NOVARTIS

SYMMETREL 100®

(Amantadine hydrochloride)

100 mg, Soft Capsules

Patient Information Leaflet

Document status: Final

Release date: 30 October 2024

Property of Novartis

Confidential

May not be used, divulged, published or otherwise disclosed

without the consent of Novartis

PATIENT INFORMATION LEAFLET

Please read this leaflet carefully before using SYMMETREL 100®

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

SCHEDULING STATUS: S4

PROPRIETARY NAME AND DOSAGE FORM:

SYMMETREL 100® Soft Capsules

1. COMPOSITION OF THE MEDICINE (i.e., what this medicine contains):

SYMMETREL 100® contains an active ingredient amantadine (present as amantadine hydrochloride)

The other inactive ingredients are rapeseed oil; soybean lecithin; wax blend composed of one part beeswax, one part hydrogenated soybean oil and four parts other partially hydrogenated vegetable oils.

2. APPROVED INDICATION AND USE (i.e., what SYMMETREL 100® is used for):

SYMMETREL belongs to a group of medicines called antiparkinsonian medicines (medicines to treat Parkinson's disease) and also to a group of medicines called antiviral medicines (medicines used to treat or prevent certain illnesses caused by viruses).

SYMMETREL is used to treat Parkinson's disease and also to prevent or treat certain influenza (flu) infections (type A). Symmetrel will not work for colds, other types of flu, or other virus infections.

Parkinson's disease is caused by a disturbance in the balance of substances which the brain uses to send signals to other parts of the body - too little dopamine and/or too much acetylcholine.

SYMMETREL helps to normalize this balance in the brain and thereby relieve stiffness and improve mobility.

3. BEFORE TAKING SYMMETREL 100®:

It is important to tell your doctor if you have other medical problems or if you are taking other medicines

Do not take SYMMETREL 100®

- If you are allergic (hypersensitive) to amantadine or any of the other ingredients of SYMMETREL 100® listed at the beginning of this leaflet.
- If you are pregnant or breast[-]feeding your baby

- If you have a severe kidney or liver disease.
- If you suffer from seizures

If any of these apply to you, tell your doctor before using SYMMETREL 100®.

Take special care with SYMMETREL 100®

Your doctor will tell you when to withhold the treatment, if necessary. Make sure you inform your doctor if your medical condition changes.

If any of these apply to you, tell your doctor before you take SYMMETREL 100®**.**

- If you have kidney or liver disease;
- If you have or have ever had a heart disease or circulation problems;
- If you have or have ever had recurring skin problems (eczema);
- If you have seizures (epilepsy);
- If you have or have ever had gastric ulceration;
- If you have mental illness;
- If you have increased pressure in the eyes (glaucoma).

Abnormally low body temperatures (below 35°Celsius) can occur particularly in children treated for influenza. In this case **talk to the treating doctor right away** and stop taking SYMMETREL.

Taking SYMMETREL with food and drink

SYMMETREL can be taken before or after meals. Do not drink alcohol when you are on treatment with SYMMETREL, as this combination may increase the risks of unwanted effects.

SYMMETREL and Elderly patients

Elderly people are particularly sensitive to the effects of SYMMETREL. The doctor will provide any special information, e.g. on careful dosage.

SYMMETREL and Children

SYMMETREL may be used in children over 5 years of age, provided the doctor's instructions are followed.

Pregnant women

If you are pregnant or think you may be pregnant, tell your doctor. SYMMETREL 100® should not be used during pregnancy. Your doctor will discuss with you the potential risks of taking SYMMETREL 100® during pregnancy.

Breastfeeding mothers

Women should tell their doctor if they are breastfeeding. The active substance in SYMMETREL passes into the breastmilk and there is the possibility of an effect on the breastfed baby. If you breastfeed your baby, you should not take SYMMETREL.

Driving and using machines

SYMMETREL 100® may cause some patients to feel sleepy or dizzy, confused or lightheaded. If this happens you should not drive or use machinery or perform other tasks that need full attention.

Taking other medicines with SYMMETREL 100®

If you are taking medicines on a regular basis, including complementary or traditional medicines, the use of SYMMETREL 100® with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional for advice if you are taking any of the following:

- appetite suppressants;
- medicines for colds or allergies;
- medicines for mental illnesses;
- medicines for abdominal or stomach spasms or cramps;
- other medicines for Parkinson's disease;
- combination diuretics (hydrochlorothiazide + potassium-sparing diuretics) used to treat high blood pressure.

4. INSTRUCTIONS ON HOW TO TAKE THE MEDICINE:

Be sure to take this medicine regularly and exactly as your doctor tells you. This will help you to get the best results and reduce the risk of side effects. **Do not suddenly stop taking SYMMETREL** without first checking with your doctor.

