 1. For Parkinson's disease

Start treatment with one capsule taken daily and gradually increase to one capsule taken twice a day.

Occasionally, higher doses are needed.

# 2. For Type A influenza

Children aged 5 to 9 years:

Take only one capsule each day.

Children aged 10 or older:

Take one capsule twice daily.

Adolescents and adults up to age 65 years:

Take one capsule twice daily.

Adults over 65 years:

Take one capsule each day.

In elderly patients without impaired kidney function:

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

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

# Follow the instructions that they give you.

For people who are elderly or have reduced kidney function, the dose may need to be reduced or taken less frequently.

Do not change the dose or dosing interval yourself, without your doctor's advice, regardless of how well you may feel.

When to take it

Try to take the capsules at about the same times each day, as directed by your doctor or pharmacist.

Taking your medicine at the same times each day will have the best effect. It will also help you remember when to take your capsules.

### To treat Parkinson's disease

Adults up to 65 years old:

For the first week, take your medicine once daily. After the first week, take one capsule twice daily.

Adults over 65 years old:

Take only one capsule daily.

To treat Type A influenza

Children aged 5 to 9, and adults over 65 years old

Take only one capsule daily.

Children aged 10 and older & adults to 65 years:

Take one capsule twice each day, starting as soon as possible after exposure to the flu virus.

If side effects occur, the dose can be reduced to one capsule 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 every 2 to 7 days to help prevent side effects.

How long to take it

To treat Parkinson's disease

You may need to take Symmetrel for a long time to control your symptoms.

#### Do not stop taking this medicine or lower the dose without first checking with your doctor.

If it is necessary to stop your medicine, your doctor will gradually reduce the amount you take each day before stopping it completely.

Some people find that this medicine loses some of its effect after several weeks. In this case, your doctor may gradually reduce the dose and stop it for a few weeks, and then start it again to see if the benefit can be regained.

# Do not let yourself run out of medicine over the weekend or on holidays.

Stopping your medicine may make your condition worse or cause severe side effects.

### To treat Type A influenza virus Keep taking Symmetrel for at least 10 days.

Sometimes it may be necessary to keep taking it until the outbreak of influenza is over

If you forget to take it

If it is almost time for your next dose, skip the missed dose and take the next one when you are meant to.

Otherwise, take the dose as soon as you remember, and then go back to taking it as you would normally.

Do not take a double dose to make up for the one that you missed.

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

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much Symmetrel. Do this even if there are no signs of discomfort or poisoning. Keep the telephone numbers for these places handy.

Some of the symptoms of an overdose may include stiffness or unusual muscle movements, seizures (fits), vomiting, difficulty breathing, fast or irregular heartbeat.

# While you are taking Symmetrel

Things you must do

Continue taking Symmetrel as your doctor tells you.

Talk to your doctor or your pharmacist if you have questions about how long to take Symmetrel.

Women of child-bearing potential should use an efficient contraceptive method during treatment and for 5 days after taking their last dose of Symmetrel. If you become pregnant while taking Symmetrel, tell your doctor immediately.

You should not take it while you are pregnant.

When you are outdoors, wear protective clothing and use at least a 15+ sunscreen. Do not use a sunlamp or tanning bed or booth.

This medicine may cause your skin to be much more sensitive to sunlight than it normally is. Exposure to sunlight may cause a skin rash, itching, redness or severe sunburn.

If your skin does appear to be burning, tell your doctor.

If you develop blurred vision or other visual problems, tell your doctor straight away.

Your doctor can refer you to an ophthalmologist who will evaluate and may advise you to stop your treatment with Symmetrel.

Tell your doctor if you or your family/carer notices that you are developing urges or cravings to behave in ways that are unusual for you and you cannot resist the impulse, drive or temptation to carry out certain activities that could harm yourself or others.

These are called impulse control disorders and can include behaviours such as addictive gambling, excessive eating or spending, an abnormally high sex drive or an increase in sexual thoughts or feelings.

Your doctor may need to adjust or stop your dose.

Be sure to keep all of your doctor's appointments so that your progress can be checked.

This helps your doctor to give you the best treatment and to prevent unwanted side effects.

Before having any surgery or emergency treatment, tell the doctor or dentist in charge that you are taking Symmetrel.

If you are about to be started on any new medicine, remind your doctor and

pharmacist that you are taking Symmetrel.

Tell any other doctor, dentist or pharmacist who treats you that you are taking Symmetrel.

Things you must not do

Do not exceed the recommended dosage. Do not give this medicine to anyone else, even if their condition seems similar to yours.

Do not use it to treat any other complaints unless your doctor tells you to.

