

# Sapropterin Dipharma

*Sapropterin dihydrochloride*

## Consumer Medicine Information

### What is in this leaflet

This leaflet answers some common questions about Sapropterin Dipharma.

It does not contain all the available information.

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

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

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

**Keep this leaflet with the medicine.**

You may need to read it again.

### What Sapropterin Dipharma is used for

Sapropterin Dipharma is used to reduce phenylalanine (Phe) in the blood of people with phenylketonuria (PKU) or tetrahydrobiopterin (BH4) deficiency. Phe is a necessary amino acid but it is harmful in excessive amounts. People with PKU or BH4 deficiency cannot process Phe normally. A Phe restricted diet will reduce Phe levels in the body and some people also need treatment with Sapropterin Dipharma.

Sapropterin Dipharma contains sapropterin dihydrochloride which is identical to the body's own natural BH4 except that it is made in a laboratory. BH4 is used by the body to process Phe in order to build another amino acid called tyrosine, which is a building block for several important brain chemicals.

People with PKU or BH4 deficiency have abnormally high levels of Phe in the blood, which can be harmful. Sapropterin Dipharma is used

together with dietary restrictions to reduce Phe in the blood. Not everyone with PKU or BH4 deficiency responds to Sapropterin Dipharma but if you do respond, you may be able to tolerate more Phe in your diet than you could without treatment.

Your doctor may have prescribed Sapropterin Dipharma for another reason. Ask your doctor if you have any questions about why Sapropterin Dipharma has been prescribed for you.

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

### Before you take Sapropterin Dipharma

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

**Do not take Sapropterin Dipharma if you have an allergy to:**

- sapropterin dihydrochloride
- any of the other ingredients listed at the end of this leaflet

Symptoms of an allergic reaction may include:

- shortness of breath, wheezing, difficulty breathing or a tight feeling in your chest
- swelling of the face, lips, tongue or other parts of the body
- rash, itching, hives or flushed, red skin

**Do not take Sapropterin Dipharma after the expiry date printed on the label of the bottle and the carton.**

If you take this medicine after the expiry date has passed, it may not work as well.

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

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

**If you are not sure whether you should start taking Sapropterin Dipharma, talk to your doctor or pharmacist.**

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

#### *Before you take it*

**Tell your doctor or pharmacist if you have allergies to:**

- any other medicines
- any other substances, such as foods, preservatives or dyes

**Tell your doctor if you are ill before you start to take Sapropterin Dipharma.**

The levels of Phe in your blood may be higher if you are currently ill and your doctor may want to check that.

**Tell your doctor if:**

- you have or have had kidney or liver disease
- you have or have had convulsions ('fits')
- you are over 50 years old

**Tell your doctor if your child is to be treated with Sapropterin Dipharma and he or she is less than 4 years old.**

More frequent monitoring is recommended in children, particularly those less than 4 years old.

**Tell your doctor if you are pregnant or intend to become pregnant.**

It is very important to control blood Phe during pregnancy as high Phe can harm you or your baby. Dietary management is the first option. Your doctor will consider the use of Sapropterin Dipharma only if strict

dietary management does not adequately reduce your blood Phe levels.

**Tell your doctor if you are breastfeeding or intend to breastfeed.**

It is not known whether Sapropterin Dipharma passes into breast milk. You should not take Sapropterin Dipharma if you are breastfeeding.

**Taking other medicines**

**Tell your doctor or pharmacist if you are taking any of the following medicines:**

- methotrexate (a medicine used to treat arthritis, psoriasis and some cancers)
- trimethoprim (an antibiotic)
- any heart medicine or angina treatment, e.g. glyceryl trinitrate, isosorbide dinitrate or sodium nitroprusside
- any medicine for the treatment of impotence
- minoxidil (a medicine used to treat hair loss and high blood pressure)
- levodopa (a medicine used to treat Parkinson's disease)

These medicines may be affected by Sapropterin Dipharma, or may affect how well it works. You may need to use different amounts of your medicines, or take different medicines. Your doctor will advise you.

**Tell your doctor or pharmacist if you are taking any other medicines, vitamins or supplements, including any that you buy without a prescription from your pharmacy, supermarket or health food shop (e.g. folic acid or vitamin B12).**

**Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Sapropterin Dipharma.**

**Follow carefully all directions given to you by your doctor, dietician or pharmacist.**

They may differ from the information contained in this leaflet.

Sapropterin Dipharma is taken as a tablet or tablets dissolved in water. Do not use any liquid other than water to dissolve Sapropterin Dipharma.

It is not possible to know whether or not Sapropterin Dipharma will work for you until you start taking it. Your doctor will monitor your blood Phe levels when you start taking Sapropterin Dipharma to see if it is working.

**How much to take and how often to take it**

Your doctor will tell you how many tablets to take. You must take Sapropterin Dipharma exactly as explained by your doctor.

Take the tablets dissolved in water as a single daily dose with a meal and at the same time each day, preferably in the morning.

**If you have PKU**

The usual starting dose of Sapropterin Dipharma in adults and children with PKU is 10 mg for each kg of body weight per day. Your doctor may adjust your dose depending on your condition and response to treatment. The recommended daily dose is between 5 mg and 20 mg for each kg of body weight per day.

**If you have BH4 deficiency**

The usual starting dose of Sapropterin Dipharma in adults and children with BH4 deficiency is 2 mg to 5 mg for each kg of body weight per day. Your doctor may adjust your dose depending on your condition and response to treatment. The recommended daily dose is between 2 mg and 20 mg for each kg of body weight per day. It may be necessary to divide the total daily dose into 2 or 3 doses, distributed over the day, to achieve the best treatment effect.

**Dipharma**

Dissolve Sapropterin Dipharma tablets in water while stirring. It may take a few minutes for the tablets to dissolve. To make the tablets dissolve faster you can crush them.