Follow your doctor’s instructions carefully. Do not exceed the recommended dosage.

How much to take of SYMMETREL

SYMMETREL should be taken at mealtimes, preferably in the morning and at midday.

For patients taking Symmetrel for Parkinson's disease:

Treatment is usually started with 1 capsule daily and gradually increased to 1 capsule twice a day.

For patients taking Symmetrel to prevent or treat flu infections:

Children aged 5-9 years: 1 capsule once daily.

Adolescents and adults (aged 10-65 years): 1 capsule twice daily.

In elderly patients without impaired kidney function a dose of not more than 100 mg daily is recommended.

In patients with impaired kidney function the dosage is usually reduced.

The dose prescribed by your doctor may be different from the doses given above. If this is the case, follow the doctor's instructions.

If you have the impression that the effect of SYMMETREL 100® is too strong or too weak, talk to your doctor or healthcare professional.

When and how to take SYMMETREL

Take SYMMETREL preferably in the morning and at midday. Swallow the tablets with some liquid.

If you forget to take SYMMETREL

If you have forgotten to take one dose, take it as soon as you realize it. If it is almost time for your next dose, do not take the missed one; just go back to your regular dosing timetable. **Do not double the dose.** If you have missed more than one dose, you should contact your doctor (see also under “How to use SYMMETREL”).

If you take more SYMMETREL than you should

If you have accidentally taken many more tablets than your doctor has prescribed you may experience confusion, disorientation, hallucinations, nausea, vomiting, accelerated breathing, irregular heartbeat, movement disorders, or seizures, inform your doctor immediately. T**alk to your doctor or pharmacist straight away.** If neither is available seek help at the nearest hospital or poison control centre.

5. POSSIBLE SIDE EFFECTS

SYMMETREL 100® may cause unwanted effects (side effects) in addition to its desired effects.

You should never change the prescribed dosage of your medicine without consulting your doctor.

Agitation, nervousness, elevation of mood, difficulty in concentrating, dizziness, lightheadedness, headache, trouble in sleeping or nightmares, tiredness, lack of energy, blurred vision, fast heartbeat, dizziness or fainting when getting up suddenly from a lying or sitting position (low blood pressure), dryness of the mouth, loss of appetite, excessive sweating, nausea, vomiting, constipation.

Confusion, trembling, diarrhoea, rash, difficulty passing urine, involuntary passage of urine.

Reversible change in liver function tests, increased sensitivity of the skin to sun.

Symmetrel may cause purplish-red, blotchy spots on the skin, sometimes in a fish-net pattern. This occurs more often in females and is usually seen on the legs and/or feet in patients who have been taking Symmetrel regularly for a few months or more.
Although the blotchy spots may remain as long as you are taking this medicine, they normally disappear gradually within 2 to 12 weeks after you stop taking it. If you have any questions about this, consult your doctor.
If any of these affects you severely, **tell your doctor.**
Consult your doctor as soon as possible if any of the following side effects occur, since they may need medical attention.

Swelling of feet or lower legs.

Hallucinations, feeling of depression, feeling of anxiety, incoherent speech, difficulty in coordination.

Disorientation, mental disorders, uncontrollable movements of mouth, tongue and limbs, fits, eye pain with reduced visual acuity.

A serious and potentially life-threatening condition with muscle stiffness, impaired consciousness and increased temperature or fever as its key symptoms (Neuroleptic Malignant Syndrome-like symptoms); heart disorder, unexplained shortness of breath; fever, sore throat or mouth ulcers due to infections (low level of white blood cells).

Severe confusion, feeling elated of overexcited have been observed.

Abnormally low blood temperature (below 35°Celsius) has been observed especially in children.

If you notice any other side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

If any of these side effects affects you severely, tell your doctor.

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

6. STORAGE AND DISPOSAL INFORMATION:

Store below 25 °C and protect from heat and moisture.

Do not store the product in the bathroom.

Keep all medicines out of the reach and sight of children.

Return any unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION

SYMMETREL is available as 100 mg capsules in packs of 20.

8. IDENTIFICATION

Reddish-brown, opaque, shiny, oblong capsules, length: 15,4 mm, diameter: 5,8 mm.

Imprinted in white, "GEIGY" on one side and "GB" on the other side.

9. REGISTRATION NUMBER

SYMMETREL 100®: A/20.2.8/768

10. NAME AND ADDRESS OF REGISTRATION HOLDER

NOVARTIS SOUTH AFRICA (Pty) Ltd

Magwa Crescent West

Waterfall City, Jukskei View

Johannesburg

2090

11. DATE OF PUBLICATION

11 February 2011

®Registered Trademark

Namibia: 90/20.2.8/00724	NS2

Manufacturer:

Catalent Germany Eberbach GmbH Gammelsbacher Strasse 2 69412 Eberbach Germany