Things to be careful of

Be careful driving, operating machinery, using tools, or doing jobs that require you to be alert while you are taking Symmetrel until you know how it affects you.

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

This medicine may cause dizziness, confusion, difficulty concentrating, impair your reactions, or cause blurred vision in some people.

# Be careful when drinking alcohol while you are taking Symmetrel.

The combination could make you more dizzy or lightheaded than usual.

### If this medicine makes you feel lightheaded, dizzy or faint, be careful when getting up from a sitting or lying position.

These symptoms may be a sign of low blood pressure. You can usually prevent them by getting up slowly and flexing leg muscles and 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.

# Side effects

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

All medicines can have side effects. Sometimes they are serious, but most of the time they are not. You may need medical treatment if you get some of the side effects.

If you are over 65 years old, you should be especially careful while taking this medicine. Report any side effects promptly to your doctor.

Symmetrel can cause confusion or disorientation, especially in older people. Your family or carer should be made aware of this.

Do not be alarmed by these lists 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 side effects and they worry you:

- strong impulse to gamble excessively
- · increased sexual drive or interest
- uncontrollable excessive shopping or spending
- · binge eating or compulsive eating
- dizziness or lightheadedness, especially when you get up too quickly from a sitting or lying position
- purplish-red blotchy spots on the skin, especially of the legs or feet and sometimes in a fish-net pattern.
   These may appear after taking
   Symmetrel for a few months and usually

- go away gradually within a few weeks after stopping the medicine.
- symptoms of sunburn (such as redness, itching, swelling or blistering of the skin) that happen more quickly than normal
- indigestion, loss of appetite, nausea (feeling sick) or vomiting
- constipation or diarrhoea
- blurred vision
- dry mouth
- swelling of feet or lower legs due to fluid buildup
- · feeling of fast or irregular heartbeat
- · tiredness or listlessness
- · difficulty concentrating
- nervousness, anxiety or depression
- · disturbed sleep or nightmares
- weakness, shakiness or trembling
- difficulty urinating (passing water) or inability to hold your urine (incontinence)
- · excessive sweating
- headache
- hair loss

### Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- signs of allergy such as rash, itching or hives on the skin; swelling of the face, lips, tongue or other part of the body; shortness of breath, wheezing, accelerated or troubled breathing
- stiff, rigid muscles accompanied by a sudden increase in body temperature, sweating, fast heartbeat and feeling disoriented
- · movement disorders
- constant "flu-like" symptoms such as chills, fever, sore throat, aching joints, sores in mouth, swollen glands
- fainting spells or seizures (fits)
- · difficulty in speaking or slurred speech
- confusion, disorientation or hallucinations (seeing, hearing or feeling things that are not there)
- abnormally high energy or level of activity (mania)
- sudden loss of vision or trouble focussing your eyes properly
- · yellow colour to the skin and eyes
- abnormally low body temperatures (below 35°C) in children treated for influenza

# Tell your doctor if you notice anything else that is making you feel unwell.

Some people may have other side effects not yet known or mentioned in this leaflet. Some side effects can only be found when laboratory tests are done.

### After using Symmetrel

## Storage

- Keep your medicine in the original container until it is time to take it.
- Store it in a cool dry place.
- Do not store Symmetrel or any other medicine in the bathroom or near a sink.
- Do not leave it in the car or on window sills.

# Keep this medicine 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.

#### Disposal

If your doctor tells you to stop taking Symmetrel or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

### Product description

#### What it looks like

Symmetrel capsules are soft brown gelatin capsules, marked GEIGY on one side and GB on the other. Each pack contains 100 capsules.

### Ingredients

### **Active Ingredient**

Symmetrel capsules contain 100 mg of amantadine hydrochloride.

#### **Inactive ingredients**

- · rape seed oil
- · lecithin
- a wax blend composed of yellow beeswax, hydrogenated and partially hydrogenated soya oils
- sodium ethyl hydroxybenzoate
- · sodium propyl hydroxybenzoate
- · gelatin
- glycerol
- iron oxide red
- Karion 83 (a mixture of sorbitol, mannitol and hydrolysed starch in water)
- · titanium dioxide
- white, edible branding ink

Symmetrel contains hydroxbenzoates and sulfites (gelatin capsules). It does not contain sucrose, gluten, tartrazine or any other azo dves

### Sponsor

Symmetrel is supplied in Australia by:

NOVARTIS Pharmaceuticals Australia Pty Limited

ABN 18 004 244 160

54 Waterloo Road

Macquarie Park NSW 2113

Telephone: 1 800 671 203

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This leaflet was prepared in April 2020.

Australian Registration Number.

Symmetrel 100 mg capsule AUST R 11057 (CMI sym080420c is based on the PI

sym080420i)