Don't worry if there are small particles in the solution. This will not affect how well it works.

Drink the solution with a meal, at the same time each day, preferably in the morning.

Only prepare the solution when you are ready to take it. Sapropterin Dipharma solution should be drunk within 15 to 20 minutes after preparing it.

**Adults**

Place the number of tablet(s) your doctor has told you to take in a glass or cup (120 - 240 mL) of water and stir until dissolved.

**Children**

For doses above 100 mg, place the number of tablet(s) your doctor has told you to take in a glass or cup (up to 120 mL) of water and stir until dissolved.

For doses below 100 mg, dissolve one tablet in 100 mL of water. Your doctor or pharmacist will tell you the volume of solution needed to give the correct dose. You will need to use an accurate measuring device for this purpose. Ask your pharmacist for an accurate measuring device. Discard any unused portion.

If necessary, Sapropterin Dipharma tablets can be dissolved in smaller volumes, e.g. for young children. The minimum volume required to dissolve each tablet is 20 mL, e.g. 1 tablet in 20 mL, 2 tablets in 40 mL and so on.

**Ask your doctor or pharmacist if you have any questions about how to prepare Sapropterin Dipharma or how much to take.**

Do not swallow the desiccant capsule contained in the bottle.

**How long to take Sapropterin Dipharma**

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**How to take Sapropterin Dipharma**

**How to take Sapropterin**

## **Continue taking Sapropterin Dipharma for as long as your doctor tells you.**

Do not stop taking Sapropterin Dipharma without telling your doctor. Your doctor will need to carefully monitor your blood Phe levels if you stop taking Sapropterin Dipharma.

### ***If you forget to take it***

**If you forget to take Sapropterin Dipharma at the right time, take it as soon as you remember on the same day.**

**Do not take a double dose to make up for a forgotten dose.**

At your next appointment, tell your doctor if you forgot to take Sapropterin Dipharma.

### ***If you take too much (Overdose)***

Immediately contact your doctor or the Poisons Information Centre (In Australia telephone 131 126. In New Zealand telephone 0800 POISON or 0800 764 766) if you think you or someone else may have taken too much Sapropterin Dipharma.

Symptoms of an overdose with Sapropterin Dipharma may include headache and dizziness.

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## **While you are taking Sapropterin Dipharma**

### ***Things you must do***

**Keep all your doctor's appointments so your progress can be checked.**

While you are taking Sapropterin Dipharma, your doctor will test your blood regularly to check your levels of Phe and

tyrosine and may decide to adjust the dose of Sapropterin Dipharma or your diet if needed.

**Contact your doctor if you become ill for any reason even if the illness is not related to the reason you are taking Sapropterin Dipharma.**

Your doctor may want to check your Phe levels as other illnesses may increase blood Phe.

Tell any other doctors, dentists and pharmacists who are treating you that you are taking Sapropterin Dipharma.

If you are about to be started on any new medicine, vitamin or supplement, tell your doctor, dentist or pharmacist that you are taking Sapropterin Dipharma.

### ***Things you must not do***

**Do not change your diet without contacting your doctor.**

Any change you make to your diet may affect your blood Phe level. You must continue your diet treatment as recommended by your doctor.

**Do not stop taking Sapropterin Dipharma unless your doctor tells you to.**

The Phe levels in your blood may increase. Your doctor will need to carefully monitor your blood Phe levels if you stop taking Sapropterin Dipharma.

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

Do not take Sapropterin Dipharma to treat any other complaints unless your doctor tells you to.

### ***Things to be careful of***

It is not known if Sapropterin Dipharma affects your ability to drive or to operate machinery. Be careful driving or operating machinery until you know if Sapropterin Dipharma affects you.

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## **Side effects**

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

The levels of Phe in your blood may be higher if you are currently ill and your doctor may want to check that.

Like other medicines, Sapropterin

Dipharma may have unwanted side effects.

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

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

- headache
- runny nose
- sore throat
- blocked or stuffy nose
- cough
- diarrhoea (loose stools)
- vomiting
- stomach ache
- allergic reactions (rash)

Some side effects may be found only by having a blood test, e.g. levels of Phe in blood tests that are too low.

Other side effects not listed above may occur in some patients.

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

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## **After taking Sapropterin Dipharma**

### ***Storage***

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

Do not leave them in the car on hot days or in the bathroom.

**Keep the bottle tightly closed to protect the tablets from moisture and light.**

Keep the desiccant tube in the bottle.

**Keep Sapropterin Dipharma where young 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***

**Once the bottle is opened, use the contents within two months or**

**dispose.**

Return any unused Sapropterin Dipharma to your pharmacist.

Also dispose of Sapropterin Dipharma as directed by your pharmacist if your doctor tells you to stop taking Sapropterin Dipharma, or the pack has passed its expiry date.

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## Product description

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### ***What it looks like***

Sapropterin Dipharma is supplied as soluble tablets. White to off white colored circular tablets, de-bossed with "11" on one side and breakline on the other side

Sapropterin Dipharma is supplied in bottles with child-resistant closure containing 30, 60 or 120 soluble tablets. Each bottle contains a canister of desiccant (silica gel).

### ***Ingredients***

Active ingredient:

- sapropterin dihydrochloride

Other ingredients:

- mannitol
- copovidone
- crospovidone
- ascorbic acid
- sodium stearyl fumarate
- colloidal anhydrous silica
- riboflavin

### ***Supplier***

Sapropterin Dipharma is supplied in New Zealand under license of

Dipharma SA by:

Te Arai BioFarma Ltd

91 Red Hill Rd, Te Arai

Wellsford, 0975

For enquiries please call  
0800 TEARAI (832724)

**This leaflet was prepared in  
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